Università
Ca'Foscari
Venezia

Master's Degree

in

Global Development and Entrepreneurship

ex. D.M. 270/2004

Final Thesis

The Agreement on Trade-Related Aspects of Intellectual Property Rights and the Safeguard of Global Public Health

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Matriculation number
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Academic Year
2022 / 2023

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Introduction

Intellectual property rights aim at protecting original ideas and creations. They give to their owner exclusive rights to use, distribute, and make profit from their creation. This allows them to protect the value of their creations and to prevent others from exploiting their ideas.

The exclusive right of financial exploitation of a registered IP represents the incentive for private entities to boost their R&D, given the possibility to rapidly recoup their investments. Despite the existing debate, IP systems shall be able to increase societal innovation rate and benefit the society through technological and human development.

Patents are a form of intellectual property able to grant exclusive rights over the commercial exploitation of an invented product or process, and they are at the centre of the debate over the pros and cons of IP systems. Patents create a legal monopoly of the invention that can lead to an actual market monopoly.

Pharmaceuticals fall within the patentable subject matter generating a major dispute over the relationship between international patent protection of medical products and the access to medicines for the safeguard of public health.

The international trade of IP related goods is regulated by the WTO Agreement on Trade-Related Aspects of Intellectual Property Rights of 1994. The Agreement, despite the flexible provisions and the provided compulsory licensing mechanism, did not constitute neither a sufficient nor efficient tool during the AIDS/HIV crisis of the 90s. Subsequently, the international community agreed in Doha in 2001 on the introduction of Article 31bis which would have allowed in case of emergency or urgency an import-export mechanism over patented pharmaceuticals under compulsory licensing contracts. This solution however presented some difficulties in the implementation procedures due to bureaucracy and practicalities.

The COVID-19 pandemic and the consequent international attempts to equally allocate vaccines re-ignited the debate between intellectual property and public health. South Africa and India tabled a proposal to the TRIPS Council to waive certain IP rights in order to tackle the pandemic. The negotiations ended with the 12th WTO Ministerial

Conference in Geneva that found a compromise in the Ministerial Decision on the TRIPS Agreement. The multiple critiques risen after the Ministerial Decision make it clear that the balance between private IP rights and public health safeguard is far from being found.

The first chapter of the dissertation deals with the definition of all the factors involved in the issuing of patents. It addresses the debate over the advantages and disadvantages of patenting considering its social and economic implications, and it goes on portraying the international institutions and conventions which defined the international legal frameworks for patents worldwide.

The second chapter is focused on the Agreement on Trade-Related Aspects of Intellectual Property Rights. It introduces the context in which the agreement was conceived and analyses its provisions, focusing on its general principles and objectives, as well as on the cooperation for its implementation and its enforcement. The chapter, whose focal point is the patents' section in the second part of the Agreement, also discusses the general lack of worldwide consensus on the Agreement itself, the difficulties in its enforcement and the issues arising from the so-called TRIPS-Plus standards.

The third chapter explores the core issue of the dissertation addressing the debate on the role of IP, and specifically of the TRIPS Agreement, in the context of public health safeguard and access to medicines. Investigating the development of the debate, the chapter peaks with the analysis of the Doha Declaration and the subsequent introduction of Article 31 bis to the Agreement. The Declaration reminded the importance of the flexibilities contained in the TRIPS Agreement and highlighted their role in the safeguard of public health. This flexibility is explicitly referred to in some articles, which the chapter investigate also taking into consideration caselaw interpretations.

The fourth chapter addresses the COVID-19 pandemic and focuses on the international initiatives undertaken to equally distribute vaccines and treatments. The relevance of vaccines in the solution of the global crisis put once again patents and IP under the spotlight. The chapter further analyses the various voices participating in the debate

over the waiver proposal, as well as the alternative solutions proposed by scholars based on compulsory or voluntary licensing mechanisms.

List of abbreviations and acronyms

ACT – Access to COVID-19 Tools (ACT) Accelerator

ARIPO – African Regional Intellectual Property Organisation

ARVs – Antiretroviral drugs

AU – African Union

BIRPI – United International Bureaux for the Protection of Intellectual Property

CEPI – Coalition for Epidemic Preparedness Innovations

C-TAP – COVID-19 Technology Access Pool

DSB – Dispute Settlement Body

DSU – Understanding on rules and procedures governing the settlement of disputes (WTO)

EPC – European Patent Convention

EPO – European Patent Office

EPT – European Patent Convention

FTAs – Free Trade Agreements

GATT – General Agreement on Tariffs and Trade

ICT – Information and Communication Technologies

IM – Imatinib Mesylate

IP – Intellectual Property

IPR – Intellectual Property Rights

IPRTA – Intellectual Property Rights Technical And Financial Assistance

IVA – Inclusive Vaccine Alliance

LDCs – Least Developed Countries

MPP – Medicines Patent Pool

NAFTA – North American Free Trade Agreement

OAPI – Organisation Africaine de la Propriété Intellectuelle

OECD – Organization for the Economic Co-operation and Development

PAIPO – Pan African Intellectual Property Organisation

PCT – Patent Cooperation Treaty

PHEIC – Public Health Emergency of International Concern

PLT – Patent Law Treaty

SDGs – Sustainable Development Goals

SMEs – Small and Medium Enterprises

UN – United Nations

UNCTAD – UN Conference on Trade and Development

VCLT – Vienna Convention on the Law of the Treaties

WHO – World Health Organization

WIPO – World Intellectual Property Organization

WTO – World Trade Organization

CHAPTER 1

An Introduction to Patents and the international harmonization of their legal framework

1.1 Introduction to Intellectual Property Rights and Patents

Intellectual property rights represent the spectrum of rights granting protection to all the inventions resulting from persons' intellect. According to the World Intellectual Property Organization (WIPO)[1], intellectual property covers all the "creations of the mind," including artistic works, images and designs, names, and symbols. IP rights award legal recognition and financial gain to the proprietors of the inventions and creations.[2]

This class of rights can be divided into two subcategories: copyrights and other related rights, and industrial property. The latter can be furtherly distinguished into rights protecting trademarks and geographical indications, and industrial property rights such as inventions, trade secrets and industrial designs. The ultimate objective for this last section is to enhance innovation and to protect the financial disbursement devolved towards technological innovation.[3]

Among the industrial property rights, patents provide exclusive rights applicable to the invention of a product or a process.[4] According to the European Patent Office, a product is to be identified as an object, chemical or device. Processes are a way of either making or doing something.[5] The term invention instead indicates a technological solution to a particular issue. According to the World Intellectual Property Office, a patent is a document whose purpose is to describe the invention and to legally restrict the

[1] Instituted through the Convention Establishing the World Intellectual Property Organization (as amended on September 28, 1979), signed in Stockholm on July 14, 1967. WIPO Lex No.TRT/CONVENTION/001.
[2] World Intellectual Property Organization, *What is Intellectual Property?,* Retrieved 10 May 2023, from https://www.wipo.int/about-ip/en/.
[3] *WTO | intellectual property (TRIPS)—What are intellectual property rights?*. Retrieved 10 May 2023, from https://www.wto.org/english/tratop_e/trips_e/intel1_e.htm.
[4] World Intellectual Property Organization, *Patents*. Retrieved 5 June 2023, from https://www.wipo.int/patents/en/index.html.
[5] European Patent Academy, *What is a Patent?,* Patent Litigation Block 1. Retrieved 10 May 2023, from https://e-courses.epo.org/wbts_int/litigation/WhatIsAPatent.pdf.

possibility to exploit it commercially to its owner only; commercial exploitation includes the manufacturing, use, selling and importation of the patented product or process. The application process and the issuing of patents is controlled by a government or regional office.[6]

Patents do not directly enable the holder to do something, accordingly they confer negative rights, therefore they entitle patent holders to prevent any commercial usage of their inventions.[7] The right the owner gets to prevent others from using its creation is territorial, so protection is limited in space, and temporary therefore limited in time, according to the law of the country or region in which the patent has been filed. The usual duration of the protection for a patented invention is 20 years.

Patents can be seen as social contracts between the inventor and the society: governments or the competent offices recognise the invention as property of the intellect who created it, providing legal protection and the opportunity to exploit it financially; in exchange, society obtains the disclosure of the technology so that it can spur further innovation and consequently generate social benefits. Often patents are also described as monopolies, however since the rights conferred only regard the prevention of the exploitation by someone who is not the owner, the inventor cannot automatically produce, use, or sell the invention. Therefore, patented inventions will not be directly linked to the emergence of monopolistic regimes.[8]

1.1.1 From patentability to licensing

In order to be patentable, an invention must comply with several criteria. The first requirement is that the product or process at stake must be identified as patentable subject matter.[9] Some examples of technologies excluded from patentability are discoveries of materials or substances existing in nature, scientific or mathematical

[6] WIPO Intellectual Property Handbook. (2008). World Intellectual Property Organization (WIPO), Wipo Publication No. 489 (E). Second Edition. p. 17.
[7] Shear, R. H., & Kelley, T. E. (2003). A Researcher's Guide to Patents. *Plant Physiology*, *132*(3), 1127–1130.
[8] *Supra*, note 6.
[9] *Ibid*. 18.

theories, plants and animals other than microorganisms and biological processes for the production of plants and animals, treatments for humans or diagnostic methods, but not the products used in them.[10] Furthermore, national or regional patent offices can deliberately exclude from patentability inventions considered as menaces to the public order or morality.[11]

The second criteria the invention must respect in order to be patentable is the industrial applicability. The invention needs to be useful and applicable to an industrial or business process. To further specify the terms, industrial applicability refers to the possibility of using in practice the invention; the adjective industrial is to be interpreted as a broad reference to each kind of industry, the industrial application thus refers to the potential exploitation of the invention through specific technical means. The delineation of this criterion varies deeply worldwide.[12]

According to the guidelines elaborated by the European Patent Office (EPO) for the examination of patent applications, industrial applicability stands for the possibility of the invention to be exploited in industry and it needs to be either *self-evident* or explicitly indicated in the description of the invention.[13] The United States Patent and Trademark Office (USPTO) instead refers to this requirement employing the term of utility. The inventor needs therefore to identify in their application a *specific*, *substantial*, and *credible* utility for their invention.[14] The Patent Cooperation Treaty (PCT) International Search and Preliminary Examination Guidelines indeed recognizes the analogies between the two terms.[15]

[10] TRT/WTO01/001. World Trade Organization (WTO) - Agreement on Trade Related Aspects of Intellectual Property (TRIPS), Article 27.1.
[11] *Ibidem*, Article 27.2.
[12] *Supra*, note 6. p. 18.
[13] *Guidelines for Search and Examination at the European Patent Office as PCT Authority*. (2023), Available at https://link.epo.org/web/pct_epo_guidelines_2023_hyperlinked_en.pdf . These guidelines are relative to the role the EPO has as International Searching Authority in the Patent Cooperation Treaty framework (see 1.2.3).
[14] United States Code, 2000 Edition, Supplement 3, Title 35 – Patents Part II - Patentability Of Inventions And Grant Of Patents, Chapter 10 - Patentability Of Inventions, Section 101 - *Inventions patentable.*
[15] *PCT International Search and Preliminary Examination Guidelines*, as in force from July 1, 2022, Part III Examiner Considerations Common To Both The International Searching Authority And The International Preliminary Examining Authority, Chapter 14.

Novelty is another crucial requirement. In order to be considered new, the invention needs to be "bestowed for the first time upon the public by the patentee."[16] Therefore the novelty prerequisite is met if the invention is not part of the prior art.

Prior art is the state of the art in the technological field of interest before the patent application has been filed.[17] The assessment of novelty therefore involves a search into the prior art, which may involve patents information databases and documents, scientific papers, the internet, and every other media, with the aim of detecting any previously on the claimed invention.

The invention seeking protection should also include an "inventive step" or non-obviousness feature.[18] This means that, at the moment of filing, the invention should not be obvious, therefore easily deduced, by a hypothetical skilled person of the technological field at stake.[19] The imaginary skilled person is an experienced practitioner who has an average knowledge of the art, and is able to carry out routine work.[20]

The difference between the inventive step and the novelty requirements is subtle. Novelty stands for the simple identification of something new compared to the prior art. The inventive step prerogative comes in only if novelty is present: it is not enough for the invention to be new, it must be the result of an intellectual and creative process and it must be consistently different from the already established knowledge in the field. Moreover, the peculiarity of the invention that grants its inventiveness and non-obviousness must be a vital part of the invention itself.[21]

The assessment of the inventive step therefore is the result of the analysis of the prior art in its entirety. It does not analyse the presence of previously disclosed information

[16] Robinson, W. C. (1890). *The law of patents for useful inventions* (Vol. 2). Little, Brown.
[17] *Supra*, note 6. 19.
[18] *Ibidem.*
[19] United States Code, 2000 Edition, Supplement 3, Title 35 – Patents Part II - Patentability Of Inventions And Grant Of Patents, Chapter 10 - Patentability Of Inventions, Section 103 - *Conditions for patentability; non-obvious subject matter-"A patent for a claimed invention may not be obtained, […] if the differences between the claimed invention and the prior art are such that the claimed invention as a whole would have been obvious before the effective filing date of the claimed invention to a person having ordinary skill in the art to which the claimed invention pertains. […]".*
[20] *Supra*, note 6. 19.
[21] *Supra*, note 6. 20.

regarding the product or process, as it happens for the valuation of the novelty, but instead it combines different subjects and elements. For the inventiveness to be rejected, the invention must result as an obvious combination of elements, which would be obvious to the skilled operator of the field.[22]

One of the typical approaches in the assessment procedure of the non-obviousness requirement is the problem-solution approach, which is the one the European Patent Office itself adopts. It consists of three steps. The first step aims at determining the closest prior art; the second step defines the technical problem that the invention addresses comparing the claimed invention with the closest prior art. The last step analyses the solution that the hypothetical skilled person, who possesses complete knowledge of the prior art, would have found to the technical problem established in step two. If this solution falls within the terms of the claims of the invention, the inventive step is denied.[23]

The last general criteria with which the invention must comply is the disclosure of the technology itself. The patent application must include a precise description of the invention that would allow an average-skilled person of the field to replicate it. The description should outline one of the ways to execute the invention and should include drawings if necessary.[24]

If the inventor believes their invention meets the patentability criteria, he/she may proceed and seek protection for his/her intellectual property. The first step to file the patent application is to decide in which office they want to carry out the process. As specified above, patent rights are territorial, meaning that the protection granted is limited to the national or regional borders of the office that issued the patent.

The principle of territoriality imposes the need to secure individual patents for each territory in which the applicant wants to claim exclusive rights on the invention. Patent applications need to be filed in regional or national offices, according to the potential

[22] *Ibid*.
[23] *PCT International Search and Preliminary Examination Guidelines*, as in force from July 1, 2022, Part III Examiner Considerations Common To Both The International Searching Authority And The International Preliminary Examining Authority, Appendix to Chapter 13 *Problem-Solution Approach*.
[24] *Supra*, note 6. 21.

exploitation strategy of the invention.[25] However, the Paris Convention for the Protection of Industrial Property adopted in 1883[26] has set the right of priority[27], meaning that once the patent application has been filed in one country Member of the Convention, the applicant can claim, within the following 12 months, the date of that first patent application as filing date in the other countries signatory of the Convention in which they will seek patent granting.[28]

The choice of the office where to file the application should be aligned with the commercial operations to which the inventor aspires, since as specified above, the IP rights linked to the patent will be restricted to the territory of the chosen competent office.[29] To obtain protection in multiple countries the application must be filed in each of these countries' office. Alternatively, some regional offices accept regional patent requests. The European Patent Office is an example of regional patent office; the EPO was constituted under the European Patent Convention (EPC)[30] which gives to the applicant the opportunity to gain protection in multiple signatory countries.[31]

Alternatively, the Patent Cooperation Treaty (PCT)[32] administered by the World Intellectual Property Organization, allows the filing of an international application, and gives the opportunity to seek protection in many countries simultaneously instead of filing distinct national applications. The request may be filed in the national patent office of the contracting state, in the regional offices, e.g., the EPO or the African Regional Industrial Property Organization (ARIPO), or directly with the WIPO.[33]

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[25] Dreyfuss, R. C., & Pila, J. (Eds.). (2018). *The Oxford handbook of intellectual property law*. Oxford University Press.
[26] WIPO Lex No.TRT/PARIS/001. Paris Convention for the Protection of Industrial Property of March 20, 1883, as revised at Brussels on December 14, 1900, at Washington on June 2, 1911, at The Hague on November 6, 1925, at London on June 2, 1934, at Lisbon on October 31, 1958, and at Stockholm on July 14, 1967, and as amended on September 28, 1979.
[27] *Ibid*. Article 4 (A).
[28] European patents and the grant procedure. Published and edited by European Patent Office Munich Germany © EPO 2022.
[29] Office, E. P., *How to apply for a European patent*. Retrieved 12 May 2023, from https://www.epo.org/applying/basics.html.
[30] WIPO Lex No.TRT/EP001/001. European Patent Convention (17th edition / November 2020).
[31] *Supra*, note 28.
[32] WIPO Lex No.TRT/PCT/001. Patent Cooperation Treaty (PCT) (as modified on October 3, 2001).
[33] *PCT FAQs*. Retrieved 12 May 2023, from https://www.wipo.int/pct/en/faqs/faqs.html.

Regardless of the method with which the patent application is filed, the procedure that goes from the filing to the granting is usually long. For instance, the EPO grant procedure can take up to three or five years.[34]

The examination process varies remarkably across countries and regions. Some legislations provide the possibility for third parties to oppose to the grant of the patent during the examination process or to challenge the invention after the patent has been already issued. The goal of these mechanisms is to allow for fast and cheap interventions from third parties to get higher quality patents and to avoid subsequent long and expensive trials in court. After the patent is granted, its validity can be revoked at any time according to specific administrative revocation and invalidation mechanisms. Lastly, before the examination process has concluded, many offices accept the submission of prior art documents by third parties if they are thought to be relevant for establishing the validity of the claims.[35]

Filing processes vary considerably, and so do their costs. These depend primarily on the kind of invention and its sophistication, on the length of the examination process and on additional costs such as translation costs for the text of the application when applying abroad or the remuneration of any consulted professionals.[36] Once the patent is issued the rights related to it are usually granted for 20 years starting from the date of filing. In order to keep the patent valid, it may be necessary to pay maintenance or renewal fees and at the end of the protection period some legislations allow for the extension of the patent.[37]

IP rights are as valuable as their enforcement. Intellectual property protection needs to be supported by an efficient judicial system able to both enforce rights and deal with civil and criminal offenses.[38] Intellectual property is not self-enforcing and its enforcement requires a massive investment of financial resources. In order to maintain

[34] Office, E. P. *FAQ - Procedure & law*. Retrieved 12 May 2023, from https://www.epo.org/service-support/faq/procedure-law.html.
[35] *Opposition and Administrative Revocation Mechanisms*. Retrieved 15 May 2023, from https://www.wipo.int/scp/en/revocation_mechanisms/index.html.
[36] *Frequently Asked Questions: Patents*. Retrieved 12 May 2023, from https://www.wipo.int/patents/en/faq_patents.html.
[37] *Supra*, note 6.
[38] *Supra*, note 6 .207.

their exclusive rights over the invention, inventors need to thoroughly investigate the infringing unauthorized uses of the patented technology on the market.[39]

When addressing patent enforcement, the first step is to precisely define the scope of the patent itself. The claims need to be specific and particular attention must be paid to the wording of the patent specification. Since patent cases for infringement in court are usually long and expensive, patentees shall assess their chances to be successful before starting a dispute. This involves checking for the validity, and thus enforceability, of the patent and the compatibility of the supposedly infringing act with the protected claims. Assessing if the alleged infringement falls into the scope of protection of the patent can result a difficult task, especially if the content of the patent is highly technical.[40]

In case of infringement, the usual remedies granted by civil proceedings are injunctions to desist from the infringement, the payment of the damages caused to the patent's owner, the disposal of infringing products and the implementation of measures to prevent further infringements.[41]

The rights the patent owner can exercise are usually restricted in several ways: the claims could be amended or declared as invalid afterwards; in addition, where the invention improves or develops an earlier patent, a license may be required and royalties may be paid to the owner of that previous patent. Patent rights in some systems can be kept only if the invention is used, either by the patentee or by licensed parties. Finally, a fundamental limitation to the rights of the patent owner can come from the reasons linked to public interest: the Government may intervene directly using the patented invention or by authorizing third parties to act on its behalf.[42]

The monetary benefit the patent owner can get through their rights may come from the licensing of their invention. A license is an agreement whereby the owner of the rights, the licensor, permits another legal person, the licensee, to exploit their patented

[39] *Supra*, note 25.
[40] *Supra*, note 6. 212.
[41] *Supra*, note 25.
[42] *Supra*, note 6.

invention commercially in one or more countries. In exchange for this concession, the patent owner gets either a lump sum or a royalty fee per sold product.[43]

The interest in licensing the patent to a third party can derive either from the inefficiency of the owner in manufacturing the invention or from the need for a large investment in order to be able to exploit the patent and compete in the field. Therefore, under some circumstances the licensing of patents may prove to be more profitable than directly exploiting them. The patent owner can both manufacture and license the invention; the competition resulting from this scenario is unlikely to adversely affect the profits of the licensor if the invention is highly demanded on the market.[44]

Licensing agreements can be either exclusive or non-exclusive. Exclusivity implies the patented invention is licensed to only one licensee, or at least one licensee for each field in which it can be applied. Non-exclusive on the other hand means more than one party is granted with a license on the same patent. The so-called cross-licensing mechanism is instead an arrangement between two parties that reciprocally license out their patented inventions, both benefitting from the shared technological knowledge.[45]

1.1.2 Advantages and Limitations of Patents

By providing exclusive recognition and material reward for inventions, patents offer protection for individuals and incentivize research and development towards patentable technologies. The mandatory publication of the patented matter is expected to facilitate the diffusion of knowledge and innovations.[46]

The market-based capitalistic economy can as well be defined as a knowledge economy, where scientific and technological knowledge is traded. The increased demand for

[43] Mulder, C. (2016). European Patents. *Forthcoming in An Introduction to IP and Knowledge Management, Editors A. Ramalho, A. Kamperman Sanders, C. Mulder & A. Moerland by Routledge*.
[44] *Supra*, note 25.
[45] *Ibid.*
[46] Abbott, F. M. (2009). *Innovation and technology transfer to address climate change: lessons from the global debate on intellectual property and public health*. ICTSD Programme on IPRs and Sustainable Development, Issue Paper, (24), 9-18.

knowledge and innovations reinforced the paradigm of patents which intervene where the market alone would not lead to the desired grade of innovation for society. [47] Knowledge is intrinsically non-rival and non-exclusive, this means that a public intervention is needed to regulate the flow of new and inventive technologies in a competitive market. The patenting mechanism allows for a rebalancing of the intellectual efforts accomplished by the innovators granting them exclusive rights on the invention. The opportunity to gain exclusive rights on the product or process will encourage private investments in R&D.

It is, however, necessary to strike a balance: weak intellectual property rights would not incentivize R&D efforts, on the other hand strong IP rights would lead to a monopolistic outcome for the new technologies at stake. Thereby, intellectual property rights represent a trade-off between private interests and positive externalities for society. The best outcome possible, which is a complete public and free exploitation of the technology and the consequent highest social benefits, is not feasible in a capitalistic market-based economy. The role of IP regulations is thus to achieve the second-best outcome with a regime of rights that both encourages R&D investments through the protected diffusion of the results of the intellectual efforts, and in the meantime allows society to get access to the knowledge behind the patented technologies.[48]

The publication of the invention, contingent to the recognition of the exclusive rights, usually works for the competitors as an incentive to innovate. Patents are thus able to build barriers that protect the inventor from free-riders, which in case of absence of the patent, would be able to exploit the invention without bearing the costs of its development and earning all the financial benefits that come from it. Competition alone works as a fuel for the offer side of the market to strive for the best product to offer to buyers, however patents can consolidate the urge of businesses for innovation, leading to even finer outcomes.[49]

[47] Guellec, D., & de La Potterie, B. V. P. (2007). *The economics of the European patent system: IP policy for innovation and competition*.Oxford University Press, Oxford.
[48] Encaoua, D., Guellec, D., & Martinez, C. (2003). *The economics of patents: from natural rights to policy instruments*. Cahiers de la MSE.
[49] Dressler, M. (2012). *Assessing the Economic Effects of Patents*. Journal of the Knowledge Economy, *3*(3), 294–301.

The debate around the actual benefits deriving from the patent system does not miss to underline the limits and drawbacks that characterize the mechanism. Many scholars challenge the direct link between the opportunity of patenting inventions and the increased rate of innovation. The main critiques to the system doubt its alleged social and economic benefits, and argue that patents lead to market distortions and negative externalities rather than incentivizing innovation.[50]

The potential distortions caused by patents are first linked to the risk of the rising of a monopoly.[51] A monopolistic market is characterised by the lack of competition which results in inefficient prices. The monopolistic entity indeed holds the power of imposing prices that are higher than the optimal established in a market regulated by perfect competition. Society not only bears the pure economic cost, but also misses out on the differentiation of the offer usually granted by the competition. Moreover, the high market power of the monopolists allows them to supersede on the quality of the product or service they offer. Indeed, being it the only possible choice of the consumer, keeping a low quality will increase profit margins without the risk of losing consumers to substitutes with higher quality.[52]

Patents set up a legal monopoly for the patent owner but this may be distinguished by the economic monopoly which can only potentially arise from the patent issuing. Therefore, the legal paradigm set by the patent cannot be directly equated with an economic monopoly, since in order to commercially exploit the invention, the product or process under discussion must comply with the national legislation. This monopoly is either way temporary, and when the patent protection expires, the invention becomes commercially exploitable. The patent system therefore, even if allegedly addresses the need of the development of new technologies, it fails to tackle the issues of their access and transfer.[53] Moreover, if it is a research tool itself that is being patented, its protection

[50] Boldrin, M., & Levine, D. K. (2013). *The Case Against Patents*. Journal of Economic Perspectives, *27*(1), 3–22.
[51] *Supra*, note 48.
[52] Carare, P. M. (2011). *Monopoly: Advantages and Disadvantages* (SSRN Scholarly Paper 1787089).
[53] *Supra*, note 49.

could become an obstacle to further innovation if its licensing is not facilitated and accessible.

The financial reward patent owners can achieve through the exclusive commercial exploitation of the patent is not directly linked with the cost of R&D, resulting in an imbalance between the private and social benefit, and therefore in a less than optimal equilibrium point. The lack of ability of the system to grant higher profits to those patented innovations with more positive outcomes for the society, directs the R&D efforts towards the most profiting fields in which a patented invention corresponds to a net competitive edge. Moreover, patents are often used as tools to increase the bargaining power (e.g., firms that own a patent portfolio) on the market rather than to claim the compensation for research expenditures.[54]

Patents do not equally apply to all industrial fields. The pharmaceuticals and chemical industries are likely to be the sectors in which empirically patents have shown to be an effective mechanism of protection.[55] However, the overall social and private benefit are not pareto optimal. The thought behind patented drugs is that without patents, there would not be innovation in the sector. The R&D costs are high and so are the clinical trials to prove effectiveness and safety of the product. The common belief is that without the protection deriving from patents generic drugs would invade the market, without considering the vast and costly procedures necessary to produce and sell the new drug for those who did not invent it. First-mover advantage has proven to be larger than presumed. Moreover, the current patenting systems are not able to encourage innovation as much as necessary. For these and several other justifications, some scholars advocate for a reform of the patent protection granted to pharmaceutical products.[56]

To conclude, patents have both social and private advantages and disadvantages, making them a two-edged sword. Patents frequently improve incentives for innovation,

[54] *Supra*, note 48.
[55] Moser, P. (2013). *Patents and Innovation: Evidence from Economic History*. Journal of Economic Perspectives, *27*(1), 23–44.
[56] *Supra*, note 50.

disclosure, and trade of technologies, but they entail costs for society due to monopoly prices and obstacles to accessing knowledge and diffusing it.[57]

1.2 Evolution of the International Legal Framework on Patents

The definition of international intellectual property law needs to differentiate public international law from private international law. Public international law regarding intellectual property involves international treaties, such as the Berne Convention and the Paris Convention, institutions like the WIPO and the World Trade Organization (WTO) and international application mechanisms such as the one set by the Patent Co-Operation Treaty (PCT). The public law that regulates intellectual property internationally is therefore constituted of treaties that set standards and models for nation states but without affecting the territorial nature and private law aspects of IP rights. These underlying features connect to the importance of domestic legal orders, that keep being essential for the implementation of the above cited international treaties.

International IP law can then be approached as private international law, leaving aside standards and general criteria, focusing on the relations between the IP owner and third parties such as users or competitors. Domestic law keeps being fundamental in governing these private law matters, combined with the associated international harmonization attempts.[58]

The need to create international patent cooperation arose with the Industrial Revolution of the nineteenth century and the consequent technological progress, and with the affirmation of concepts such as alienable rights deriving from the French and American Revolutions which reinforced the national interests in developing IP rights regulations.[59] The need to harmonize intellectual property laws furthermore emerged with the

[57] *Supra*, note 48.

[58] Grosse Ruse-Khan, H. (2021). *Intellectual Property and International Law: A Research Framework*. In I. Calboli & M. L. Montagnani (Eds.), Handbook of Intellectual Property Research (1st ed., pp. 15–33). Oxford University Press, Oxford.

[59] Afifi, F. (1993). *Unifying international patent protection: the world intellectual property organization must coordinate regional patent systems*. Loyola of Los Angeles International and Comparative Law Journal, 15(2), 453-484.

intensification of international exchange of goods and knowledge. The diversity of the legal systems around the world made it difficult to protect industrial property rights across borders and led to the first step towards global IP rights: the Paris Convention for the Protection of Industrial Property.[60]

1.2.1 The Paris Convention for the Protection of Industrial Property

The International Congress on Industrial Property, held in Paris in 1878, was the prosecution of the Congress of Vienna for Patent Reform of 1873. The city of Vienna hosted in 1873 an international exhibition of inventions, the participation to which was hindered by the lack of legal protection offered to foreign inventors for the intellectual properties they would have exhibited. The Congress in Paris set the goal to organize a new diplomatic meeting to elaborate the basis of a uniform international IP legislation. In 1880 a new Conference was hosted in Paris and a draft convention was adopted. In 1883, following a new diplomatic congress, the Paris Convention for the Protection of Industrial Property was finally approved and signed by eleven countries: Belgium, Brazil, El Salvador, France, Guatemala, Italy, the Netherlands, Portugal, Serbia, Spain, and Switzerland. It entered into force on the 7th of July 1884 but It was not until after the Second World War that the number of members began to increase significantly. The initial text of the convention has been revised multiple times until the latest act signed in Stockholm in 1967.

The text of the convention can be subdivided into four parts. The first subset of articles includes the substantive law that sets the principle of the national treatment in the member countries. The second category explains the right of priority for patent filing procedures. The third part contains additional rights and obligations for legal persons and provides rules member countries should abide to with their legal systems. The last category pertains the administrative infrastructure necessary to implement the Convention.[61]

[60] *Supra,* note 6.
[61] *Ibidem.*

The first clause of the first article aims at constituting a Union of countries for the protection of industrial property. The article sets the general objectives of the convention, the matter protected under its provisions defining all the possible declinations of the concept of industrial property and the tools that regulate its protection.[62] The Convention applies to the safeguard of industrial property matters including utility models, patents, trademarks, industrial designs, service marks, trade names, geographical indications and the repression of unfair competition.[63] Article 2 of the convention specifies that citizens of a country of the Union should benefit from the same treatment reserved to respective national citizens when dealing with countries different from theirs. They should enjoy the same protection abroad as the citizens of the country they are dealing with regarding matters of industrial property.[64] Article 3 extends the principle of national treatment to those who are either domiciled or have a business establishment in one of the countries of the Union, even if their nationality lies outside the borders of the convention.[65]

The Convention introduced the concept of the right of priority in the case of patents, marks, and industrial designs. This principle is a fundamental step forward in the international legal framework that grants IP protection. The related article 4 states that the person seeking IP protection in a Country of the Union, therefore who has filed an application for one of the above specified tools, can subsequently file for protection in any other country of the union with the right of using as filing date the day of the first application.[66] The first filing is valid as basis for the priority right even if the first application shall be rejected or retrieved. Article 4C sets the periods within which the applications following the first filing should be pursued in order to benefit from the right of priority. The first clause establishes a period of twelve months for patents. This right allows the patentee to seek protection in multiple countries without the necessity to file

[62] *Supra*, note 26. Article 1..
[63] *Summary of the Paris Convention for the Protection of Industrial Property (1883)*. (n.d.). Retrieved 18 May 2023, from https://www.wipo.int/treaties/en/ip/paris/summary_paris.html.
[64] *Supra*, note 26. Art. 2, clause 1.
[65] *Ibid*. Article 3.
[66] *Supra,* note 63.

several applications at the same time in order to be granted the priority on the invention.[67]

Focusing on the specific provisions regarding patents, article 4bis institutes the principle of independence. Patents granted by different countries, are they members of the Union or not, shall be considered independently from other patents issued for the same industrial property in other countries.[68] Specifically, the application for patents during the priority period does not make the above patents dependent on each other, regarding both invalidity and durability.[69] Especially, when granting a patent that was applied for through the priority principle, the office issuing the patent can't deduct the priority period from its durability.

Article 4ter states the right of the inventor to be named in the patent. Convention article 5A deals with importation of patent-protected items, failure to work patented inventions, and compulsory licenses. Compulsory licenses in case of insufficient use or failure to use the patented invention are meant to prevent abuses of the exclusive rights granted to the patent owner, this article does not apply to compulsory licenses requested under different conditions.

The last group of articles includes the administrative and financial provisions. As already specified, the aim of the Convention is to create a Union of Countries for the protection of Industrial Property. Along with the creation of legal standards for the member countries, the Convention establishes three administrative institutions which are the Assembly, the Executive Committee, and the International Bureau of WIPO.[70]

Article 13 defines the role of the Assembly as the governing organ of the Union with the power of controlling and policymaking. It makes sure the Convention is implemented and that the Union works properly. Article 14 states the responsibilities and functioning of the Executive Committee which is made of one fourth of the countries and assists the Assembly, making sure its programs are respected.

[67] *Supra*, note 26. Article 4.
[68] *Ibid*. Article 4bis, clause 1.
[69] *Ibid.* Article 4 bis, clause 2.
[70] *Supra,* note 6.

The administrative body is the International Bureau of the WIPO, as specified in article 15, and its head is the Director General of the WIPO.

Article 19 allows member countries to make special agreements outside of the convention, as far as these agreements do not go against its articles. These special agreements may be bilateral or multilateral pacts to provide additional provisions regarding industrial property.

Lastly, the dispute settlement mechanism must be cited. It is dealt with in article 28 which states that interpretative and applicative issues regarding the Convention, not settled by negotiation, shall be brought directly to the examination of the International Court of Justice.[71]

1.2.2 The World Intellectual Property Organization

The Paris Convention lets the states determine the substantive law and the patent granting procedures, consequently it does not provide enough standards for an international legal harmonization.
In the attempt to find a solution to the challenge of harmonizing the international patent system the United Nations established the World Intellectual Property Organization (WIPO).[72] The Convention Establishing the World Intellectual Property Organization signed in Stockholm in 1967, came into effect in 1970, and was amended in 1979.[73]

Both the Paris and the Berne Convention[74] stated in their provisions that the administrations of the conventions needed the establishment of international secretariats. Initially the two conventions had two separate administrative bodies, which were then jointed in 1893. Before it became the WIPO, the United International Bureaux for the Protection of Intellectual Property was named BIRPI, from the acronym of the French version of the name. Being the WIPO an intergovernmental organization, all the

[71] *Ibid.* 261
[72] *Supra*, note 59.
[73] *Supra,* note 6. 4.
[74] WIPO Lex No. TRT/BERNE/001. Berne Convention for the Protection of Literary and Artistic Works, as amended on September 28, 1979.

administrative provisions of the treaties that were administered by the BIRPI had to be edited. In 1974 the WIPO became officially a specialized agency of the UN through an agreement that recognized that WIPO, under the competence of the UN and its bodies, owns the responsibility for acting according to its administered treaties and agreements in order to promote intellectual creativity and the technological transfer of industrial property to developing countries to boost their development.[75]

The final mission of the WIPO is to lead the formation of an international intellectual property system that is balanced and allows for creativity and innovation to bloom.[76]

As stated in the third article of the Convention, the WIPO has the purposes of promoting the protection of intellectual property and ensuring the cooperation between the IP Unions that origin from the administered treaties.[77] These Unions, as specified in the 7th clause of the second article, are the Paris Union, the Berne Union, the Special Unions and Agreements established in relation with the previous two and any other agreement that acts as a promoter of IP protection and that is administered by the WIPO.[78] The fourth article of the Convention explicates some crucial functions the Organization must fulfil in order to respect these objectives.[79]

Beside the administrative role, the Organization also carries out normative activities, manages programmes that ensure technical and legal guidance to states, acts for the standardization and international classification regarding IP and provides services for the registration and filing procedures related to international applications.[80]

Article 5 deals with the theme of membership. Any state which is member of one of the Unions administered by the Organization can become member of the WIPO. If the applicant is not a member of the administered treaties it can get membership if it is member of the UN or its Specialized Agencies, of the Atomic Energy Agency, of the

[75] *Supra*, note 6. 5.
[76] World Intellectual Property Organization, *Inside WIPO*. Retrieved 16 May 2023, from https://www.wipo.int/about-wipo/en/index.html.
[77] WIPO Lex No. TRT/CONVENTION/001. *Convention establishing the World Intellectual Property Organization*. Article 3.
[78] *Ibid.* Article 2, clause VII.
[79] *Ibid.* Article 4.
[80] *Summary of the Convention Establishing the World Intellectual Property Organization (WIPO Convention) (1967)*. Retrieved 16 May 2023, from https://www.wipo.int/treaties/en/convention/summary_wipo_convention.html.

International Court of Justice or if invited to join the WIPO directly by the General Assembly.[81] The General Assembly is the organ in which all the Governments of the Member States are represented.[82] The main functions of the Assembly are to appoint the Director General and to review their reports and those of the Coordination Committee, to adopt the financial regulations of the WIPO and the biennial budgets of the Unions.[83]

The WIPO Conference is the body responsible for adopting amendments to the Convention, whereas the Coordination Committee advises on financial and administrative matters to the other bodies of the WIPO and it drafts the Agendas for the Conference and the General Assembly. The WIPO Secretariat is the International Bureau, whose head is the Director General.[84]

As Article 10 specifies, the headquarters of the Organization are in Geneva.[85] Article 11 instead points out the guideline for the finances of the Organization. The WIPO has two different budgets, the budget of the Conference and the common budget of the Unions.[86] The main sources come from the fees paid for international filing and registration services and from the contributions of the member states. The contributions are computed according to the classes into which the States are divided.[87]

The activities conducted by the Organization has progressively diversified and intensified. A clear example of its growing agency is the rising use of international treaties that aim at facilitating registration procedures for IP protection across borders, such as the Patent Cooperation Treaty (PCT), the Madrid Agreement and Protocol Concerning the International Registration of Marks, the Hague Agreement Concerning the International Deposit of Industrial Designs, and the Patent Law Treaty.

WIPO also showed an increasing commitment towards less developed economies, assisting them in the development of their administrative structures and in the

[81] *Supra*, note 77. Article 5.
[82] *Ibid.* Article 6, clause 1.
[83] *Supra,* note 80.
[84] *Ibid.*
[85] *Supra*, note 77. Article 10.
[86] *Ibid.* Article 11.
[87] *Supra,* note 80.

enforcement of IP laws. WIPO's Development Cooperation Program aims at assisting developing countries with legal, administrative, and practical guidance to help them achieve better socio-economic results through their intellectual property systems.[88] In particular, WIPO took on a fundamental role in the implementation of the World Trade Organization Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS) in the Least Developed Countries (LDCs).

Another focal point in the Organization's agenda is the development of the creative potential of small and medium enterprises (SMEs).[89] The Organization has a specific program to sustain these realities through tools that allow SMEs to self-assess their IP assets and to manage them. Moreover, SMEs represent almost one fourth of the users of the WIPO's Arbitration and Mediation Centre (AMC).[90] The AMC is indeed another service carried out by the Organization which offers, as stated by the name, mediation, and arbitration services for intellectual property disputes between private parties.[91]

Another fundamental role covered by WIPO concerns the law enforcement. In the ninety's the Organization had two committees: the Advisory Committee on Enforcement of Industrial Property Rights and the Advisory Committee on the Management and Enforcement of Copyright and Related Rights in Global Information Networks. In 2002 the two were merged into the Advisory Committee on Enforcement that deals with all issues related to intellectual property enforcement in the member countries.[92]

WIPO's agenda ultimately pursues a policy of empowerment, trying to expand IP protection benefits to all the members of our society, helping them get access to the knowledge and tools of beneficial functioning intellectual property systems.[93]

1.2.3 The Patent Cooperation Treaty

[88] *Supra,* note 6. 196.
[89] *Ibid.* 6.
[90] World Intellectual Property Organization, *IP is Key to SMEs' Future Development*. Retrieved 5 June 2023, from https://www.wipo.int/about-wipo/en/offices/china/news/2021/news_0033.html.
[91] *Supra*, note 6. 232.
[92] *Ibid.* 220.
[93] *Ibid.* 7.

The Patent Cooperation Treaty (PCT) was a result of the efforts made by WIPO to build a better international cooperation. The main achievement of the Treaty was the establishment of a unitary application process, valid for all the countries party of the treaty in which the inventor wants to seek protection.[94] National patent systems require an application for each state in which IP protection is sought, except for regional patent systems where the patent office operates for several states. As set by the Paris Convention, once the application for protection has been filed in one country, the applicant can claim the right of priority for the following twelve months for subsequent applications in other countries. However, this implies many different procedures which translates into high expenses. To reduce the effort derived from these multiple applications, in 1966 the Executive Committee of the International (Paris) Union for the Protection of Industrial Property asked the BIRPI to elaborate a solution. This resulted in the Washington Diplomatic Conference of June 1970 which finally adopted the Patent Cooperation Treaty, that entered then into force in 1978.[95]

The PCT did not introduce an international patent granting procedure, the right and duty to grant or deny protection still reside in the national patent offices where protection is pursued.

The PCT is a complementary treaty to the Paris Convention, to which a state must be party in order to become a signatory of the PCT. To sum up, the main goal of the treaty is to simplify procedures and to reduce costs for inventors who seek patent protection in many different countries.[96]

The first step of the application mechanism requires the filing with a national, regional office or WIPO, respecting the formal requirements[97] set by the treaty and paying one set of fees. The filing is followed by the international search. The ISA of choice (International Searching Authority)[98] analyses the filed documents and the prior art, and

[94] *Supra*, note 59.
[95] *Supra, note 6.* 276-277.
[96] *Ibid.*
[97] *Supra*, note 32. Article 3 *The international Application*; Article 4 *The Request*.
[98] *Ibid.* Article 16 - The International Searching Authority. As the clause 1 of the article states, "International search shall be carried out by an International Searching Authority, which may be either a national Office or an intergovernmental organization, […]". The 3rd clause specifies

then drafts an opinion on the patentability of the IP. The PCT sets high quality standards to comply with in this phase. The searching authority must have at least the minimum documentation prescribed by PCT, that is all the patent documents of the major industrialized countries from 1920 onwards, as well as non-patent literature. The search ends with a report that can state either a favourable or unfavourable result; in the first case, no citations of prior art appeared to hinder the granting of the patent; the second scenario instead gives the applicant the opportunity to modify the claims that were found to be similar to prior art.

The third phase is the international publication, whose purpose is to publicly disclose the innovation and to define the scope of protection. The disclosure of the invention occurs eighteen months after the filing date of the international application.

Before the application is handled by the national offices, the applicant may request an international preliminary examination. This consists of a further patentability analysis, usually regarding the version of the application modified accordingly with the written opinion resulted from the first search. Preliminary Examining Authorities file a report which, if positive, provides the applicant an even stronger hope in seeing the patent granted by the elected offices.[99]

The application flow then can enter the national phase. If the applicant thinks their chance to get the patent granted is low, they can either withdraw the application or do nothing and let it expire. If the international phase gave them confidence on the patentability of their invention they can proceed with the payment of the national fees in the designated offices and if necessary, provide a translation of the international application.[100]

The first chapter of the treaty deals with international application and search. The third Article sets the requirements to file the application. Article 4 specifies that the international request should indicate the desire to follow the PCT route for international application, and moreover the applicant is required to express all the States ("designated

"International Searching Authorities shall be appointed by the Assembly. Any national Office and any intergovernmental organization satisfying the requirements referred to in subparagraph (c) may be appointed as International Searching Authority."

[99] *Supra,* note 6. 279-281.

[100] *Ibid*. 281-282.

States") or regional offices in which they want to pursue patent protection in the last phase.[101] The following articles set the rules for the description, the claims and the drawings, the profile of the applicant, the filing date, and the international search and publication. The second chapter of the treaty focuses on the step of the international preliminary examination, the third treats some more general provisions, whereas the fourth chapter deals with the Patent Information Services and the Committee for the Technical Assistance.[102] This Committee is made of elected members among the Contracting states whose task is to organize technical assistance on patent systems improvement for contracting states classified as developing countries. The assistance involves training of professionals and equipment supply.[103]

The fifth chapter includes the administrative provisions, regarding therefore the constitution of the Assembly, the Executive Committee, and the International Bureau.[104]

The Treaty is ultimately administered by WIPO which acts as a Secretariat to the bodies cited above such as the PCT Assembly. WIPO coordinates the whole PCT system, and aids new Contracting states, also publishing the PCT Applicant's Guide, and organizing courses and seminars. It is responsible for receiving and keeping all the documents from application procedures, performing the examination of formalities, publishing the international application on the Patentscope[105], communicating the documents to national and regional offices and many other tasks.[106]

The advantages of PCT benefit both patent offices, applicants, and national economies. Patent Offices can process more demands since those coming from the PCT route require less effort in the inspection phase. Patent Offices save part of publication costs: if the international publication is in the same language of the country, no translation is needed; if the language is different the patent office is only required to translate the abstract of

[101] *Supra,* note 87.
[102] *Supra*, note 97.
[103] *Ibidem*, Article 51.
[104] *Ibidem.*
[105] The Patentscope is a database that includes all the published International PCT applications, patent documents from several national and regional offices and non-patent literature. - *PATENTSCOPE*. (n.d.). Retrieved 6 June 2023, from https://www.wipo.int/patentscope/en/index.html.
[106] *PCT FAQs*. Retrieved 12 May 2023, from https://www.wipo.int/pct/en/faqs/faqs.html.

the application. The revenues of the offices are not damaged by the Treaty, since the main source of income for the offices is renewal fees which are not affected by PCT.

The international procedure also grants higher legitimacy to the patent when approving licensing agreements. Applicants can reduce their costs greatly, following the PCT international procedure allows the applicant to prepare only one application, being able to save on translation expenses, at least until the international PCT phase ends. National economies and industries will benefit from the stronger basis provided by international search and preliminary examination for investments in that specific invention. Technological progress in general is highly beneficial to the economy of a country and since PCT facilitated international patent protection, it consequently allowed for easier transfers of protected technology and licensing processes. Licensed technology usually leads to foreign investment and therefore to employment and diffusion of knowledge. The last advantage that deserves to be mentioned is the circulation of fundamental technical information through the international publication. The patent offices of the Contracting states can indeed claim a copy of all published PCT applications. Access to this kind of information is crucial for developing countries.[107]

1.2.4 The Patent Law Treaty

On June 2000 at a Diplomatic Conference held in Geneva a new treaty was adopted, the Patent Law Treaty (PLT). The objective of the PLT, which entered into force on the 28th of April 2005, was to harmonize and streamline formal procedures regarding applications and patents before national and regional patent offices. Except from the requirements for the date of filing, the PLT sets the maximum requirements that a patent office in a contracting state could apply.[108] The two general principles of the Treaty, as stated in the second Article, are the "more favourable requirements" and no regulation of substantive patent law. According to the first concept, the Contracting party is allowed to define prerequisites for applicants and owners that are more favourable than those stated in

[107] *Supra*, note 6. 282-285.
[108] WIPO Lex No.TRT/PLT/001, Patent Law Treaty (adopted by the Diplomatic Conference on June 1, 2000).

the Treaty. The latter principle specifies instead that the Treaty does not mean to interfere with the applicable substantive law of the Contracting states.[109]
Any State party of the Paris Convention or of the WIPO may become party of the PLT, as well as any intergovernmental organization whose at least one of the member states is party of the Paris Convention, and could grant patents for the member states.[110]

As stated in Article 3, the Treaty is applicable to all patents for invention and addition and to all the applications filed in national and regional offices, or that entered the national phase of the PCT route. For national and regional applications, the Treaty establishes a single set of formal requirements that are internationally standardized, and moreover the formal requirements provided by the PCT are incorporated in the PLT to avoid having two different international standards.[111] The Treaty also addresses the issue of the loss of rights that can result from errors in the compliance with formalities standards, providing some relief procedures.[112]

These and many more provisions allow for a general simplification and standardization of the formal requirements, resulting in a lower risk of mistakes in the formalities and thus in a lower risk of loss of rights and in a reduction of the costs. For these reasons the PLT is as advantageous for investors as it is for applicants and patent attorneys. These entities can indeed rely on a fixed set of formalities in all the contracting parties of the PLT. Patent offices also benefit from the harmonization and furthermore from the simplification of the procedures that allow them to operate more efficiently and in a more cost-effective way.[113]

1.2.5 The European Patent Convention

[109] WIPO Lex No.TRT/PLT/001, Patent Law Treaty (adopted by the Diplomatic Conference on June 1, 2000), Article 2 – General Principles.
[110] *Supra,* note 6. 301.
[111] *Supra*, note 99, p.302.
[112] *Supra*, note 98, Article 11-1-i, Article 11-1-ii, Article 11-2.
[113] *Supra*, note 99, p. 305.

The Convention on the Grant of European Patents, also known as the European Patent Convention (EPC), was signed in Munich on 5 October 1973 and entered into force in 1977.[114]

The EPC established an autonomous patent system aimed at granting European patents.[115] The preamble of the Convention sets the goal of incrementing international co-operation between the member states on the matter of protection of patents. The aim was to harmonise and streamline the patent granting process in Europe. Nowadays, the EPC members are thirty-nine, to which we shall add four validation states and one extension state. All the members of the European Union are part of the European Patent Convention.

Article 4 of the Convention established a European Patent Organisation structured with two organs, the European Patent Office and the administrative council, that shall work jointly in order to grant European patents. According to article 6, the headquarter of the EPO shall be in Munich.

European patent applications can be filed before the national patent office of a country member to the Convention or before the EPO.[116] English, French and German are the official languages of the European Patent Office. If the application is filed in any other language, it must be accompanied by a translation in one of the three official languages.[117]

The European patent obtained results in a bundle of national patents. After the European application procedure, the European patent needs to be validated before the national offices of the countries where the patent owner wants to seek protection in. Through one unique procedure protection can be sought in up to forty-four member countries.

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[114] The 17th edition (November 2020) of the European Patent Convention, its Protocols and Implementing Regulations take into account amendments up to the "Decision of the Administrative Council of October 13, 2022, Amending Rules 46, 49, 50, 57, 65, 82, 126, 127 and 131 of the Implementing Regulations to the European Patent Convention (CA/D 10/22)", which enters into force on different dates (February 1, 2023 and November 1, 2023). Article 2 of this Decision introduced amendments to Rules 46, to 50, 57, 65 and 82 (in force on February 1, 2023) as provided in the 17th edition.

[115] *Supra*, note 43.

[116] *Supra*, note 114. Article 75(1) and Rule 35.

[117] *Ibid*. Article 14.

National validation procedures are usually expensive and complex due to the different validation requirements and the national fees. Therefore, in 2012 the European Union Council elaborated two regulations that created a European patent with unitary effect called the unitary patent.[118] Additionally, an Agreement for the establishment of a Unified Patent Court was signed in 2013.[119]

The Unitary Patent System entered into force on June the 1st 2023. Since that day, the Unified Patent Court has gained the exclusive jurisdiction as specialised patent court for infringement and revocation actions for both European and unitary patents.

Unitary patents have unitary effect of IP protection in the participating European Union states. All the procedures are handled by the EPO, from filing to post-grant administration necessities. Renewal fees are centralised and so are the rules of the substantive patent law that the UPC Agreement harmonised. The phase before the grant of the patent follows the same guidelines set by the European Patent Convention. After the granting of a European patent, the patentee can request the unitary effect provided by the UPC.[120] If the demand is successful, the patent owner will benefit from all the advantages of unitary patents, such as the uniform protection, the single renewal fee, a single ownership, and a single court to which they can appeal to. [121]

1.3 Obstacles and challenges in the harmonization of patent law in developing countries

Effective IPR systems can create a favourable environment for creativity and innovation. Nonetheless, many developing countries still lack a functioning IP regulation thus

[118] Council Regulation (EU) No. 1257/2012 of the European Parliament and of the Council of 17 December 2012 implementing enhanced cooperation in the area of the creation of unitary patent protection (UP Reg). / Council Regulation (EU) No. 1260/2012 of 17 December 2012 implementing enhanced cooperation in the area of the creation of unitary patent protection with regard to the applicable translation arrangements (Transl. Arr.).
[119] Agreement on a Unified Patent Court and Statute. Council of the European Union, Document No. 16351/12 (11 January 2013). Official Journal of the EU Council 175 (2013) pp. 1-40.
[120] Office, E. P. *When was the Unitary Patent system launched?* Retrieved 21 July 2023, from https://www.epo.org/applying/european/unitary/unitary-patent/start.html.
[121] *Supra*, note 43.

hindering the social and economic benefits coming from intellectual property rights enforcement.[122]

In 2001, the UK Government's Commission on Intellectual Property Rights commissioned a study to Mart Leesti and Tom Pengelly on the policy making, administration and enforcement of intellectual property rights in poor countries. The report highlighted the lack of expertise in the matter of IP in national academic institutes and the consequent shortages of professionals able to work in the policy making process of IP regulations in developing countries. The institutional and policy-making apparatus indeed requires highly developed technical knowledge in order to elaborate effective and tailor-made IP regulations but often the responsibility in least developed countries falls in the hand of foreign affairs or international trade ministries. This leads to a systematic inefficiency in the national legislations which is the confused result of a combination between the adherence to international treaties, existing and outdated laws and fragmented statements made by the appointed ministries and government officials.

Financial and human resources limitation lead to difficulties in the administration and implementation of new legal provisions in the area of IP, but efficiency is further hindered by a general low comprehension of IP matters both by the business world and by the exponents of the political and scientific communities.[123] There is an absence of general understanding around the theme of intellectual property rights, both within the population and IP owners themselves. Infringement is not perceived as a severe offense and policymakers themselves are unaware of the benefits that functioning IP protection could bring to the development of the national economy.[124]

Administrative procedures are as important as the policymaking process when analysing the efficiency of an IPR national system. Administration regards applications for protection, examination of formalities, granting, registrations, publications, and

[122] Olubiyi, I. A., Emerole, U. A., & Adetula, A. F. (2022). *Contemporary Challenges to Intellectual Property Rights in Developing Countries: Looking Beyond the Laws (Nigeria as a Case Study).* IIC - International Review of Intellectual Property and Competition Law, 53(1), 5–30.
[123] Leesti, M., & Pengelly, T. (2002). *Institutional issues for developing countries in intellectual property policymaking, administration & enforcement*. Commission on Intellectual Property Rights.
[124] *Supra*, note 103.

oppositions procedures. The lack of trained staff and of automated or computerized processes are the major obstacles to build highly effective offices.

Beside the deficiencies shown in the national administrations, another issue emerged: the difficulty to actively participate in the international rule making processes, given also by the fact that many countries, not only lack expertise, but also, they do not have a steady representation in the WTO and WIPO meetings.[125]

One of the major challenges that globally affect the efficiency of IP systems is the enforcement of their laws. The principle of territoriality deeply hinders cross-border IP enforcement. The protection of IP rights relies on domestic legislation and is confined to the territory over which the national or regional government exercises sovereignty. The concept of territoriality therefore intervenes when an infringement occurs complicating the establishment of the competent jurisdiction.[126] Economic development, international trade and todays increasing cross-border mobility puts growing pressures on this fragmented system of laws.[127]

Among the external challenges in the adaptation and implementation of IP regulations globally, another difficulty that needs to be cited is the internet, that enhancing international connectivity, makes it easier to infringe protected IP. Moreover, the widespread poverty of developing countries is one of the main obstacles to IP protection. High unemployment rates for instance constitute fertile ground for illegal activities such as counterfeiting and piracy. The lack of financial resources will lead consumers to prefer counterfeited goods for their lower prices, and IP owners to not proceed with the prosecution of those who infringed their rights.[128]

The challenge for emerging economies, is to exploit IP benefits through effective IP protection systems, without importing the problems that developed and technology-exporting countries were not able to solve in this regard. As Reichman stated, there are two possible approaches developing countries can follow in establishing their IPR regimes. The first is to stick with the models of IP regulations formulated in OECD

[125] *Supra*, note 123.
[126] *Supra*, note 25.
[127] D. Chisum, "Normative and Empirical Territoriality in Intellectual Property: Lessons from Patent Law" (1997) 37 Virginia Journal of International Law 603.
[128] *Supra*, note 122.

countries. This approach may reduce the internal national debate on the legitimacy of the IP policies and may also accommodate the pressures coming from OECD countries themselves. The alternative approach is called the "counter-harmonization" which would consist in a more experimental path based on the countries specificity and on a transnational system of innovation in IP law.[129]

1.3.1 Challenges in the harmonization in Sub-Saharan Africa

The African continent presents various IP systems. The two major regional organisations are the Organisation Africaine de la Propriété Intellectuelle (OAPI) and the African Regional Intellectual Property Organisation (ARIPO). Eighteen countries of the African continent, mainly in Northern Africa, are not members of the organizations and rely instead on national regulations only.[130] ARIPO and OAPI mainly follow a linguistic basis, being the ARIPO for English-speaking African Countries and the OAPI for francophone countries. Moreover, the current IP system in the continent is based on a regionalism that does not include the most powerful African economies, Nigeria, and South Africa.[131]

Throughout the last decades, a common belief and hope have been arising around the concept of a unified Pan African Intellectual Property Organisation (PAIPO). The benefits that would come from a unified and supposedly stronger African IP organization are the harmonization of regulations within the continent, facilitating trade within but also beyond the continent; a uniformed internal IP law, that would make it easier for investors to operate in the African market; an Africa-wide IP institute that would have more voice in international debates, speaking up for all the needs of the continent. A unified policy would also facilitate awareness and knowledge building throughout the continent.

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[129] Reichman, J. H. (2014). *Intellectual Property in the Twenty-First Century: Will the Developing Countries Lead or Follow?* In M. Cimoli, G. Dosi, K. E. Maskus, R. L. Okediji, & J. H. Reichman (Eds.), *Intellectual Property Rights* (pp. 111–181). Oxford University Press.

[130] Banda, M. (2017). *Challenges for the harmonisation of Africa's intellectual property systems through the Pan-African Intellectual Property Organisation (PAIPO),* African Journal of Intellectual Property, Vol.1 Number 2*,* (pp.99-106).

[131] Mupangavanhu, Y. (2015). *African Union Rising to the Need for Continental IP Protection? The Establishment of the Pan-African Intellectual Property Organization*. Journal of African Law, 59(1), 1–24.

Nonetheless, the project received many critiques, for instance the accusation of being biased towards developed countries' standards, or the absence of transparency in the drafting process of the statute of the organization. The implementation of PAIPO has been hampered mainly by the substantial differences in the OAPI and ARIPO systems. The initial PAIPO Concept Paper[132] drafted by the African Union actually does not provide an explanation of how these systemic differences would be addressed and this led to a lack of public and political support.[133] According to the Final Draft of the statute that establishes PAIPO, the organization is set to be a specialized agency of the African Union (AU),[134] but OAPI and ARIPO are not linked to the African Union and therefore do not share its fundamental objective of regional integration, and this is argued to be a crucial obstacle to the creation of PAIPO.[135]

[132] EX.CL/315 (X) Rev.1 Executive Council Tenth Ordinary Session 25 – 26 January 2007 Addis Ababa, Ethiopia. Retrieved 10 June 2023, from http://archives.au.int/handle/123456789/4318.
[133] *Supra*, note 130.
[134] African Union lex ref: AU/STRC/522. Final Draft Statute of the Pan-African Intellectual Property Organization, Art. 2. Available at https://au.int/sites/default/files/newsevents/workingdocuments/27580-wd-paipo_statute_english.pdf.
[135] *Supra*, note 131.

CHAPTER 2

The Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS)

2.1 Introduction to the Agreement on Trade-Related Aspects of Intellectual Property Rights

The Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS) constitutes the Annex 1C of the Agreement that on April 15 of 1994 established the World Trade Organization. The Marrakesh Agreement Establishing the World Trade Organization was the result of the negotiations that took place under the context of the General Agreement on Tariffs and Trade (GATT) in the Uruguay Round ended on the 15th of December in 1993. In this framework, the aspects of intellectual property rights related to trade officially entered the international discourse for the first time. The WTO Agreement, and therefore its Annex 1C, became effective on January the 1st, 1995.[136]

The main goal of the World Trade Organization, as stated in Article II, is to generate a common framework to regulate international trade relations between its Members.[137] Article III defines the functions of the Organization; the WTO mainly shall assist the implementation and administration of the treaty and shall provide a forum for negotiations.[138]

The WTO has a sound structure organized in three levels of hierarchy. The highest authority is represented by the Ministerial Conference which is composed of representatives for each one of the Members. The second level is the General Council, which works as a Dispute Settlement Body and as the Trade Policy Review Body; moreover, it coordinates the three councils on the third level of the power pyramid: the Council for Trade in Goods, the Council for Trade in Services, and the Council for Trade-Related Aspects of Intellectual Property Rights.[139] The TRIPS Council has the role of

[136] *Supra,* note 6. 345.
[137] *Marrakesh Agreement Establishing the World Trade Organization.* Article II "*Scope of the WTO*." Available at *https://www.wto.org/english/docs_e/legal_e/04-wto.pdf.*
[138] *Ibid.* Article III "*Functions of the WTO*".
[139] *Ibid.* Article IV "*Structure of the WTO*".

overseeing the TRIPS Agreement, and controlling the compliance of the Members with the obligations therein. Therefore, the Marrakesh Agreement inevitably was also the premise for the establishment of a solid relationship between the WTO and the World Intellectual Property Organization.

The TRIPS Agreement includes provisions regarding copyrights and related rights, trademarks, geographical indications, industrial designs, patents, layout-designs of integrated circuits[140], and undisclosed information. The Agreement incorporates three main areas which are the standards, the enforcement, and the dispute settlement. It provides minimum standards that Member states should respect, letting them free to use them as a starting point to implement stricter measures.[141]

2.1.1 Principles and General Provisions

The general objectives of the Agreement are listed in the Preamble and encompass the reduction of distortions and impediments in international trade, promoting the protection of IP rights. The Preamble also recognizes the need to intervene around the matter of the enforcement of trade-related intellectual property rights, providing adequate standards and effective dispute settlement procedures. Intellectual property rights are defined as private rights whose importance is related to national public policy purposes. The text also acknowledges the different needs developing countries have and their consequential necessity of flexibility in the implementation of the provisions of the Agreement.[142]

[140] Article 35 of the Trade-Related Aspects of Intellectual Property Rights regards the protection of layout-designs of integrated circuits that must comply with "Articles 2 through 7 (other than paragraph 3 of Article 6), Article 12 and paragraph 3 of Article 16 of the Treaty on Intellectual Property in Respect of Integrated Circuits and,". The Treaty on Intellectual Property in Respect of Integrated Circuits (IPIC) defines integrated circuit and layout-design in Article 2, clause I and II. Available at https://www.wipo.int/wipolex/en/text/294976.

[141] *WTO | intellectual property—Overview of TRIPS Agreement*. Retrieved 18 June 2023, from https://www.wto.org/english/tratop_e/trips_e/intel2_e.htm.

[142] WIPO Lex No. TRT/WTO01/002. Agreement on Trade-Related Aspects of Intellectual Property Rights (as amended on 23 January 2017), *Preamble*. Available at https://www.wipo.int/wipolex/en/treaties/details/231.

The first obligation member states need to comply with is to grant the protection of intellectual property to all the natural or legal persons of other Members. The persons bound to receive this treatment are all the WTO Members that would respect the eligibility criteria of previous IP conventions. These conventions are the Berne Convention, the Paris Convention, the Rome Convention[143] and the Treaty on Intellectual Property in Respect of Integrated Circuits.[144] Specifically, as stated in Article 2 of TRIPS, regarding the second, third and fourth part of the Agreement, that respectively deal with standards, enforcement and acquisition, and maintenance of IP rights, Members should conform with the norms outlined in the Articles 1 to 12 and Article 19 of the Paris Convention. Moreover, none of the provisions of the TRIPS Agreement can interfere with the obligations of the Conventions cited above.[145]

National Treatment and Most-Favoured-Nation Treatment are respectively dealt with in Article 3 and 4 and are equally applicable to all the categories of IP in the Agreement, safeguarding their protection around matters such as their availability and acquisition, their scope, maintenance, and enforcement. National Treatment requires Members to provide the same treatment to both their nationals[146] and other Members' nationals regarding IP protection. Most-favoured nation treatment should instead prevent discrimination between nationals of other member countries, implying the applications of the same terms to all the Members of the Agreement.[147]

Article 7 deals again with the objectives of the Agreement. As stated therein, effectively protected, and enforced intellectual property rights would be able to promote innovation and transfer of technology, bringing mutual advantage to producers and consumers, resulting in a higher level of economic and social welfare and in more justice.[148]

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[143] Rome Convention for the Protection of Performers, Producers of Phonograms and Broadcasting Organizations. 1961. Available at https://www.wipo.int/wipolex/en/treaties/textdetails/12656.
[144] *Supra*, note 142. Article 1.3 *Nature and Scope of Obligations*.
[145] *Ibidem*, Article 2 *Intellectual Property Conventions*.
[146] "Nationals" in the Agreement are to be intended as natural or legal persons who are domiciled or have a real industrial or commercial establishment in the customs territory considered.
[147] *Supra,* note 141.
[148] *Supra*, note 142. Article 7 *Objectives*.

The last article of the first part is Article 8, "Principles". This reminds the final right of members to shape laws and regulations, adopting measures that are coherent with the Agreement itself, in order to safeguard public health, nutrition and public interest in strategic sectors of the country that can promote its development. For instance, "appropriate measures" can be undertaken by Members to block abuses of IP rights by their holders or to prevent practices which "unreasonably" limit trade or hinder the transfer of technologies internationally.[149]

2.1.2 Enforcement of Intellectual Property Rights

The third part of the Agreement covers the issue of the enforcement procedures that shall be put in place to grant prevention of infringements and effective action against them when they occur. Article 41 includes the general obligations Members should respect. The first clause warns on the fact that the application of enforcement measures, only meant to prevent infringement, shall not create barriers to trade. The Agreement does not impose the creation of a separate judicial system, devoted to IP issues only and different from the one that regulates the enforcement of general laws nationally. Moreover, enforcement procedures should be "fair and equitable" and not unreasonably expensive nor complex.[150]

The second section of this part of the TRIPS deals with civil and administrative procedures and remedies. Article 42 further specifies the features that allow for a procedure to be defined fair and equitable. It lists the principles necessary to grant a due process. Article 43 defines how to apply the rules on evidence in certain situations. Articles between 44 and 49 cover injunctions, damages, and other remedies. Article 46 imposes that judicial authorities shall have the authority to either destroy or deploy via non-commercial channels all the infringing goods, as an attempt to discourage infringement.

[149] *Ibid.* Article 8 *Principles*.
[150] *Ibid.* Part III, Enforcement Of Intellectual Property Rights, Section 1- General Obligations. Article 41.

The following section covers provisional measures and it consists of Article 50 of the Agreement. The article requires member countries to provide their judicial authorities with the tools and powers to order provisional measures effectively. These are needed either to prevent an infringement itself or to stop the distribution of infringing goods on the market.[151]

Section four of the enforcement chapter regards the special requirements related to border measures. The Agreement puts more attention on internal enforcement mechanisms which would allow to stop the infringement at the source; however, since this would not always be possible, the TRIPS highlights the importance of measures for borders enforcement in order to develop a chain of cooperation with customs administrations, able to control the circulation of infringing goods.[152] The TRIPS enables the holder of an IP right, who has proofs to suspect an imminent importation of counterfeit trademarks or pirated copyrights, to file an application for the suspension of the release into free market circulation of these suspected goods by the customs authorities (Article 51).[153] Article 52 covers the matter of this application procedure, article 53 deals with security or equivalent assurance, article 54 is about the notice of suspension and article 55 tackles its duration. The following articles of this section are about the indemnification of the importer and of the owner of the goods (article 56), right of inspection and information (article 57), ex officio action (article 58), remedies (article 59) and *de minimis* imports (article 60).

The last section of the enforcement chapter addresses criminal procedures. The provisions of the Agreement leave members with a wide flexibility of action however, Article 61 suggests that the penalties shall include imprisonment and monetary fines in order to sufficiently discourage crimes violating IP rights.[154]

2.1.3 Dispute prevention and settlement

[151] *Ibid*. Part III, Article 42-61.
[152] *WTO | intellectual property—Overview of TRIPS Agreement—Enforcement*. Retrieved 25 June 2023, from https://www.wto.org/english/tratop_e/trips_e/intel2b_e.htm#enforcement.
[153] *Supra,* note 6. 356.
[154] *Supra,* note 152.

The fourth part of the Agreement, consisting of article 62, contains general provisions on the procedures for the acquisition and maintenance of intellectual property rights and related *inter-partes* procedures.[155] The objective of this part is to guarantee that unnecessary difficult procedures, to acquire or maintain IP rights, are not put in place causing the risk to hinder the protection demanded by the Agreement. The first paragraph of Article 62 states that Members could impose the compliance with reasonable procedures and formalities as a condition for the acquisition and maintenance of IP rights. If so, paragraph two specifies that members are required to enable the granting or registration of the intellectual property in a reasonable period. Procedures for acquisition and maintenance of IP rights, and if present administrative revocation or opposition and other *inter-partes* procedures, shall comply with Article 41 of the Agreement which sets out the general principles for decisions and review.[156]

The fifth part of the Agreement deals with the mechanisms for dispute prevention and their settlement. Article 63 is titled *Transparency* and requires TRIPS Members to make the laws, the judicial decisions, and administrative rulings publicly available in a national language in order to allow governments and rights holder to get acquainted with them. Moreover, members are required to notify the TRIPS council on their laws and regulations pertaining the subject matter of the Agreement.[157]

Article 64 recalls articles 22 and 23 of the GATT 1994[158], which defined the system to settle disputes within the WTO context. WTO dispute settlement mechanism is then further explained in the Understanding on Rules and Procedures Governing the Settlement of Disputes (DSU), which is the Annex 2 to the WTO Agreement.[159] The TRIPS

[155] *Supra,* note 6. 356.
[156] *WTO | intellectual property—Overview of TRIPS Agreement—Other provisions*. Retrieved 25 June 2023, from https://www.wto.org/english/tratop_e/trips_e/intel2c_e.htm#top.
[157] *Supra*, note 142. Part V, Article 63..
[158] The General Agreement on Tariffs and Trade (GATT 1947), Article XXII *Consultation*, Article XXIII *Nullification or Impairment,* Available at https://www.wto.org/english/docs_e/legal_e/gatt47_e.pdf.
[159] Uruguay Round Understanding on Rules and Procedures Governing the Settlement of Disputes, Annex 2 of the WTO Agreement, Available at https://www.wto.org/english/tratop_e/dispu_e/dsu_e.htm.

Agreement itself applies these provisions to the consultations and the dispute settlement system regarding its subject matter.[160]

Article 2 of the DSU establishes a Dispute Settlement Body (DSB) whose purpose is to administer the provisions of the Understanding. The DSB shall have the power to establish panels and adopt the reports of the arbitrations, the panels, and the Appellate Body. Furthermore, DSB oversees the implementation of the rulings of the cited reports and has the authority to suspend concessions in case of non-compliance with the said rulings.[161]

Disputes between WTO members shall be ideally solved through negotiations. Alternatively, WTO Members may request the establishment of a dispute resolution panel. After the panel issues a report, a legal appeal may be brought before the WTO's Appellate Body. This Body can support, overturn, or modify the conclusions of the panel. If a party does not comply with the result of the dispute, either trade compensations or sanctions may be imposed.[162]

The second paragraph of article 64 of TRIPS specified that, for a period of five years from the entry into force of the GATT 1994, subparagraphs 1(b) and 1(c) of the above cited Article 23 shall not be applied to dispute settlement in the context of the TRIPS. The two subparagraphs cover the cases of "non-violation" dispute settlement.[163] Article 64.3 of the TRIPS Agreement stated that the TRIPS Council should have examined the provisions and if necessary, the Ministerial Conference could have planned an extension of the five years period.[164]

[160] *Supra,* note 6. 357.
[161] *Supra*, note 159. Article 2 *Administration*.
[162] European Commission Website, *WTO dispute settlement*. (2023, April 28). Available at https://policy.trade.ec.europa.eu/enforcement-and-protection/dispute-settlement/wto-dispute-settlement_en.
[163] *Supra*, note 158. Article XXIII. Paragraph 1(b): "as the result of the application by another contracting party of any measure, whether or not it conflicts with the provisions of this Agreement". Paragraph 1(c): "as the result of the existence of any other situation".
[164] *WTO | intellectual property (TRIPS)—Documentation used in technical cooperation*. Retrieved 26 June 2023, from https://www.wto.org/english/tratop_e/trips_e/ta_docssec6_e.htm.

2.2 Substantive standards of protection for patents

The second part of the Agreement concerns the minimum substantive standards that member states shall comply with regarding the availability, scope, and use of intellectual property rights. This part is divided into eight sections, each one devoted to a specific intellectual property category, respectively copyright and related rights, trademarks, geographical indications, industrial designs, patents, layout designs of integrated circuits, protection of undisclosed information and control of anti-competitive practices in contractual licenses.[165]

Focusing on the fifth section that deals with patents, its provisions cover the availability, scope, and the use of patents, including articles between 27 and 34. [166]

Article 27 handles patentable subject matter. Every invention, either product or process, independent from its field of technology, shall be patentable, if it respects the characteristic of novelty, inventive step, and industrial applicability. The article also specifies that patents shall be *available* and their rights should be easily *enjoyable* regardless of the place of invention, the technological field and if the product or process is either imported or locally made. This clause is however subject to the fourth paragraph of Article 65, paragraph eight of Article 70 and the third paragraph of article 27 itself.

The patentability of the invention is subject to the second and third paragraph of article 27. The second paragraph allows Members to leave out from patentability the inventions considered to be a potential threat for the public order or the morality of the state, with the aim of protecting the environment, human, animal or plant lives or their health. Article 27.3 enables the member states to rule out from patentability those inventions that either involve diagnostic, therapeutic and surgical methods for the treatment of humans or animals, or varieties of plants or animals other than micro-organisms.[167]

Article 28 deals with the rights conferred to the patentee. A patent bestows exclusive rights to its proprietor. A differentiation is then made between the protection conferred to a product and a process. Article 28.1 (a) specifies that in the case of a product, the

[165] *Supra,* note 6. 349.
[166] *Ibid*. 352.
[167] *Supra*, note 142. Part II, Article 27 *Patentable Subject Matter*.

patent allows to prevent third parties from commercially using and benefitting from the invention without the owner's consent. 28.1 (b) states that if the protected matter is a process, third parties cannot make use commercially of the said process or the primal products that result from it. It is the second clause of article 28 that establishes the patent owner's opportunity to either transfer directly or by succession the rights over the invention to third parties and to stipulate licensing agreement with third parties.[168]

Article 29 sets the standards for the conditions on patent applicants. Clarity and completion are the requirements for the disclosure of the invention when filing a patent application. The information disclosed should be sufficient for a person skilled in the technology field involved to carry out the invention. Article 29.2 allows members to require additional information from applicants regarding their foreign applications.[169]

The following article addresses the exceptions to the conferment of the rights; members may provide exceptions to the rights of exclusivity granted by the patent, given that the exceptions do not interfere with the natural exploitation of the patent itself or with the interests of the patent owner, in the light of the interests of third parties as well.[170]

Article 31 regulates the use of patented inventions without the authorization of its owner, where the law of the member state permits it.[171] This practice commonly takes the name of compulsory licensing.[172]

Article 31 (b) sets as a prerequisite for the mechanism that the potential user of the patented invention shall first attempt to reach a commercial agreement with the patent owner. If this path did not work within a reasonable time, the alternative would be the licensing without the patentee's consent.

In the event of national emergency, in a circumstance of extreme urgency or in case of public non-commercial employment of the invention, this requirement could be waived by the member state. In the first two cases the patent holder should be notified as soon

[168] *Ibid.* Article 28 *Rights Conferred.*
[169] *Ibid.* Article 29 *Conditions on Patent Applicants.*
[170] *Ibid.* Article 30 *Exceptions to Rights Conferred.*
[171] *Ibid.* Article 31 *Other use Without Authorization of the Right Holder.*
[172] *Supra,* note 6. 353.

as *reasonably practicable*, when the use of the invention is for a public and non-commercial purpose the government shall notify the rights' holder *promptly*.[173]

The specific authorization granted limits the exploitation of the invention to a precise scope and duration.[174] The use of the patented invention under these conditions shall be *non-exclusive* and *non-assignable.* The use under these conditions shall be limited mostly to the supply of the domestic market of the same country that grants the authorization.[175] The authorization shall be continuously reviewed regarding the circumstances that led to it, if the initial circumstances that led to it do not persist and they are unlikely to reoccur, the authorization shall be revoked.[176]

The holder of the patent shall perceive a remuneration regardless of the cause that led to the unauthorized use. Anything related to this use shall be subject to judicial review or to a review from an independent body.[177]

The conditions imposed by subparagraph (b) and the limitation of the supply to the domestic market are waived when the use of the invention without the authorization of the patent holder is supposed to be a remedy to an anticompetitive dynamic. In this case, the amount of the remuneration owed to the patent's holder shall be computed accordingly. The competent authorities shall be authorized to reject the ending of the compulsory licensing if the initial condition that led to the approval initially may occur again.[178]

Article 31 (l) also deals with the case of compulsory licensing when a patent, to which it refers to as *second patent*, in order to be exploited needs to make use of another patent, the *first patent*. The first clause of the subparagraph specifies that in order to get to exploit the first patent, the second patent must involve an economically relevant inventive step if compared to the claims of the first. The second condition of this case of compulsory licensing provides for the opportunity for the owner of the first patent to

[173] *Supra*, note 142. Part II, Article 31 (b) *Other use Without Authorization of the Right Holder*.
[174] *Ibidem*, Article 31 (c).
[175] *Ibidem*, Article 31 (d), (e), (f).
[176] *Ibidem*, Article 31 (g).
[177] *Ibidem*, Article 31 (i), (j).
[178] *Ibidem*, Article 31 (k).

get a *cross-licence* to exploit the second patent. The agreed use of the first patent is non-assignable, with exception for the assignment of the second patent.[179]

Article 32 states that once a patent has been either revoked or forfeited, there shall be always the possibility for this decision to be subject to judicial review.[180] According to the following article, a twenty-year period counts from the date of filing as the expiration date of the term of protection available.[181]

The last article of the section that sets the substantive standards for patents deals with patented processes. If there is a judicial proceeding regarding the infringement of a patent that protects a process to manufacture a product, the suspected infringer shall prove that the procedure to obtain the final product differs from the patented process even if the result is identical. The defendant therefore carries the so-called *burden of proof*.[182]

2.2.1 Article 31bis and the Annex to the TRIPS Agreement

With the Doha Declaration on the TRIPS Agreement and Public Health of the 14th of November 2001, the TRIPS Council was instructed to find better conditions for compulsory licensing to facilitate the access to pharmaceuticals products in those countries that do not have manufacturing capacity in that sector.[183] Article 31 bis is the result of this demand. The first clause states that the limitation of the production to the domestic market specified by Article 31 (f) does not apply when the compulsory licence regards the production and export of pharmaceutical products. Export can happen from an exporting country member of the WTO to an eligible importing member.[184]

[179] *Ibidem*, Article 31 (l).
[180] *Ibidem*, Article 32 *Revocation/Forfeiture*.
[181] *Ibidem*, Article 33 *Term of Protection*.
[182] *Ibidem*, Article 34 *Process Patents: Burden of Proof.*
[183] Declaration on the TRIPS Agreement and Public Health, Paragraph 6, Adopted on 14 November 2001 (WT/MIN(01)/DEC/2), Available at https://www.wto.org/english/thewto_e/minist_e/min01_e/mindecl_trips_e.htm.
[184] *Supra*, note 142. Part II, Article 31 bis.

To sum up, the interaction between the importing and the exporting countries starts with a notification made by the potential importing member to the TRIPS Council specifying the pharmaceutical products they need and granting that a compulsory license has been or will be issued. After the TRIPS Council has received the notification, the exporter can issue an export compulsory license that must comply with article 31 except for the clause (f). The exporting member must as well notify the TRIPS Council after emitting the license.[185]

It is the Annex to the TRIPS Agreement that further specifies these provisions. Eligible importing members are least-developed member countries and any member that has previously notified the Council for TRIPS, warning on the intention to use Article 31bis provisions as an importer. The motivations behind the application of the mechanism still refer to Article 31, therefore the country may appeal to compulsory licensing in case of national emergency, extreme urgency or for government use. Exporting members are countries with productive capacity in the field of pharmaceuticals, that apply the system in order to export these products to an eligible importing member. Some members[186] stated that they will not use the mechanism as importing members, and others would not employ the system if not in case of either emergency or urgency.[187]

The second paragraph in the annex indicates the conditions for the notification procedures. The eligible importing country needs to specify the name of the pharmaceutical product and the quantity they need. The notification shall reconfirm the insufficiency or the absence of the ability to manufacture internally the products.[188]

The assessment of the manufacturing capacities in the pharmaceutical field is regulated by the appendix of the annex itself. Least-developed countries are automatically considered to have inadequate or no capacities to produce pharmaceutical products. The other eligible importing countries need to demonstrate their incapability either establishing they have no manufacturing capacity in the field or that their manufacturing

[185] Igbokwe, E. M., & Tosato, A. (2022). Access to Medicines and Pharmaceutical Patents: Fulfilling the Promise of TRIPS Article 31bis. *Fordham L. Rev.*, *91*, 1791.
[186] "Australia, Canada, the European Communities with, for the purposes of Article 31bis and this Annex, its member States, Iceland, Japan, New Zealand, Norway, Switzerland, and the United States." Footnote 3, Annex to the TRIPS Agreement.
[187] Annex to the TRIPS Agreement, Paragraph 1 (b), 1 (c).
[188] *Ibidem*, Paragraph 2 (a).

capacity is not enough to meet the national needs.[189] The second paragraph of the Annex further specifies that the eligible importing countries that notify the Council need to confirm that, in case of a patent issued in their territory and that protects a pharmaceutical product, they will grant or has granted a compulsory licence respecting the provisions of the Agreement.[190]

The second paragraph of Article 31bis specifies that the exporting member issuing the compulsory license must provide an appropriate remuneration to the patent holder in question considering the economic value that the authorized use of the pharmaceutical products have for the eligible importing member. The obligation to provide a remuneration shall not be observed if the licence is accorded for the same product in the eligible importing member and if remuneration is already paid in the exporting member cited above.[191]

The Annex explains in more detail the conditions that a compulsory licence granted by the exporting member must comply with. The licensed exporter must manufacture only the quantity able to respond to the needs of the importing members that expressed their needs to the Council. The products manufactured through the licence should be easily distinguished from regular products through colours, shapes or labels that should not imply higher final prices. The licensed manufacturer should make available on a website the data on the number of products to be shipped to each importing country and the distinguishable characteristics of the products.[192] Moreover, the exporting member country has the duty to notify the Council for TRIPS regarding the licence they granted providing precise information on the licensee, the products and the countries importing them.[193]

Trying to protect the systems from illegitimate use that differs from the public health intervention, the Annex establishes the duty of eligible importing member states to take measures, according to their capabilities, to avoid that the imported products are

[189] Appendix to the Annex to the TRIPS Agreement, *Assessment of Manufacturing Capacities in the Pharmaceutical Sector.*
[190] *Supra*, note 187. Paragraph 2 (a) iii.
[191] *Supra*, note 142. Part II, Article 31bis, Paragraph 2.
[192] *Supra*, note 187. Paragraph 2 (b).
[193] *Ibidem*, Paragraph 2 (c).

exported again to other countries. On the other hand, every member that is not a party of the compulsory licensing contract, shall be able to implement legal instruments that hinder the importation and sale of products manufactured in their markets.[194]

The third paragraph of Article 31bis mentions the specific situation in which a developing or least-developed country involved in a compulsory licence system is also part of a regional trade agreement[195]. Article 31 (f), regarding the restriction of the licensed production to domestic market, is not to be applied if the developing or least-developed country is a WTO member and at least half of the members to the regional agreement on trade are part of the UN list of least-developed countries. This provision is only valid in the context of pharmaceutical products and allows that the imports and the products manufactured through a compulsory licence in the first member state can be exported to the markets of the developing or least-developed countries parties to the trading region that may face the same health threat.[196] The Annex then encourages the creation of regional patent systems linked to the abovementioned regional agreements in order to promote economies of scale and to facilitate the development of the pharmaceutical sector in developing countries.[197]

The last paragraph of Article 31bis points out that the article itself and the Annex to the TRIPS are not meant to affect the rights and the obligations set by the Agreement.[198] Instead, the Annex itself recognizes the relevance of the promotion of technology transfer in the pharmaceutical field and promotes the use of the system towards this purpose.[199]

The compulsory licensing system outlined in Article 31 and 31bis should be reviewed each year by the Council for TRIPS to verify its effectiveness.[200]

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[194] *Ibidem*, Paragraph 3, 4.
[195] Regional Trade Agreement is to be deemed as stated in the Article XXIV of the General Agreement on Tariffs and Trade and the Decision of 28 November 1979 (L/4093) on *Differential and More Favourable Treatment Reciprocity and Fuller Participation of Developing Countries*.
[196] *Supra*, note 142. Part II, Article 31bis, Paragraph 3.
[197] *Supra*, note 187. Paragraph 5.
[198] *Supra*, note 142. Part II, Article 31bis, Paragraph 5.
[199] *Supra*, note 197.
[200] *Ibidem*, Paragraph 7.

2.3 **The implementation of the TRIPS Agreement**

2.3.1 The Transitional Arrangements

The period accorded by the TRIPS to the WTO members to adapt to the new IP standards depends on their level of development.[201] According to the Transitional Arrangements explained in Article 65 in the sixth part of the Agreement, the general period members have before being obliged to comply with the provisions of the TRIPS is of one year starting from the date of its entry into force.[202] Developed countries therefore had to apply the provisions before the 1st of January 1996.[203]

The second paragraph of the article specifies that if the member is a developing country has the right to furtherly extend the period of adaptation to four years. This granting is also destined to the countries that are undergoing a societal and economic transformation towards a free market economy. Articles 3, 4 and 5 of the Agreement however are excluded from this delayed adaptation, and must be applied within the first year from the entry into force of the agreement by every Member.[204]

The fourth paragraph of the article then addresses developing countries on the subject matter of the protection of product patent. For product patents in the areas of technology that are particularly difficult to safeguard in their respective territories, developing countries were provided a further extension of five years for the adaptation to the corresponding provisions of the Agreement.[205] Therefore, developing countries could delay the compliance with TRIPS standards on product patents until 1 January 2005. [206] Since that date, developing countries that did not provide patent protection for

[201] *Supra,* note 156.
[202] *Supra*, note 142. Part VI, Article 65 *Transitional Arrangements*.
[203] *Supra,* note 156.
[204] *Supra*, note 142. Part VI, Article 65.2.
[205] *Ibid*. Part VI, Article 65.4.
[206] Hoen, E. (2016). *Private patents and public health: changing intellectual property rules for access to medicines,* 21.

pharmaceuticals products or agricultural chemicals when the TRIPS entered into force, have been required to comply with the provisions of the Agreement.[207]

The countries that used this additional period had to allow the filing of patent applications since January the 1st 1995, according to the so-called *mailbox* system.[208] The mailbox rule implied the establishment in these countries of mechanisms able to receive patents filings for pharmaceutical products and to keep track of the priority dates, once the 2005 deadline would have been reached the applications in the mailbox would have been examined and, if patentable, become effective.[209]

Moreover, any member to which the extension periods at stake have been accorded, shall grant that over this period the potential new laws and regulations implemented in the country will not make the member's IP legal framework less consistent with the provisions of the Agreement.[210]

A further extension is granted to least-developed countries, that for the first ten years after the entry into force of the Agreement, would not be required to comply with its provisions, besides Article 3, 4, and 5. The Council for TRIPS, as specified in Article 66.1, has the faculty to furtherly elongate the extension period upon request of a least-developed Member.[211] This initial period has been extended three times since, and the deadline is now the first day of July 2034.[212]

Paragraphs eight and nine of Article 70 furtherly deal with patent protection, including provisions for the transition towards the TRIPS requirements in those member countries that, when the Agreement entered into force, did not comply with its standards of protection specifically in the pharmaceutical and agricultural chemicals fields.

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[207] Abbott, F. M. (2002). *WTO TRIPS Agreement and its Implications for Access to Medicines in Developing Countries*. Study Paper 2a, United Kingdom Commission on Intellectual Property Rights.
[208] World Trade Organization - Fact Sheet: Trips and Pharmaceutical Patents, Developing countries' transition periods. Available at https://www.wto.org/english/tratop_e/trips_e/factsheet_pharm04_e.htm.
[209] *Supra*, note 207. See also Article 70.8 of TRIPS (note 142).
[210] *Supra*, note 142. Part VI, Article 65.5.
[211] *Ibidem*, Article 66.1 *Least-Developed Country Members*.
[212] *Supra,* note 156.

The transitional arrangements also consider the treatment of the subject matter already existing at the date of entry into force of the Agreement. The first paragraph of article 70 specifies that the clauses of the Agreement do not create obligations towards *acts* occurred before the date of entry into force. The second paragraph instead underlines that the Agreement generates obligations towards the whole subject matter existing prior the date of application of the Agreement and that is either already protected in the country on that date or is going to meet the criteria to be protected.[213]

2.3.2 Cooperation and Technical Assistance

Cooperation is enhanced on many different levels and in multiple clauses of the Agreement. First and foremost, the Agreement requires the establishment of a thorough cooperation between the WTO and the WIPO.[214] Article 68, after specifying the role of the Council for TRIPS, sets the goal to establish, within the first year after its first gathering, appropriate arrangements that would allow to cooperate with the bodies of the WIPO itself.[215]

Being member to the agreement means to commit to cooperate with other members to defeat the infringements of IP rights in the international trade of goods. Article 69 states that countries shall be willing to share valuable information to prevent and hinder infringements, and shall promote cooperation between customs authorities particularly regarding counterfeited marks and piracy in copyright goods.[216] Cooperation must be considered also in the transfer of technology that article 66.2 encourages. Developed member countries should elaborate ways to incentivize national businesses and institutions in the exportation of technologies to least-developed countries to support the creation of a robust technological basis.[217]

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[213] *Supra*, note 142. Part VII, Article 70 *Protection of Existing Subject Matter*.
[214] *Supra,* note 6. 346.
[215] *Supra*, note 142. Part VII, Article 68 *Council for Trade-Related Aspects of Intellectual Property Rights*.
[216] *Ibidem*, Article 69 *International Cooperation*.
[217] *Ibidem*, Part VI, Article 66.2.

With the goal of facilitating the implementation of the TRIPS in developing and least-developed countries, developed countries should offer technical and financial assistance as suggested by article 67. The technical cooperation advocated in this article concerns the support for the elaboration of IP laws, but also the assistance in the reinforcement of the institutions with initiatives such as the training of the employees.[218]

Many of the developing countries that became members of the Agreement had already formulated a system of IP laws and administrative procedures prior to the date of entry into force of the TRIPS. The technical cooperation hoped for in the Agreement shall support the transition towards a balanced and functioning IP system.[219] The final aim is to grant a holistic approach to assist the development of the TRIPS-related policies, considering the general policy context.[220]

The programmes carried out throughout the years are documented yearly in the Council for TRIPS' reports. The interventions saw the participation of intergovernmental organizations and the WTO itself. The WTO indeed organised technical cooperation strategies aimed at building a better understanding and knowledge around the rights and obligations that Members inherit from being part of the TRIPS.[221] The Organization offers advanced trainings to officials, policymakers, and academics in the headquarters of Geneva, but also national and regional workshops.[222] One of the core issues dealt with in these cooperation programmes has been public health and the tool of compulsory licensing cited above in Articles 31 and 31bis.

The WTO has then extended the support given to developing countries through the multiple partnerships established with organizations such as the World Intellectual Property Organization and the United Nation Conference on Trade and Development

[218] *Ibidem*, Article 67 *Technical Cooperation*.
[219] WTO - *Implementing The Wto Trips Agreement Through Partnership & Technical Cooperation*, Available at https://www.wto.org/english/tratop_e/trips_e/ta_docs_e/trips_tech_coop_e.pdf.
[220] *WTO | intellectual property (TRIPS)—Technical cooperation*. Retrieved 8 July 2023, from https://www.wto.org/english/tratop_e/trips_e/intel9_e.htm.
[221] *Supra*, note 219.
[222] *Supra*, note 220.

(UNCTAD).[223] The collaboration with WIPO was pursued based on an agreement made with the WTO in 1995 in Geneva.[224]

The WIPO is also part of a trilateral technical cooperation programme with the World Health Organization. A thorough cooperation was carried out with the WHO due to the closeness of this organization to the theme of IP and public health.[225] In order to spread awareness on this issue the WIPO eLearning Centre also introduced the course "Promoting Access to Medical Technologies and Innovation."[226]

Least-developed countries were instead provided with further assistance in order to meet their wider needs. The TRIPS Council can be directly notified by the countries about their priority needs, and a series of coordinated actions should follow in order to provide the technical assistance in the areas where support is most needed.[227] It was indeed due to the TRIPS Council Decision of the 29th of November 2005[228], that extended the transition period for LDCs, and to facilitate the cooperative assistance, that least-developed countries were encouraged to deliver to the Council all the information regarding their specific needs. In this regard, the International Centre for Trade and Sustainable Development, following the meeting of the Intellectual Property Technical Assistance Forum in 2006, drafted a working paper to facilitate the assessment of the national needs in LDCs. The paper offers a diagnostic system with the purpose of evaluating the needs to prepare an efficient intellectual property rights technical and financial assistance (IPRTA) programme.[229]

2.3.3 A brief analysis of the main criticisms of the Agreement

[223] *Supra*, note 219.
[224] *Agreement Between the World Intellectual Property Organization and the World Trade Organization,* Geneva, 22 December 1995, Available at https://www.wto.org/english/tratop_e/trips_e/wtowip_e.htm.
[225] *Supra*, note 219.
[226] *Supra*, note 220.
[227] *Supra*, note 219.
[228] IP/C/40 – WTO. Council for Trade-Related Aspects of Intellectual Property Rights. *Extension Of The Transition Period Under Article 66.1 For Least-Developed Country Members.* Available at https://www.wto.org/english/tratop_e/trips_e/ta_docs_e/7_1_ipc40_e.pdf.
[229] Leesti, M., & Pengelly, T. (2007). *Assessing technical assistance needs for implementing the TRIPS Agreement in LDCs.* ICTSD Program on Intellectual Property Rights and Sustainable Development, International Centre for Trade and Sustainable Development, Geneva.

The actual implementation of the Agreement presented many challenges. One of the main critiques to the results obtained by the TRIPS is the issue of the enforcement and its relative provisions. Peter K. Yu, focuses on the causes that led to a lack of effectiveness in the area of enforcement. According to the author, the Agreement failed to obtain a widespread consensus on intellectual property enforcement internationally, drafting enforcement standards that are considered too weak by developed countries and too challenging and abstract by less-developed members.

The first problem cited is the path that led to elaboration of the Agreement itself, the TRIPS was in fact the first international agreement that introduced comprehensive enforcement measures on IP issues.

Due to their late introduction, intellectual property enforcement laws result internationally underdeveloped. Strong enforcement measures imply high costs, and this is pointed as another plausible cause. Less developed countries struggle particularly in finding the resources to invest in a system able to enforce intellectual property rights. The lack of enforcement hinders the attractiveness of the country to the eyes of foreign investments and lessen the utility that effective border measures could have. In those countries that still need high public investments to satisfy the basic needs for the livelihood of the population, the shift of resources required to enforce IP rights would directly threaten fundamental human rights.[230]

TRIPS provides minimum standards without attempting to harmonise the laws and practices of the member countries. The Agreement requires members to elaborate effective mechanisms for enforcement but it does not provide for a way to verify the actual functionality of those mechanisms.[231]

The provisions have been mainly developed to set up broad standards rather than to provide precise regulations.[232] The provisions either present many unclear and

[230] Yu, P. K. (2010). *TRIPS and its Achilles' Heel*. Journal of Intellectual Property Law, *18*, 479.
[231] Malbon, J., & Lawson, C. (Eds.). (2008). *Interpreting and implementing the TRIPS agreement: Is it fair?* Edward Elgar Publishing.
[232] Reichman, J. H. (1996). Enforcing the Enforcement Procedures of the TRIPS Agreement Symposium: Intellectual Property Law in the International Marketplace: Comment. *Virginia Journal of International Law*, *37*(2), 335–356.

undefined terms or contain norms that empower the authorities of the countries instead of setting specific standards and actions to put in place. One example is the fifty-ninth Article which states that "competent authorities shall have the authority to order the destruction or disposal of infringing goods." Therefore, the article itself does not require to act against infringing goods, but instead it only calls for the existence of such authority.

Moreover, the introduction and great expansion of the internet and its related technologies has represented one of the major obstacles to the enforcement of the standards of the Agreement since its entry into force. Being the TRIPS established in 1995, it drastically failed to address the issue of the protection of intellectual property rights online.[233]

Throughout the years, issues on enforcement arose worldwide and were brought before the Dispute Settlement Body. For instance, in June 1997 the United States of America raised some concerns in respect of Sweden on the matter of the TRIPS obligation to make available effective provisional measures in civil proceedings regarding IP rights (WT/DS86/1). The alleged violation involved Articles 50, 63 and 65 of the TRIPS Agreement. In order to fulfil the obligation, Sweden elaborated and passed a legislation that amended the national acts covering IP matters. The legislation conferred to judicial authorities the authority to order provisional measures in civil proceedings involving IP rights.[234] The same exact scenario arose for Denmark, that on March 2001 in order to comply with the TRIPS obligations, amended its Administration of Justice Act.[235]

In 2007 the United States requested consultations with China on the issue of IP protection and enforcement, on Articles 9, 41, 46, 59, 61 of TRIPS.[236] A Panel was established by the DSB to evaluate the Complainant's allegations. One of the key panel findings results from the interpretation of the term "commercial scale" in Article 61. The

[233] *Supra*, note 230.

[234] WTO - Sweden — Measures Affecting the Enforcement of Intellectual Property Rights, IP/D/10/Add.1 WT/DS86/2, Available at https://docs.wto.org/dol2fe/Pages/SS/directdoc.aspx?filename=q:/IP/D/10a1.pdf&Open=True.

[235] WTO - Denmark - Measures Affecting the Enforcement of Intellectual Property Rights - Notification of Mutually Agreed Solution, IP/D/9/Add.1 WT/DS83/2, Available at https://docs.wto.org/dol2fe/Pages/SS/directdoc.aspx?filename=q:/IP/D/9A1.pdf&Open=True.

[236] WTO - Request for Consultations by the United States, China—Measures Affecting the Protection and Enforcement of Intellectual Property Rights, WT/DS362/1. Available at https://www.wto.org/english/tratop_e/dispu_e/cases_e/1pagesum_e/ds362sum_e.pdf.

Panel did not find incompliance of the Chinese criminal procedures with the TRIPS article. The provision does not require to criminalise all the copyrights and trademarks infringements, but to provide criminal procedures and penalties where the counterfeiting and piracy happen on a commercial scale. China's measures, as found by the Panel, do not include criminal liability below a threshold defined numerically in terms of profits or number of the traded infringing goods. The Panel did not directly approve the establishment of these thresholds, but rejected the US allegations against the lack of criminal liability because of insufficient factual evidence.[237]

The inadequacy of IP protection granted by the TRIPS Agreement led to the implementation of stricter and more precise standards through other negotiation channels. The so-called TRIPS-plus standards are primarily the result of bilateral, plurilateral, regional trade agreements.[238] Therefore, any provision, part of an Agreement negotiated after the entry into force of the TRIPS Agreement, that establishes more protective standards on the matter of intellectual property rights can be identified as a TRIPS-plus standard.[239]

Countries that aimed at implementing higher IP protection progressively shifted from the WTO forum to more specific negotiations aimed at signing Free Trade Agreements, able to convince reluctant countries to establish more restrictive IP standards in exchange for preferential access to FTAs members' markets. [240] Even if the number of countries that are parties to a Trips-plus FTA is small, the provisions they include often affect other WTO members. For instance, advantageous patent requirements elaborated to comply with an FTA with a specific country need to be applied to all WTO members' applicants due to the principle of the most-favoured-nation treatment.[241]

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[237] WTO - China - Measures Affecting the Protection and Enforcement of Intellectual Property Rights - Understanding between China and the United States Regarding Procedures under Articles 21 and 22 of the DSU - WT/DS362/15. Summary of the dispute to date available at https://www.wto.org/english/tratop_e/dispu_e/cases_e/1pagesum_e/ds362sum_e.pdf.
[238] Ho, C. M. (2011). *An Overview of' TRIPS-Plus' Standards.*
[239] Bernieri, R. C. (2009). *Compulsory Licensing and Public Health: Trips-Plus Standards In Investment Agreements*. Transnational Dispute Management TDM, Forthcoming.
[240] Ruse, H. G. (2011). *The International Law Relation Between Trips And Subsequent Trips-Plus Free Trade Agreements: Towards Safeguarding Trips Flexibilities?,* Journal Of Intellectual Property Law, Vol. 18.
[241] *Supra*, note 238.

The TRIPS-plus typical measures involve expanding the subject matter that can be protected, limiting the exceptions of IP rights safeguarding, extending the terms of protection, or implementing TRIPS provisions before the end of the transition period granted by the Agreement.[242]

TRIPS-plus standards are often subject to critiques due to the rigidity they cause to the implementation and interpretation of certain obligations of the TRIPS Agreement itself.[243] For example, certain FTAs either limit the country's freedom in the procedures for the assessment of the novelty of the invention or prevent the reinforcement of patentability requirements.[244]

Some typical TRIPS-plus standards tend to negatively affect access to medicines, for example the FTAs provisions that limit the grounds to issue compulsory licenses for public health reasons.[245] Indeed, the World Health Organization highlighted the health-related risks bore by certain TRIPS-plus obligations, recommending that FTAs may neither reduce access to medicines nor be an obstacle to TRIPS flexibilities for public health and human rights.[246]

Moreover, TRIPS-plus requirements are often the result of external political or economic pressures. Developing countries usually are pressured to implement these kinds of provisions to avoid trade sanctions or withdrawal of preferential trade routes from richer nations. The bargaining power of the negotiating country is bigger if they have an attractive market and the negotiation results much more distorted than in the WTO context.[247] For instance, the "Special 301" Report elaborated by the US Office of Trade Representatives lists all the countries that fail to provide effective IP rights protection.[248]

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[242] *Supra*, note 231.
[243] *Supra*, note 240.
[244] *Supra*, note 238.
[245] World Health Organization - *Impact Assessment of TRIPS Plus Provisions on Health Expenditure and Access to Medicines.* Report of a workshop organized by the International Health Policy Programme, Ministry of Public Health, Thailand and the World Health Organization, Regional Office for South-East Asia. Bangkok, 22-24 November 2006. Available at https://apps.who.int/iris/bitstream/handle/10665/205326/B2072.pdf.
[246] Hoen, E. (2006). Report of the Commission on Intellectual Property Rights, Innovation and Public Health. Bulletin of the World Health Organization, 84 (5). Recommendation 4.26.
[247] *Supra*, note 238.
[248] United States Code, Title 19 - Customs Duties. Chapter 12 - Trade Act Of 1974. Subchapter I - Negotiating And Other Authority. Part 8 - Identification of Market Barriers and Certain Unfair

The countries listed in the report may be subject to high pressures to adequately modify their laws by entering a bilateral or multilateral FTA negotiation. To conclude, the implications and distortions of these FTAs are usually difficult to assess prior the publication of the signed agreements, since the negotiations often happen in secret. [249]

Another controversial theme is the way the TRIPS Agreement addresses competition. Intellectual property rights and competition are strictly linked and the balance between the two of them is essential to enhance development and innovation.[250] Professor J. Schovsbo criticises the provisions of the Agreement that deal with competition law. In his paper the standards set in the Agreement regarding competition laws are described as *weak and imprecise*.

The first general reference to market competition in the Agreement is article 8(2) which mentions the opportunity member countries have of elaborating measures that prevent an abusive use of IP rights which may result in trade distortion. The article does not introduce any obligations in these terms. It is then important to cite article 31 and the mechanism of compulsory licensing as an attempt to find a balance between market competition and social welfare. Article 40 again addresses licensing agreements, recognizing their risk of distorting the competition on the market.[251] It allows the countries to forbid licensing agreements when they are deemed to be anti-competitive.[252] Generally, the TRIPS Agreement fails in providing concrete guidelines on the competition laws that member countries shall implement in order to efficiently complement the IP treaty.

The failure in harmonizing competition rules worldwide not only makes it difficult to regulate behaviours regarding IP, leading to misuse, but also interferes with the

Trade Actions. Sec. 2242 - *Identification of countries that deny adequate protection, or market access, for intellectual property rights*.

[249] *Supra*, note 238.

[250] Schovsbo, J. (2011). *Fire and water make steam–redefining the role of competition law,* in Intellectual property rights in a fair world trade system: proposals for reform of TRIPS, 308.

[251] *Ibid*.

[252] Cottier, T., & Meitinger, I. (2000). *The TRIPs Agreement Without a Competition Agreement?* SSRN Electronic Journal.

functioning of competing global markets, whose efficiency is fundamental to grasp all the advantages of IP legal systems.[253]

[253] *Supra*, note 250.

CHAPTER 3

The TRIPS Agreement and its flexibilities for public health

3.1 Public Health and Intellectual Property Rights

Since ancient times human settlements took care of public health building infrastructures such as public baths and water conduits and preventing the spreading of contagious illnesses. Access to medicines was insignificant until the 18th and 19th centuries, when pharmacology started to develop as a science and nation states understood that a healthy population was a key ingredient to a growing industrialized country. Therefore, public health policies started introducing medicines, such as the mass inoculations mandated by the United States and by many European countries to tackle smallpox and other highly contagious diseases.[254]

During the 20th century, national governments started to engage in a major expansion of public health initiatives. A solidaristic approach to healthcare spread across Europe, Japan, and the USSR, where a social insurance for health was introduced for the fraction of the population with the lowest incomes. After the Second World War, the principle of a "universal health coverage"[255] started to diffuse and inspire the implementation of healthcare systems based on public subsidies.

Alongside with the adoption of the universal health coverage model those years witnessed a booming rise of the pharmaceutical sector and access to medicines became fundamental for the effectiveness of the national healthcare systems.[256]

Access to medicines thus gained relevance in the context of international law as a derivative human right, resulting from the right to life. Domestic laws progressively

[254] *Supra*, note 185.
[255] The World Health Organization defines "universal health coverage" as "all individuals and communities receive the health services they need without suffering financial hardship. It includes the full spectrum of essential, quality health services, from health promotion to prevention, treatment, rehabilitation, and palliative care across the life course".
[256] *Supra*, note 185.

acknowledged this individual right, recognizing the access to pharmaceutical products as a crucial requirement to grant the safeguard of health and healthcare rights.[257]

The complexity of the chain that brings pharmaceutical products from the producers to the citizens in need challenged national governments. Approving, procuring, distributing, and maintaining affordable prices of medicines entered the range of priorities of nation states.

Over the century, policymakers worldwide attempted to find a balance between the incentives able to stimulate the development of new drugs, such as the opportunity to patent the inventions, and the ability of granting universal access to treatments. The way governments tried to address the issue led to many diverse solutions. Compulsory licensing of patents was a frequent option that governments implemented to make an exception over the exclusive patent rights of pharmaceutical inventions for the public good.

To further complicate the domestic management of the issue it was the lack of international guidelines or mandatory standards on the patentability requirements. Thus, this resulted in a heterogeneous framework of the patentable subject matter in the medical field.[258] For instance, the US has always allowed the patenting of both pharmaceutical processes and products, providing for compulsory licensing in very limited scenarios.[259] The United Kingdom, France and Canada enabled the protection of both products and processes but provided for compulsory licensing mechanisms that limited exclusive rights allowing for the development of fair competition on the product. Other countries such as Argentina, Austria, Egypt, Greece, India, Spain and Türkiye, allowed for patent granting of manufacturing processes.[260] These IP systems

[257] Heymann, J., Cassola, A., Raub, A., & Mishra, L. (2013). *Constitutional rights to health, public health and medical care: The status of health protections in 191 countries*. Global Public Health, *8*(6), 639-653.
[258] *Supra*, note 185.
[259] Dutfield, G., (2007). *The Pharmaceutical Industry, the Evolution of Patent Law and the Public Interest: A Brief History*, in Emerging Issues In Intellectual Property 109, 122–24, 135–46; Guido Westkamp ed.
[260] For a complete survey see Jayasuriya, D. C. (1988). *Pharmaceuticals: Patents and the Third World*. J. World Trade, *22*, 117. (specifying that, as of 1988, 49 countries did not grant patents for pharmaceutical products, including Argentina, Brazil, Chile, Columbia, Congo, Ecuador, Egypt, India, Indonesia, Mexico, South Korea, Syria and Thailand).

safeguarded the production technique without granting any protection for the final product, thus allowing competitors to find different ways to produce the same final pharmaceutical product if obtained through a different process. Another small group of countries instead, neither granted the opportunity to patent products nor processes in the pharmaceutical sector.

The vastly heterogeneous patent system landscapes began to change during the eighties. Developed countries with affirmed pharma industries started to put pressures on governments in order to strengthen IP protection over medical innovations. The patentability criteria for pharmaceutical inventions were enlarged in many countries of Western Europe, Canada, and Japan. Product and process patent protection in the pharmaceutical field was introduced in those years in China.[261] It was at the end of the century that the issue gained international relevance seeing the opposing views of developed and developing countries. The first group had well-established patent systems able to safeguard medical inventions and called for higher protection of pharmaceutical IP worldwide.[262] The second group opposed a strong resistance to the requests of the rich countries invoking their priority to grant the access to medical treatments and drugs to their citizens.[263]

The confrontation between these two factions resulted in an intense negotiation process that led in 1995 to the signing of the Trade-Related Aspects of Intellectual Property Rights Agreement. Due to the tensions and the worries of developing countries regarding the safeguard of public health with the introduction of stronger IP rules, the Agreement provided a certain degree of flexibility in its implementation.[264]

The relationship between public health and IP became increasingly important until the peak it reached with the HIV/AIDS pandemic that in the nineties afflicted many developing countries with restricted access to antiretroviral drugs.[265] The relationship between policy-making, public health, and intellectual property protection and

[261] *Supra*, note 185.
[262] Gutterman, A. S. (1993). *The North-South debate regarding the protection of intellectual property rights*. Wake Forest L. Rev., *28*, 89.
[263] *Supra*, note 185.
[264] *Supra*, note 206.
[265] Abbott, F. M. (2002). *The Doha declaration on the TRIPS agreement and public health: lighting a dark corner at the WTO*. J. Int'l Econ. L., *5*, 469.

therefore the TRIPS Agreement, became a hot topic and abruptly entered the public discourse.[266]

The HIV crisis exposed the gaps in the systems operating to maintain public health. The difficulty encountered by countries to get access to AIDS medicines peaked just after the creation of the WTO and the TRIPS. Before the agreement, many countries did not allow for the patenting of pharmaceutical products and access to medicines was primarily granted by the presence of a flourishing industry of generic drugs.[267] Prior to the TRIPS, developing countries granted the access to affordable medicines thanks to the absence of IP protection or through compulsory licensing. With the introduction of the Agreement instead, given the obligation of all WTO members to guarantee patentability in all technological sectors (the deadline for which was 2005 for developing countries), the only way possible to achieve affordable access to health treatments was to emit a compulsory license to a domestic producer.[268]

In 1996 a major medical breakthrough would have allowed to make the HIV infection into a chronic disease through the combination of different antiretrovirals drugs (ARVs). However, the necessary medicines could be purchased only from the pharmaceutical producers that created them. With limited quantities available on the market and astronomical prices, the monopoly on these patented meds made it almost impossible for developing countries to access them. By the early 2000, 24.5 million of people were living with HIV in Africa and only one every thousand people could access the highly active antiretroviral therapy.

Some Indian companies offered generic versions of ARVs at lower prices, however due to the presence of patented ARVs in the countries that most needed them, imports from India were difficult. The international health community urged for a solution able to rebalance the relationship between patent protection and access to life-saving medicines, providing more flexibility for patent law when public health is threatened.[269]

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[266] Musungu, S. F., & Oh, C. (2006). *The use of flexibilities in TRIPS by developing countries: Can they promote access to medicines?* South Centre. World Health Organization.
[267] *Supra*, note 206.
[268] *Supra*, note 185.
[269] *Supra*, note 206.

At the Ministerial Conference of the WTO in Seattle 1999, NGOs and the general public pressured for a rebalancing of the patent system in order to facilitate public health safeguard.[270] The debate culminated in the Fourth WTO Ministerial Conference in 2001 and in the contingent Doha Declaration on the TRIPS Agreement and Public Health. The Declaration gave the explicit authorization to countries to make use of measures to defeat the IP barriers that hinder public health. The document empowered member countries to use the flexibilities granted in the provisions of the Agreement with the aim of seeking social and economic welfare and preserving public health.[271]

3.2 The Doha Declaration: Declaration on the TRIPS Agreement and Public Health

The journey that led to the Doha Declaration adopted on the 14th of November 2001 is marked by the same constant opposition between developing and developed countries. Pharmaceutical companies claimed the benefits that patent protection can bring to research and development. Developing countries urged for action amid the HIV/AIDS crisis and criticised the lack of investments for the diseases that afflicted poor countries, since finding effective medicines would have not led to high profits.

The concerns of developing countries regarding the implementation of the TRIPS Agreement and its impact on the access to medicines resulted in the call for a special session of the TRIPS Council. The meeting held in June 2001 paved the way to the Ministerial Declaration of Doha. Many WTO members elaborated opinion papers whose focus was indeed access to medicines. A delegation of developing countries drafted a precise statement which included all the concrete difficulties generated by the TRIPS provisions and focused on aspects such as Articles 7 and 8, transitional arrangements, and flexibilities.

[270] *Ibid*.
[271] Tesoriero, A. (2022). *Using the flexibilities of Article 30 TRIPS to implement patent exceptions in pursuit of Sustainable Development Goal 3*. The Journal of World Intellectual Property, *25*(2), 516–535.

Following another meeting in July, the TRIPS Council met again in September and finally in November during the fourth session of the WTO Ministerial Conference the Declaration on the TRIPS Agreement and Public Health was adopted.[272]

The Declaration is made up of seven paragraphs.[273] It acknowledges the gravity of the global risks that public health is facing, especially due to the HIV/AIDS pandemic.[274] It recognises that the TRIPS Agreement needs to directly take action to address these issues, also acknowledging the crucial role that intellectual property covers in the development of new medicines and the effects that patent protection causes to prices.[275]

One of the main affirmations, which embraces the requests of developing countries, is that the Agreement shall *not prevent Members from taking measures to protect public health*. It underlines the importance of interpreting and implementing the Agreement in a way that supports the right that each WTO Member has to safeguard their public health and to foster the access to medicines.[276]

The Doha Declaration recalls the flexibility provided by the Agreement for the purpose of pursuing public health. It empowers the states to take advantage of the flexibilities while interpreting the provisions for implementation.[277]

The fifth paragraph focuses on four points. The first clause underlines that the provision of the TRIPS Agreement shall be interpreted in the light of the objectives and principles of the Agreement.[278] Therefore, it directly refers to articles 7 and 8 and it recommends that all interpretative issues are to be solved referring to those provisions.[279] It is important to notice the direct reference to public health that article 8 had already

[272] *Supra*, note 265.
[273] Declaration On The Trips Agreement And Public Health, Ministerial Conference Fourth Session Doha, 9 - 14 November 2001. WT/MIN(01)/DEC/2.
[274] *Ibid*. Paragraph 1.
[275] *Ibid*. Paragraph 2, 3.
[276] *Ibid*. Paragraph 4.
[277] *Supra*, note 271.
[278] *Supra*, note 273. Paragraph 5 (a).
[279] Sykes, A. O. (2002). *TRIPS, Pharmaceuticals, Developing Countries, and the Doha Solution*. Chi. J. Int'l L., *3*, 47.

included, as it states, *Members may, in formulating or amending their laws and regulations, adopt measures necessary to protect public health* [...].

Paragraph 5(b) recalls the right of Countries to issue compulsory licenses according to the criteria they themselves establish as possible scenario to emit these licenses.[280] The grounds for issuing the compulsory licenses are of national discretion, and so is the decision of what constitutes a national emergency or other circumstances of extreme urgency as stated in paragraph 5(c)[281]. This recalls article 31 of the Agreement which enables, in case of national emergencies, to obviate the negotiating phase and directly issue a compulsory license. Therefore, paragraph 5(c) strongly reaffirms the sovereignty of the member in the implementation of the waiver and it represents a strong tool in any case in which a Member is accused of an unjustified declaration of national emergency. [282]

Paragraph 5(d) states that "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."[283] The paragraph recalls the freedom members have in establishing their own rules about IP rights exhaustion and indirectly affirms that parallel imports may be allowed.[284][285]

Parallel import happens when, without the consent of the patentee, a patented product is imported and resold in a country after being legitimately introduced in the market of the exporting country.[286] Once the IP regime recognises the exhaustion, the patent

[280] *Supra*, note 273. Paragraph 5 (b).
[281] *Ibid*. Paragraph 5 (c).
[282] *Supra*, note 265.
[283] *Supra*, note 273. Paragraph 5 (d).
[284] Article 6 of the TRIPS Agreement refers to the issue of exhaustion: "nothing in this Agreement shall be used to address the issue of the exhaustion of intellectual property rights." According to Sykes (2002), "This obscurely worded provision concerns the question whether a patent holder retains any rights over the resale of a product once it has been introduced into the stream of commerce, or whether the initial sale by the right holder "exhausts" its rights". Moreover, article 6 does not specify if a Member shall adopt a national, regional or international level of exhaustion (Regional Seminar on the Effective Implementation and Use of Several Patent-Related Flexibilities, 2011, Available at https://www.wipo.int/edocs/mdocs/patent_policy/en/wipo_ip_bkk_11/wipo_ip_bkk_11_ref_topic14.pdf).
[285] *Supra*, note 279.
[286] *Supra*, note 206.

owner loses the right to control the further commercialization of the patented goods. The countries that implement international exhaustion regimes automatically permit parallel imports in their territory, as it will be further analysed in this chapter. [287]

In paragraph 6 of the Declaration, Ministers recognized that "WTO Members with insufficient or no manufacturing capacities in the pharmaceutical sector could face difficulties in making effective use of compulsory licensing under the TRIPS Agreement." The Council for TRIPS was thus instructed to find a solution to this issue by the end of 2002.[288] This paragraph explicitly highlighted the challenges that countries with low or no manufacturing capacity in the pharmaceutical field face when trying to emit compulsory licensing, admitting that the original TRIPS provision was not able to administer this issue.

The last paragraph of the Declaration recalls article 66.2 of the Agreement, encouraging technology transfer to least-developed countries. The paragraph also postponed the end of the transition period regarding the implementation of TRIPS provisions covering patent rights for pharmaceutical products to January the 1st, 2016, without excluding the possibility to seek further extensions as granted by article 66.1. The Council for TRIPS is further encouraged to act in order to grant this opportunity.[289]

The Ministerial Declarations within the WTO context are not legally binding and their language would be superseded by the language of the treaties in case of disputes over some contradictory provisions. However, the Doha Declaration has primarily an interpretative purpose and it does not appear to contradict any TRIPS provision, therefore in case of disputes it is likely to be a reliable authority.[290]

The Declaration represented a turning point in the way the relationship between patents and medicines had been perceived worldwide. It paved the way to an interpretative approach of the TRIPS which facilitates the access to medicines in poorer countries,

[287] Bonadio, E. (2011). *Parallel Imports in a Global Market: Should a Generalised International Exhaustion be the Next Step?.* European Intellectual Property Review, 33(3), pp. 153-161.
[288] *Supra*, note 273. Paragraph 6.
[289] *Ibid*. Paragraph (7).
[290] *Supra*, note 279.

finally recognizing the magnitude of this problem. However, it is also crucial to notice that the declaration did not solve the issues related to article 31(f).

The article provides that compulsory licenses shall be issued "predominantly for the supply of the domestic market of the Member authorizing such use".[291] Developing countries hoped for Doha to offer an interpretative clarification of the issue, reassuring on the fact that TRIPS provisions did not directly prevent Members from emitting compulsory licenses to foreign suppliers, nor kept them from granting compulsory licenses to supply foreign markets.[292]

If article 31(f) was to be strictly interpreted in a manner that allows nations to emit compulsory licenses to domestic manufacturers with the purpose of supplying the domestic market only, many developing countries would not be able to take advantage of this provision due to their lack of technical and manufacturing capacities.[293]

The resolution of the issue was however delayed and, as stated in Paragraph 6, the TRIPS Council would have borne the responsibility to find a remedy.

3.2.1 Decision on the "Implementation of Paragraph 6 of the Doha Declaration on the TRIPS Agreement and Public Health"

The 2005 deadline for developing countries to introduce patent protection and the end of the mailbox receiving system of patent application, as required by article 70.8 of the TRIPS, led to an increasing pressure on the public health-IP negotiations.

Prior to this date, producers of generic medicines, mainly developing countries such as India, Brazil, and Argentina, could export their products to all the developing countries that did not provide IP protection for those foreign patented medicines. As the transitional phase ended, this possibility of access to lower priced medicines would have been lost, the patent holders could intervene and stop the production and exportation

[291] *Supra*, note 142. Part V, Article 31(f).
[292] *Developing Countries Push for TRIPs to Allow Cheaper Medicines*, Inside U.S. Trade, vol. 19, No. 25, p. 7 (June 22, 2001).
[293] *Supra*, note 279.

of these drugs, either in the country where the generic drug was produced or in the destination country.[294]

With the approaching deadline, increasing pressure was put on the Council for TRIPS to address the challenge launched by the sixth Paragraph of the Doha Declaration.

The debate on how to address the problem initially considered article 30 of the TRIPS as a starting point. The proposed solution stated that any country in need of a medicine would have been allowed to import it after issuing a compulsory license, interpreting this scenario as a limited exception to patent rights.

To support this motion, the World Health Organization during the TRIPS Council in September 2002 encouraged to find a solution that did not imply difficult procedures and granted the same level of public health safeguard both to the countries with pharmaceutical manufacturing capacities and to those lacking it. The above reinterpretation of article 30 would have permitted to third parties to produce, distribute, and export medicines protected by patents to face public health needs. NGOs as well supported this path.

Negotiations saw the opposition between developing countries, which supported a feasible solution through the automatic process that the reworking of article 30 would have granted, and developed countries that were trying to limit the freedom of action of the former. The difficult and long discussions led almost to accept the compromise drafted in the *December 16 Motta text.* However, the text was judged to be ambiguous and under some aspects in contrast with the Doha Declaration.

Discussions went on and in January 2003 another proposal was rejected. The dismissed solution suggested to interpret the paragraph 6 of the Doha Declaration "as being essentially designed to address national emergencies or other circumstances of extreme

[294] Cottier, T. (2006). *The Doha Waiver and its Effects on the Nature of the TRIPS System and on Competition Law: The Impact of Human Rights* (SSRN Scholarly Paper 1036381).

urgency".[295] NGOs and developing countries raged against this proposal since it would have put huge limits to compulsory licensing.[296]

On the 30th of August 2003 a decision was finally made. The Implementation of paragraph 6 of the Doha Declaration on the TRIPS Agreement and Public Health (WT/L/540) waived the obligations of exporting members under article 31(f) and was then followed by the Amendment to the TRIPS Agreement. It waives the obligation to limit the issuing of compulsory licenses only for the supply of the domestic market. The exception is applicable to the pharmaceutical products that a WTO member considers crucial to address its public health problems.[297]

The General Council of the WTO adopted in 2005 the Protocol Amending the TRIPS Agreement which implemented the decision over paragraph 6 in the TRIPS Agreement with the introduction of the Article 31 bis. The amendment also added the Annex to the Agreement and the Appendix to the annex, both referring to the subject matter of article 31 bis.

After being ratified by two-thirds of the members, the amendment protocol entered into force. The specifics of article 31 bis have been analysed in the second chapter.

The introduction of the Article 31bis system was welcomed quite well. The introduction of a specific mechanism for compulsory licenses of pharmaceutical products carried the hope for a fairer TRIPS Agreement.[298]

However, the attempts to translate into practice the mechanism were unsuccessful. Ghana reportedly considered to take advantage of the 31bis mechanism in 2005 with the intention to import HIV drugs, but then decided to abandon this route and directly bought the medicines on the market. Another failed attempt was made by Nepal in 2008. The country notified the TRIPS Council in order to import a chemotherapeutic drug.

[295] Oh, C. (2003) *General Council "suspends" decision on TRIPS paragraph 6 solution (as informal consultations continue on "Chairman's Understanding"*), TWN Info Service on WTO Issues, Retrieved from https://twn.my/title/twninfo9.htm.
[296] *Supra*, note 206.
[297] *Supra*, note 294.
[298] *Supra*, note 185.

When a generic medicines producer from India applied for the compulsory license as exporter it was sued by a local patent owner and therefore forced to withdrew.[299]

The only successful example is the Canada-Rwanda case. In July of 2007 Rwanda notified the TRIPS Council on the intention to apply the 31bis mechanism to import 260,000 doses of Apo-Triavir, a combination of three drugs produced by the Canadian company Apotex Inc. A long bureaucratic and legal process started in order to implement the mechanism in the Canadian legal system, to negotiate with the patent holder and issue the necessary compulsory licenses. In September 2008 the pharmaceutical products in question were finally delivered to the importing country.

Despite the goal being achieved, the process received numerous critiques. Médecins sans Frontières reported the difficulties in the Canadian implementation of the paragraph 6 system that caused the process to be lengthy, which in case of deathly diseases becomes unacceptable. Apotex itself described the procedure "costly and complicated."[300]

The procedural complexities are just one of the factors hindering the use of the Article 31 bis system. Igbokwe and Tosato in their analysis reported that the procedural dimension of the mechanism is highly complex and problematic both for the developing and the developed countries. The Doha Declaration gave the explicit recommendation to alleviate the difficulties faced by the members in applying the article 31 compulsory licensing system. However, the solution found does not improve the applicability of the system.

Another factor that throughout the decades was pointed out to be an obstacle to the exploitation of the system is the fear that developing countries have of retaliatory actions carried out by developed countries. Various means of vindictive retaliation can be employed, including punitive trade policies and the withdrawal of pharmaceutical products from the market.

TRIPS-Plus standards resulting from FTAs Agreements have been causing a growing concern on the employability of the system. Some FTAs directly limited compulsory

[299] *Supra*, note 185.
[300] *Supra*, note 206.

licensing, for instance the US-Jordan FTA[301], the US-Singapore FTA[302], and the US-Australia FTA[303]. The signatory countries agreed on issuing compulsory licensing only in case of anti-competitive practices of patentees, for public non-commercial purposes, and in circumstances of extreme urgency. These FTAs generated many criticisms. Consequently, to the public outrage, the following FTAs[304] negotiated by the US explicitly referred to the Declaration of Doha and did not include limits to the compulsory licensing mechanism.

Lastly, the system implies high costs for the manufacturer. Economies of scale are hardly achieved and the manufactured goods must also comply with the article 31bis requirement of different packaging and labelling. The production requires a big up-front investment and the market conditions that would grant the profitability of an export compulsory license are rarely present. Export compulsory licensees moreover are subject to the risk of litigation, patent holders can sue the compulsory license procedure and even if unsuccessfully they would delay the outcome and increase the costs.[305]

3.3 The flexible nature of the TRIPS Agreement

The negotiations that led to the Trade-Related Aspects of Intellectual Property Rights Agreement itself saw the opposition of two factions: developed countries that pursued higher IP protection, and developing countries whose priority was to obtain a certain degree of freedom in the establishment of their IP systems. The result was the introduction of flexible measures in the overall strict framework introduced by the TRIPS Agreement.[306]

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[301] United States-Jordan Free Trade Agreement Art. 1.2, Oct. 24, 2000, 41 I.L.M. 63.
[302] United States-Singapore Free Trade Agreement art. 16.7(2), May 6, 2003, 42 I.L.M. 1026.
[303] United States-Australia Free Trade Agreement, art. 17.9(7)(b)(iii), May 18, 2004, 43 I.L.M. 1248.
[304] United States-Panama Trade Promotion Agreement, art. 15.10, June 28, 2007; United States-Peru Trade Promotion Agreement, art. 16.10(2), Apr. 12, 2006; United States-Colombia Trade Promotion Agreement, art. 16.10(2), Nov. 22, 2006. United States-South Korea Free Trade Agreement, art. 18.11 Feb. 10, 2011.
[305] *Supra*, note 185.
[306] *Supra*, note 266.

The Agreement imposes a good level of homogeneity to the foundations of IP systems of the members but leaves some autonomy for the national implementation phase and the term flexibility refers to the freedom that countries can have when implementing the agreement.[307]

These flexibilities include different kind of exceptions to patent rights, compulsory licenses for medicines, a mechanism for parallel importation, corrective actions against anti-competitive practices, limits to the patentable subject matter, and rejection of the extension of patents term.[308]

The term caught greater attention with the rise of the debate on public health mentioned above. In the context of public health safeguard, the World Intellectual Property Organization pointed out four categories of flexibilities: compulsory licensing and government use, exhaustion of rights, research exemption and exceptions of regulatory review.[309]

Musungu et al. divided the TRIPS flexibilities into two categories: the time flexibilities linked to the transition periods, and the substantive flexibilities.

The first category refers to the transition periods granted by the Agreement to developing and least-developed countries. As previously analysed, articles 65 and 66 of the TRIPS Agreement granted a transitional period to the countries that needed to implement new laws and standards in order to be compliant with the agreement.

The second category of flexibilities got in the spotlight with the debate on intellectual property protection and public health and regards the freedom countries have when implementing specific provisions of the Agreement.[310] For instance, national lawmakers are provided with a fair amount of freedom in determining both the patentability criteria (article 27) and the requirements for the protection of undisclosed test data in the national implementation of the provision (article 39).[311]

[307] *Supra*, note 206.
[308] Nkomo, M. (2011). The under-utilization of TRIPS flexibilities by developing countries: the case of Africa. In *WIPO-WTO COLLOQUIUM PAPERS* (p. 126).
[309] *Supra*, note 206.
[310] *Supra*, note 266. 12.
[311] *Supra*, note 206.

Substantial flexibilities on the matter of patents protection regard both the pre-grant and post grant phase of the patent issuing procedure, letting members free to allow both observations and oppositions of third parties before or after the patent has been granted.[312]

TRIPS flexibilities have been tailored to facilitate the removal of the obstacles that IP protection could generate to the development of least-developed countries. These flexibilities however are subject to ambiguous interpretation and difficult implementation, they in fact are not self-executing provisions. They shall be incorporated in the domestic legislations of the member countries in order to be effectively accessible. [313]

Correa and Hilty present a valuable framework on the factors and principles usually involved and required in the interpretation of TRIPS articles to implement their flexibilities. [314]

The first factor is the value of the GATT and WTO jurisprudence. Even though it is not related to IP, it may be used as an interpretative guideline for TRIPS. However, being intellectual property a matter of private rights, the application of GATT and WTO jurisprudence for the interpretation of TRIPS shall consider the specificity of the IP rights matter, whose principles often differ from the legislative priorities of international trade. Ultimately, the goal of the interpretation of TRIPS flexibilities shall be under any circumstance the consistency with the general objectives of the Agreement itself.[315]

The second component of the interpretative framework, is the Vienna Convention on the Law of the Treaties (VCLT) and in particular the article 31[316]. The article suggests as one of the initial stages for interpretation the determination of the *ordinary meaning* of the wording. It states that 'a treaty shall be interpreted in good faith in accordance with

[312] *Supra*, note 308. 125; Correa, C. M., & Hilty, R. M. (Eds.). (2022). *Access to Medicines and Vaccines: Implementing Flexibilities Under Intellectual Property Law*. Springer International Publishing, 7.
[313] *Supra*, note 308. 126).
[314] Correa, C. M., & Hilty, R. M. (Eds.). (2022). *Access to Medicines and Vaccines: Implementing Flexibilities Under Intellectual Property Law*. Springer International Publishing, 13.
[315] *Ibid*.
[316] Convention on the Law of Treaties, opened for signature 23 May 1969, 1155 UNTS 331 (entered into force 27 January 1980). Available at https://legal.un.org/ilc/texts/instruments/english/conventions/1_1_1969.pdf.

the ordinary meaning to be given to the terms of the treaty in their context and in light of its object and purpose' […] 'a special meaning shall be given to a term if it is established that the parties so intended'.[317] GATT and WTO panels and the WTO Appellate Body explicitly referred to this principle throughout the years.[318]

Article 32 of the VCLT contributes to build the interpretative guidelines. It deals with the supplementary means of interpretation and suggests that the preparatory work of the treaty and the circumstances of its conclusion may be as well used to interpret its provisions whereas the application of article 31 may result to be insufficient.[319]

As suggested by article 31 of the VCLT, interpretation must consider the context of the provision. Often the preambles of WTO agreements have been viewed as the right foundation to contextualise ambiguous provisions. In the case of TRIPS, the Preamble certainly offers a context for interpretation which is furtherly specified by articles 7 and 8 of the Agreement, which deal with the objectives and principles.

The identification of the object and purpose of the Agreement is thus another crucial factor for a fair interpretation of the Agreement. Beside the provisions of articles 7 and 8, the Doha Declaration constitutes a key document for determining the object and purpose of TRIPS.[320]

Interpretive issues are not the only obstacles to the exploitation of TRIPS flexibilities. Free Trade Agreements and the TRIPS-Plus standards they often set represent an obstacle for the flexible nature of the Agreement. The US and EU are seeking to increase IP safeguard in agreements with developing countries. The usual requests featured in these agreements include data exclusivity on pharmaceutical test data, the extension of the patent protection term of pharmaceuticals, broadening of the patentability criteria to include the possibility to patent every new use of known substances and limitations to the employability of compulsory licensing.[321]

[317] *Ibid*. Article 31 *General rule of interpretation*.
[318] *Supra*, note 314. 14.
[319] *Supra,* note 316. Article 32 *Supplementary means of interpretation.*
[320] *Supra*, note 314. 19.
[321] *Supra*, note 206. 85.

Tesoriero highlighted how access to medicines is fundamental for countries to comply with the obligations under the SDG Agenda. The Agenda itself cites the Doha Declaration as a reference to provide access to essential medicines and vaccines. Target 3.b specifically endorses the use of the flexibilities in the TRIPS provisions to pursue universal access to medicines.[322]

The TRIPS Agreement is therefore highly compatible with the development approach of the SDGs in terms of granting public health support. Articles 7 and 8 themselves call for finding a balance between social and economic welfare, promoting public interests, and tailoring intellectual property frameworks to pursue technological and socio-economic development.[323]

Member states are likely to face difficulties in applying flexibilities for the safeguard of their public health relying on human rights allegations. Human rights are not explicitly cited in the Agreement, and the Dispute Settlement Body shall not include this external concept in the administration of TRIPS disputes. Instead, the legitimacy of the use of the flexibilities for public health purposes shall be evaluated according to the principles contained in the Agreement, as it was in the Australia-Tobacco Plain Packaging decisions.[324] In that occasion the panel applied articles 7 and 8 to interpret the term "unjustifiably" in article 20 which was the protagonist of the dispute.[325]

3.3.1 Article 6: Exhaustion and Parallel Imports

The first flexible provision worth noticing is the exhaustion of IP rights mentioned in Article 6 of the Agreement and furtherly cited in paragraph 5(d) of the Doha Declaration.

[322] United Nations, Sustainable Development Goal 3. Available at https://sdgs.un.org/goals/goal3.
[323] *Supra*, note 271.
[324] Panel Report, Australia–Certain Measures Concerning Trademarks, Geographical Indications and other Plain Packaging Requirements Applicable to Tobacco Products and Packaging, WTO Docs WT/DS435/R, WT/DS441/R, WT/DS458/R, WT/DS467/R (28 June 2018) ('Australia-TPP No. 1'); Appellate Body Report, Australia–Certain Measures Concerning Trademarks, Geographical Indications and other Plain Packaging Requirements Applicable to Tobacco Products and Packaging, WTO Docs WT/DS435/R, WT/DS441/R (9 June 2020) ('Australia-TPP No. 2').
[325] *Supra*, note 271.

Article 6 of the Agreement prohibits TRIPS dispute settlement procedures on the issue of exhaustion.[326] Paragraph 5(d) of Doha states that the regime established by the Members to rule the exhaustion of IP rights shall not be challenged.[327] Since article 6 does not specify whether members shall adopt national, regional, or international exhaustion regimes, members developed widely differentiated legal frameworks worldwide.

National exhaustion means that the rights of the patentees are exhausted for the goods that entered the market in the country with their consent. In the context of a regional union, the exhaustion can be regional and it takes place whenever a patented good is put on the market of a country member to that union with the consent of their patent holder. International exhaustion takes place when the introduction on any market in the world of the patented goods with the consent of the patent owner will result in the exhaustion of the relative IP rights.[328]

The exhaustion regime is therefore strictly linked to the issue of parallel imports and the kind of exhaustion system chosen influences the trade dynamics of the country.

For instance, an IPR owner, who registered the IP in two countries A and B, sells the product in both. If the first sale happens in country A but country B has a national exhaustion regime, the sale in A does not impact the rights of the IP owner over the resale of the goods in country B. If country B instead implements an international exhaustion regime, the sale in country A, or wherever in the world, exhausts the rights in country B. Regional exhaustion is a compromise between the two regimes above and the right to resell the protected product is lost after the first sale that happens in the regional union.

Adopting an international exhaustion regime allows parallel imports. For instance, when B has adopted an international regime of exhaustion, a third party can import a patented

[326] Article 6 of the TRIPS Agreement: "For the purposes of dispute settlement under this Agreement, subject to the provisions of Articles 3 and 4 nothing in this Agreement shall be used to address the issue of the exhaustion of intellectual property rights".
[327] *See notes* 283-284.
[328] WIPO - Regional Seminar on the Effective Implementation and Use of Several Patent and Use of Several Patent-Related Flexibilities, Topic 14: Exhaustion of Rights, 2011, Available at https://www.wipo.int/edocs/mdocs/patent_policy/en/wipo_ip_bkk_11/wipo_ip_bkk_11_ref_topic14.pdf.

product purchasing it from the patentee in country A to resell it in country B. The patent owner can't oppose this parallel import since his rights are exhausted after the first sale in the market A. National exhaustion does not allow parallel import, whereas regional exhaustion regimes permit parallel imports among the countries of the region.[329]

These dynamics are also relevant in the context of access to medicines. Parallel imports allow for competition and therefore for price discrimination. Importing countries thus shall enjoy beneficial effects in terms of general access to medicines and prices.[330] For instance, the pharmaceutical sold by the patentee in one country is exported with a lower price by a buyer to a different country where the price established by the patentholder is higher. This mechanism therefore hinders the ability of the patentee to engage in price discrimination in different national markets, but grants lower prices for essential drugs.[331]

The flexibility provided by Article 6 was criticised by the opponents of parallel imports. Trying to limit the flexibility over the establishment of the exhaustion regime, some claimed that Article 28 of the TRIPS Agreement recognises to patentees the right to "prevent third parties from making, using, offering for sale, selling or importing" a patented product, therefore limiting the flexible interpretation and implementation of Article 6. However, this argument was rejected since a footnote in Article 28 itself confirms that the provision is subject to Article 6 and, as highlighted in Doha, countries can adopt the exhaustion regime they deem the most appropriate without the possibility of being challenged for it.[332]

3.3.2 Articles 7 and 8: TRIPS interpretative fundamentals

[329] *Supra*, note 287.
[330] Calboli, I. (2020). *Intellectual Property Exhaustion and Parallel Imports of Pharmaceuticals: A Comparative and Critical Review* (SSRN Scholarly Paper 3853065).
[331] *Supra*, note 279.
[332] *Supra*, note 330.

Articles 7 and 8 embody the object and purpose of the TRIPS Agreement. They were the result of the pressures made by developing countries to find a guarantee of the flexible interpretation and implementation of the provisions of the agreement.

Article 7 sets the objectives of the Agreement, it highlights the role of IPR in the promotion of technological innovation and for the transfer of technologies. IP rights shall bring advantage both to producers and consumers and improve the general economic and social welfare, balancing rights and obligations.[333] The article implicitly clarifies that the purpose of TRIPS is not the protection of intellectual property rights alone, instead it encourages technological innovation and development. Article 7 recommends to interpret the TRIPS in a way that safeguards both social and economic welfare bringing advantages to the whole society.[334]

Yu states that this article paves the way for *future exceptions and limitations,* as it calls for an alternative interpretation of the TRIPS provisions when it is necessary to restore the balance between economic and social welfare.[335]

Article 8 is titled *principles* and allows states to implement measures that safeguard public health and nutrition but also promote public interests in sectors deemed to be crucial for the socio-economic and technological development of the country. Members shall adopt these measures elaborating and implementing regulations and laws, given that such provisions comply with the clauses of the Agreement. The second clause of the article allows states to implement measures to impede the abuse of IP rights by their owners and to prevent the insurgence of practices that put barriers to both trade and the transfer of technologies.[336]

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

[334] *Supra*, note 271.

[335] Yu, P. K. (2009). *The Objectives and Principles of the TRIPS Agreement*. Houston Law Review 979.

[336] TRIPS Agreement, Article 8 *Principles*: "1. Members may, in formulating or amending their laws and regulations, adopt measures necessary to protect public health and nutrition, and to promote the public interest in sectors of vital importance to their socio-economic and technological development, provided that such measures are consistent with the provisions of this Agreement. 2. Appropriate measures, provided that they are consistent with the provisions

The article grants a great level of autonomy to Members in order to enable them to protect societal welfare through the adoption of adequate public policies. The clause does not provide guidelines on the criteria to determine the *sectors of vital importance* for the countries, therefore members can freely define the scope and content of laws and regulations aimed at protecting their public interests. However, the requirement that these measures must be *consistent* with the other provisions of TRIPS, generated a debate over the actual admissible public interests to be safeguarded through public policies in the context of IP.[337]

The uncertainty around the two articles has been partially solved in Doha and with the Australia-Tobacco Plain Packaging decisions 1 and 2 (Australia-TPP)[338].

The Doha declaration highlighted the importance of the interpretation and implementation of TRIPS provisions in order to deal with public policy issues. The declaration specifically refers to the objectives and principles as a guide to interpret and implement the TRIPS provisions in a manner supportive of Members' public health.[339] The document furthermore encourages the use of the flexibilities of the Agreement to address public concerns.[340]

The Australia-TPP (No. 1 and No. 2) further confirmed the central role the two articles have when the TRIPS provisions need to be interpreted. The case regarded a complaint about a supposed violation of article 20[341] of the TRIPS Agreement by the Australian tobacco plain-packaging legislation. The alleged violation of article 20 came from the Australian legislation on cigarette and cigar packaging that set a series of specific

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of this Agreement, may be needed to prevent the abuse of intellectual property rights by right holders or the resort to practices which unreasonably restrain trade or adversely affect the international transfer of technology."

[337] *Supra*, note 271.

[338] *Supra*, note 324.

[339] *Supra*, note 273. Paragraph 5 (a).

[340] *Ibid*. Paragraph 4.

[341] TRIPS Agreement, Article 20 *Other Requirements* "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."

requirements to be respected by word marks such as the font, size, and colour (TPP Measures). Article 20 of TRIPS prescribed that "the use of a trademark in the course of trade shall not be unjustifiably encumbered by special requirements". The panel thus had to interpret the meaning of the terms *use of a trademark in the course of trade*, *unjustifiably*, *encumber*, and *special requirements*. The result was that the TPP Measures did represent special requirements encumbering the employment of the trade mark *in the course of trade*, however these special requirements were not hindering trade mark use unjustifiably, therefore the measures were deemed to be compliant with TRIPS.

The Panel's reasoning behind the decision originated from Article 31 of the Vienna Convention on the Law of Treaties which indicates that the first step for interpretation shall be the determination of the ordinary meaning of the term.[342]

The panel translated the term *unjustifiably* as the ability to provide a "good reason for the relevant action" but since Article 20 does not make explicit reference to what reasons could be legitimate, the panel looked at the preamble, the objectives, and principles of the Agreement to further interpret the term.[343] Article 7 is relevant because it sets the general intention of the Agreement to keep a balance between the interests of the stakeholders involved in the IPR context. Article 8 highlights the freedom and autonomy countries have in establishing the public interests that justify certain measures while implementing and amending the TRIPS provisions.[344]

The judgment delivered by the panel stated that the Australian TPP Measures "are capable of and in fact do contribute to Australia's objective of improving public health [...] [this] provides sufficient support for the application of the resulting encumbrances on use of trade marks".[345]

The two decisions confirmed the importance of Articles 7 and 8 for the interpretation of TRIPS provisions and of its flexibilities. They to some degree formulate the international standards for the safeguard of public interest in the context of intellectual property.

[342] *Supra*, note 316. Article 31.
[343] Australia-TPP No. 1 [7.2396] – [7.2401]; Australia-TPP No. 2[6.649].
[344] *Supra*, note 271.
[345] Australia-TPP No. 1 [7.2604]; Australia-TPP No. 2 [6.632].

However, the utility of the two articles goes beyond the interpretative scope. They can also represent a shield for less-developed countries against strict and impactful TRIPS-Plus provisions that often harm the principles of TRIPS. [346]

3.3.3 Article 27: flexible patentability

Article 27 of the TRIPS Agreement covers the theme of patentable subject matter. Specifically, the first paragraph provides that patents shall be available for any invention, product or process, in *all fields of technology*. The second paragraph addresses the inventions that members may exclude from patentability. The provision states that *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*. Such exclusions can be determined also *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.*[347]

Article 27.3 further specifies which subject matter may be excluded from patentability, being it either *diagnostic, therapeutic and surgical methods for the treatment of humans or animals*; or *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*.[348]

One of the greatest achievements in terms of international IP protection is the TRIPS obligation to grant patent protection in all fields of technology as provided by article

[346] *Supra*, note 335.
[347] TRIPS Agreement, Article 27(2) "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."
[348] TRIPS Agreement, Article 27 (3) "[…] 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. The provisions of this subparagraph shall be reviewed four years after the date of entry into force of the WTO Agreement."

27.1. The transition periods the Agreement accorded to developing countries imposed them to introduce patent protection in all fields by 2005.[349]

It is worth mentioning a remarkable case that involved the Swiss pharmaceutical company Novartis and the Union of India[350]. India 1970 revision of the Patent Act did not provide patent protection to pharmaceutical products in order to perpetuate the national profitable business of generic drugs manufacturing. In 2005, India adopted its Patent Amendments Act allowing for pharmaceutical patents. Section 3(d) of the Patents Act became the centre around which the case was built. Section 3(d) aimed at hindering the practice of patent "evergreening" and at ensuring the access to affordable medicines.

The term of patent evergreening refers to the practice of filing patents that differ from the first granted patent just because of minor modifications or improvements. The purpose is in fact to extend the validity of the exclusive rights over the first patented invention. The Indian Patent Act in section 3(d) classifies as not patentable inventions, *the mere discovery of a new form of a known substance which does not result in the enhancement of the known efficacy of that substance or the mere discovery of any new property or new use for a known substance or of the mere use of a known process, machine or apparatus unless such known process results in a new product or employs at least one new reactant.*

The Novartis case originated from the mailbox filing that Novartis did in 1998 to claim protection of the beta crystalline form of the active ingredient Imatinib Mesylate (IM) as a treatment for certain cancer forms.[351] The ingredient IM had already been publicly disclosed in 1995, therefore the mailbox application claimed that the new beta crystalline form had better characteristics and performance.[352]

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[349] Grosse Ruse-Khan, H., & Romandini, R. (2017). *Patentability of Pharmaceutical Inventions Under TRIPS: Domestic Court Practice as a Test for International Policy Space.* Mercurio, B. Kim, D., Contemporary issues in pharmaceutical patent law London, Routledge, 9-46.

[350] Novartis AG vs. Union of India (2007), Available at http://judis.nic.in/judis_chennai/qrydispfree.aspx?filename=11121.

[351] Indian Patent Office, Application No. 1602/MAS/1998; see the analysis of the patent application in Novartis v Union of India, 2009 IPAB TA/1-5/2007/PT/CH, Order 100/2009 of 26 June 2009, available at https://spicyip.com/docs/NovartisvsUnionofIndia.pdf.

[352] *Supra*, note 349.

The mailbox application was rejected since the examination process concluded that the beta crystalline lacked novelty. Novartis challenged the decision over the patent and the constitutionality and TRIPS compliance of section 3(d) before the Madras High Court. In 2009 the case reached the Supreme Court of India, which issued its decision in April 2013 confirming the non-patentability of the beta crystalline IM.[353]

The ongoing debate on patentability throughout the decades included the issue of whether naturally occurring substances may be patentable subject matter. The European Union lawmaker in order to deal with the issue, codified the "isolation doctrine" for biological material. In an attempt to pursue the article 3 of Directive 98/44/EC of 1998 on the safeguard of biotechnological inventions, the doctrine states that even if previously occurred in nature, biological material can be considered an invention when isolated from its natural environment or manufactured through a technological process.[354]

In the US, the Myriad case before the U.S. Supreme Court in 2011 gave a relevant ruling on the patentability of biochemical substances. The case before the Supreme Court involved product claims to protect sequences of genomic deoxyribonucleic acid (DNA) and sequences of artificially created DNA. Process claims to obtain and use natural substances are possible both in Europe and in the US. However, the court had to rule over the validity of a product claim on the isolated DNA sequences.[355]

Product claims grant IP protection for the substance itself, whereas process claims over naturally occurring substances would allow for subsequent innovator to find and protect alternative ways to obtain or use the substance.

In the Myriad case the plaintiff, the Association for Molecular Pathology, invoked the exception to patentability of a "product of nature", therefore not eligible according to the United States Code title 35.[356] Myriad Genetics' claims both concerned isolated DNA

[353] Novartis AG v Union of India, Indian Supreme Court Judgment of 1st April 2013, Paragraphs 131-136, 157. Available at https://main.sci.gov.in/jonew/judis/40212.pdf.
[354] *Supra*, note 349.
[355] *Ibid*.
[356] United States Code, Title 35 – Patents, Section 101, Inventions Patentable "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."

molecules and the molecule obtained once the covalent bonds of chromosomal DNA have been broken, which differs from the original DNA. The plaintiff challenged the claims regarding the isolated DNA.[357]

The United States District Court for the Southern District of NY denied all the patent claims, even those on the artificially created DNA. The Court of Appeals for the Federal Circuit applied the European doctrine and recognised the validity of the isolated DNA claims.[358] The Supreme Court came to an intermediate solution: recognised the patentability of artificially created DNA but rejected the validity of the patent claims over the isolated DNA as a "product of nature", therefore not respecting the patent eligibility criteria of the US Code.[359]

Recalling article 27.1 of TRIPS, patent protection is provided for inventions and not for discoveries, therefore naturally occurring substances shall not be patentable.

However, the Agreement does not provide a definition of *invention*. The ordinary meaning of the term, considering its generating verb *invent,* according to the Oxford Dictionary of English, refers to the creation of "something that has not existed before".

Naturally occurring substances would not be required to be patentable according to this interpretation, since not invented. Thus, TRIPS Article 27.1 would not directly oblige members to allow a product claim on this kind of substances, however, given the interpretative flexibility granted to Members implementing the Agreement, they would be free to do so.[360]

Article 27.3 allows for an exception from patentability for *plants and animals other than micro-organisms*, and for *biological processes for the production of plants or animals*. It would indirectly recognize the patentability of microorganisms without specifying if they need to be the result of an invention or they can be naturally occurring. Moreover, the article specifies the excludability of plants and animals from patents, as if under article

[357] *Supra*, note 349.
[358] United States Court of Appeals for the Federal Circuit , Ass'n for Molecular Pathology v. U.S. Patent & Trademark Office, 702 F. Supp. 2d 181 (S.D.N.Y. 2010) aff'd in part, rev'd in part, 653 F. 3d. 1329 et seq. (Fed. Cir. 2011).
[359] Association for Molecular Pathology v. Myriad Genetics, Inc. 133 S. Ct. 2107, 2117-18, 186 L. Ed.2d 124 (2013).
[360] *Supra*, note 349.

27.1 it was permitted. However, there is universal consensus over the non-patentability of plants and animals occurring in nature, even if implicitly not stated in the article. The specification of article 27.3 therefore shall be referred to animals, plants and microorganisms that result from an invention.

Interpreting article 27.3 through the words of article 27.1 implies that the requirement of being an invention in order to be patentable shall be applied to such microorganisms as well. After the US Supreme Court ruling against the patentability of isolated forms of naturally occurring substances, other WTO members will likely follow this approach.

Focusing on the analysis of Article 27.2, some terms need to be interpreted in order to clearly understand the meaning of the provision and its flexibility.

The exclusion from patentability can occur if it is deemed to be necessary to protect *ordre public* and morality. To give a definition of *necessary* Henckels suggests a comparison with the interpretation given of Article XX of GATT[361] throughout the years.[362] The article specifies that nothing in the agreement shall prevent members to adopt measures *necessary to protect public morals* or *necessary to protect human, animal or plant life or health.*

From US-Patents[363] to Shrimp-Turtle[364], the general interpretation of the term *necessary* was that a discriminatory trade provision, allowed by the article, was necessary only if any other measure compliant with GATT or any more reasonable measure could not be applied in order to protect public order or lives and health.[365]

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[361] General Agreement on Tariffs and Trade, Article XX, General Exceptions "Subject to the requirement that such measures are not applied in a manner which would constitute a means of arbitrary or unjustifiable discrimination between countries where the same conditions prevail, or a disguised restriction on international trade, nothing in this Agreement shall be construed to prevent the adoption or enforcement by any contracting party of measures: (a) necessary to protect public morals; (b) necessary to protect human, animal or plant life or health; […]."

[362] Henckels, C. (2006). *The Ostensible Flexibilities in TRIPS: Can Essential Pharmaceuticals Be Excluded from Patentability in Public Health Crises*. Monash UL Rev., 32, 335.

[363] United States Tariff Act of 1930, Section 337. WTO Doc L/6439 - 36S/345 (1989) (Report of the Panel).

[364] United States - Import Prohibition of Certain Shrimp and Shrimp Products, WTO Doc WT/DS58/AB/R (1998) (Report of the Appellate Body).

[365] *Supra*, note 362.

The interpretative implication of this GATT article on 27.2 of TRIPS is that a member invoking an exclusion from patentability referring to this article shall demonstrate that no other measure more compliant with TRIPS could have been reasonably taken. In the context of pharmaceuticals, the denial of patentability goes against the basic rights of intellectual property and liberalised international trade of protected IP products. Thus, the most TRIPS-compliant measure to be reasonably available in a scenario of public health safeguard would be the compulsory licensing mechanism of article 31.[366]

Also, the interpretation of the terms *morality* and *ordre public* needs to be furtherly clarified. Henckels suggests how the meaning of the two words can be traced back to earlier drafts of the article. Previous versions of article 27.2 included public interest, national security, public health, and nutrition as criteria to allow exceptions to patentability. The initially broader scope of the article suggests that the terms used in the final draft should be interpreted as a general reference to human health.[367]

European law may be a useful reference as well. The EPO, in the context of Article 53(a) of the European Patent Convention[368], defines morality as *a belief being founded on the totality of the accepted norms which [are] deeply rooted in [...] the culture inherent in European society and civilisation. Accordingly, inventions the exploitation of which was not in conformity with the conventionally accepted standards of conduct pertaining to this culture [are] to be excluded from patentability.*[369] Being morality strictly linked to the culture of the member states, in the context of the WTO, the diversity between the members does not allow to define a universal concept of morality as for the European context.[370]

[366] *Ibid*.
[367] *Ibid*.
[368] European Patent Convention, Article 53 Exceptions To Patentability "European patents shall not be granted in respect of: (a)inventions the commercial exploitation of which would be contrary to "ordre public" or morality; such exploitation shall not be deemed to be so contrary merely because it is prohibited by law or regulation in some or all of the Contracting States; […]."
[369] Case Law of the Boards of Appeal, Assessment of an objection according to Article 53(a) EPC, raised in T 0356/93 (Plant cells) 21-02-1995. Available at https://new.epo.org/en/legal/case-law/2022/clr_i_b_2_2_2_b.html.
[370] *Supra*, note 362.

The concept of *ordre public* comes from the French legal background and it can be compared to the notion of public policy.[371] Public policy represents the ensemble of the fundaments of a society without which its institutions are endangered.[372] According to the EPO, ordre public also includes the safeguard of public security and the physical safety of the individuals making up a society.[373] *Ordre public* shall *be interpreted strictly* according to the European Court of Justice, in order to safeguard any fundamental interest of the state.[374]

Ordre public is thus less abstract and more homogeneous across WTO countries. The issues of human, animal or plant life and health shall be placed under the scope of this concept and the exclusion of some basic inventions from patentability to grant access to them in developing countries may be seen as a matter of *ordre public*.

Article 27.2 provides that the exclusion from patentability must relate to a denial of *commercial exploitation* of the invention. It is therefore the commercialization of the invention that must be prevented to safeguard morality or *ordre public*.[375] The risk of damaging *ordre public* or morality thus comes from the commercial exploitation of the invention and not from the invention itself. This logic implies that members claiming exclusions according to article 27.2 shall also prohibit the commercial exploitation of the invention domestically. If the invention itself is deemed as immoral domestic legislation should completely prevent its use. If the invention itself brings advantages to the society but its commercialization would, for instance, raise barriers to price, and therefore endanger morality or public policy, then the invention should be allowed to exist but monitored on the aspects of its affordability or accessibility.[376]

Ruse Khan and Romandini in the conclusions of their article highlight how the obligations imposed by Article 27 are actually limited and subject to interpretation. Members, in the

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[371] *Ibid*.
[372] Morin, J. F. (2003). Daniel Gervais-*The TRIPS Agreement: Drafting History and Analysis*, London, Sweet & Maxwell, 2003. Rev. quebecoise de droit int'l, 16, 375.
[373] *Supra*, note 362.
[374] *Ibid*.
[375] Weissman, R. (1996). *A Long, Strange, TRIPS: The Pharmaceutical Industry Drive to Harmonize Global Intellectual Property Rules, and the Remaining WTO Legal Alternatives Available to Developing Countries*, 17. University of Pennsylvania Journal of International Economic Law. 1069-1081.
[376] *Supra*, note 362.

context of pharmaceuticals, are obliged to grant patent protection for both pharmaceutical products and processes, however they are free to exclude from patentability naturally occurring substances and later versions of a patented invention that does not present superior characteristics, as enough enhanced efficacy. However, they argue that even if these exclusions are legal according to TRIPS, they may not be wise from a policy perspective.[377]

3.3.4 Article 30: Exceptions to Rights Conferred

Article 30 of TRIPS states:

> *Members may provide limited exceptions to the exclusive rights conferred by a patent, provided that such exceptions do not unreasonably conflict with a normal exploitation of the patent and do not unreasonably prejudice the legitimate interests of the patent owner, taking account of the legitimate interests of third parties.*[378]

This article presents many ambiguous terms which allow for flexible interpretations and implementations. It is structured according to a three-step test which recalls Article 9.2 of the Berne Convention[379] the debate on which became thus relevant for its interpretation.[380]

The first step to be respected is that the exceptions must be limited. The second step requires that the exceptions do not *unreasonably* interfere with the ordinary patent exploitation and do not *unreasonably* damage the patentee's legitimate interests. The third step refers to the balancing assessment between the interests of the patentee and the third party.

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[377] *Supra*, note 349.
[378] TRIPS Agreement, Article 30.
[379] *Supra*, note 74. Article 9(2) "It shall be a matter for legislation in the countries of the Union to permit the reproduction of such works in certain special cases, provided that such reproduction does not conflict with a normal exploitation of the work and does not unreasonably prejudice the legitimate interests of the author."
[380] Antons, C. (2016). *Article 27 (3)(b) TRIPS and plant variety protection in developing countries.* In TRIPS plus 20: From Trade Rules to Market Principles (pp. 389-414). Springer Berlin Heidelberg.

Exceptions offer to members an opportunity to strike a balance between the economic interests of the patentee and societal interests.[381] The article does not specify which exceptions are allowed, granting member states a great flexibility in the implementation. Common exceptions adopted by Member states are those for private and non-commercial use, research or experimenting.[382]

In the context of access to medicines, an example of exception under article 30 is the "regulatory review exception" or "Bolar exception"[383]. This exception facilitates the entry of generics in the market permitting the use of a patented invention by a third party to obtain regulatory approval, allowing generic manufacturers to sell the products as soon as the patent expires.[384]

A partial interpretation of the article was given in 1999 in the Canada-Patent Protection of Pharmaceutical Products case.[385] The decision regarded the compliance with article 30 of two exceptions allowed by Canadian law. The first exception is the above cited regulatory review exception, the second was the *stockpiling exception*. The latter allowed competitors to produce and store, stockpile, a patented drug for 6 months prior to the expiration of the patent.[386]

The WTO Panel examined the article focusing on the analysis of the "limited" requirement, leaving aside all the other ambiguous terms such as *legitimate interests* and *normal exploitation*.[387] The conclusion of the Panel was that the wording limited exception allows only for a "narrow curtailment of the legal rights" of the patentee.[388] The Expert Report of the Standing Committee on the Law of Patents in 2011, criticised the narrow interpretation of the panel on the term *limited,* highlighting the risk that

[381] *Supra*, note 271.
[382] *Supra*, note 314. 136.
[383] *Supra*, note 271.
[384] *Supra*, note 314. 135.
[385] Panel Report, Canada-Patent Protection of Pharmaceutical Products, WTO Doc WT/DS114/R (17 March 2000) ('Canada-Patents').
[386] *Supra*, note 271.
[387] Garrison, C. (2006). *Exceptions to Patent Rights in Developing Countries* (Project on IPRs and Sustainable Development, Issue Paper No. 17, UNCTAD-ICTSD), 23.
[388] Panel Report, Canada-Patent Protection of Pharmaceutical Products, WTO Doc WT/DS114/R (17 March 2000) ('Canada-Patents') [7.44].

this interpretation bears to "deprive member countries of the real potential offered by the use of exceptions".[389]

More importantly, the Panel ignored the second and third step of article 30, implicitly pointing out their futility and, even if it recognised that articles 7 and 8 were the reference for the objects and principles of TRIPS, it did not consider them as a guideline to interpret the provision.[390]

Interpreting the article through the lens of article 7 and 8, as it was done for article 20 in the Australia-TPP case, will show that the third step, aiming to strike a balance between private and public interest, is the core of the provision. Thus, there is notable consensus on the need to consider article 30 as an indivisible sum of its three steps in order to grant the efficacy of the exceptions.[391]

Referring to the Australia-TPP case, where the core of the interpretation given by the Panel on article 20 was the term *unjustifiably*[392], Tesoriero suggests that article 30 should be interpreted focusing on the term *unreasonably*. In order to understand if the exception *unreasonably* conflicts with the normal exploitation of the patent and if the interests of the patentee are *unreasonably* prejudiced, Tesoriero highlights three factors to be analysed. The first factor is the nature and extent of the conflict and prejudice caused by using the patent on the market through the exception. The second and third factors to be examined are the reason that justifies the exceptions and whether this reason legitimize enough the conflict and prejudice.[393]

3.3.5 Article 39: Protection of Undisclosed Information

[389] WIPO - Standing Committee on the Law of Patents, Experts' Study on Exclusions from Patentability and Exceptions and Limitations to Patentees' Rights, (15th sess, WIPO SCP/15/3 Annex I, 3 February 2011). 71.
[390] *Supra*, note 271.
[391] *Ibid*. 525.
[392] See paragraph 3.3.2.
[393] *Supra*, note 271. 525.

The analysis moves straightforward to article 39 since wide room has already been given above to the interpretation and implications of Article 31.[394]

In the seventh section of the Agreement article 39 deals with the protection of undisclosed information. Specifically, article 39.3 is the centre of a debate on the protection of test data for pharmaceuticals.

Article 39.3 states that "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 protect 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 the data are protected against unfair commercial use."[395]

To contextualise the provision, it is necessary to make a premise on the usual procedure of registration of pharmaceutical products before their marketing. In order to be able to register a medicine, the producer is required to provide data on the test run on the efficacy, quality, and safety of the product. The protection of these test data differs across jurisdictions, but two are the most common approaches. One approach provides exclusive use of the data to the first applicant over a given period, on the other hand some countries allow access to test data to review drugs application of competing and subsequent products with the same physical and chemical features.[396]

For instance, European Union members have provided since 1987 a period of exclusive data protection for the confidential information filed for marketing applications of pharmaceuticals, primarily to compensate for the lack of patent protection for this field in some of these countries. The exclusivity period does not allow national health authorities to consult the data when evaluating subsequent applications. The minimum period is six years, and it becomes ten if the product is deemed of "high

[394] See paragraphs 2.2.1; 3.2.1.
[395] TRIPS Agreement, Article 39.3.
[396] Correa, C. M. (2002). *Protection of data submitted for the registration of pharmaceuticals: implementing the standards of the TRIPS agreement*. Geneva: South Centre.

technology."[397] The North American Free Trade Agreement instead provides for a minimum period of data exclusivity of five years.[398]

TRIPS establishes only minimum standards to be respected, and the key provision that regulates the matter of data exclusivity, article 39.3, includes some terms that need clarification.[399]

The first condition introduced by the article is that protection for test data must be granted only if such data are required by national authorities as a prerequisite to obtain marketing approval of the product. Therefore, article 39.3 only applies to those countries that includes this requirement.[400]

The data to which the article refers are the datasets reporting the results of the scientific tests for agrochemical and pharmaceutical products over their impact and efficacy on humans and the environment in general. They must be *undisclosed data,* public information submitted for the marketing registration do not need protection under the scope of this article.[401]

Article 39.3 leaves plenty of room for interpretation for the expression *new chemical entity.* The term new is not precisely defined, members may apply the patentability standard of novelty, or refer to the date of the first application for the approval of the medicine. The condition to be new could be either universal or national and it could be even deemed as fulfilled for instance if a product, used in a technological field

[397] *Ibid*. 9.
[398] North American Free Trade Agreement (1992), Article 1711 *Trade Secrets*. Paragraph 6 "Each Party shall provide that for data […] that are submitted to the Party after the date of entry into force of this Agreement, no person other than the person that submitted them may, without the latter's permission, rely on such data in support of an application for product approval during a reasonable period of time after their submission. For this purpose, a reasonable period shall normally mean not less than five years from the date on which the Party granted approval to the person that produced the data for approval to market its product […]. Subject to this provision, there shall be no limitation on any Party to implement abbreviated approval procedures for such products on the basis of bioequivalence and bioavailability studies."
[399] *Supra*, note 396.
[400] *Ibid*. 14.
[401] *Ibid*. 15.

different from the pharmaceutical one, is then found to be applicable as pharmaceutical product.[402]

Considerable effort and unfair commercial use both require further interpretation. The former term refers to the purpose of the negotiating parties to mandate protection for the investment made by the developer of the new product to obtain the data.[403]

The definition of *unfair commercial use* constitutes the core of the interpretative issue, since it establishes if the use of test data for the marketing approval of pharmaceutical and agrochemical products that follow the first application is legitimate (second-entry marketing applications).

According to the VCLT principle of ordinary meaning, unfair would indicate something that is *not equitable or honest or impartial,* however the interpretation of this concept is linked to morality and societal values and it will likely be different across time and space. Thus, the article calls for protection against unfair commercial practices, but it lets Members determine which practices shall be considered unfair.[404]

The approaches countries can adopt regarding the approval of second-entry marketing applications are essentially four. The first option is to require that the second applicant either runs the tests required or uses the past test data after obtaining the authorization of the originator. The second option allows subsequent applicators to rely on the original test data through a compensation paid to the originator of the tests. The third way implies the examination of the second application through the data presented by the first applicant. The last approach does not examine or consider the confidential information contained in the first application.[405]

The first two options imply a certain form of data protection, the third one implies a use of the data made by the national authority evaluating the application, while the last approach does not involve any use of the test data.

[402] *Ibid*. 16-17.
[403] *Ibid*. 18-19.
[404] *Ibid*. 25-27.
[405] *Ibid*. 31

Some interpret the use of the test data by the national evaluating authority as an *unfair commercial use* given the indirect advantage that the competitors can get. However, case law throughout the years supported the view according to which granting approval to a second applicant based on the similarity to a previously marketed product does not constitute a *use* of the confidential data.

Two important disputes have resulted in relevant interpretations of the issue: Ruckelshaus v. Monsanto Co.[406] and the Bayer Inc. v. The General Attorney of Canada, the Minister of Health, Apotex Inc. and Novopharm Ltd.[407]

The Ruckelshaus v. Monsanto Co. case regarded the use of the data from an application of an agrochemical product previously registered and marketed by Monsanto Co. Even if the subsequent applicant financially compensated Monsanto, the latter claimed that the data use damaged the expectations on the return on the investment. The Supreme Court legitimated the use made by the authority of the original submitted data to examine subsequent applications and confirmed Monsanto's entitlement to being compensated but not the right of exclusivity over those data.[408]

The Bayer Inc. case was brought before the General Court of Appeal of Canada in 1999. The court judged as legitimate the use of the first registration to assess the subsequent application. The national authority did not request the use of undisclosed information and simply compared the two applications. The ruling affirmed that in the case in which the health authority uses the data from the originator's application to assess the second entrant request, according to Canadian Law[409] and NAFTA provisions, the minimum period of five years of data protection from competitors shall be respected. If the examination of the second entrant's product does not imply the use of those confidential data, data exclusivity rules are not to be applied.[410]

[406] Ruckelshaus v. Monsanto Co. No. 83-196, Argued February 27, 1984, Decided June 26, 1984, 467 U.S. 986.
[407] Bayer Inc. v. Canada (Attorney General) et al. Federal Court of Appeal, Stone, Rothstein and Sexton, JJ.A. May 19, 1999.
[408] *Supra*, note 396. 33-35.
[409] Canadian Food and Drug Regulations, Subsection C.08.004.1 (1).
[410] *Supra*, note 396. 36-39.

Countries therefore maintain substantial flexibility. They are not obliged to grant the data exclusivity under the conditions of the article. With the aim of improving access to medicines, the suggested interpretation of the article would allow for national health agencies to access test data of previously patented pharmaceutical products once a manufacturer of generic drugs seeks the approval of the same product in the proximity of the patent expiry date.

3.3.6 Article 73: Security Exceptions

The compliance with TRIPS provisions can be interrupted according to its article 73 in case national *essential security interests* are threatened.

Article 73 provides that the obligations under TRIPS shall not prevent members from making exceptions due to security issues. Article 73(b) states that members shall not be hindered by TRIPS in "[…] taking any action which it considers necessary for the protection of its essential security interests". The article cites specific threats such as risks related to fissionable materials, or traffic of arms, war or *other emergency in international relations (73.b.iii)*.[411] The article presents the same exact wording of the *Security Exception* article XXI of the General Agreement on Tariffs and Trade.[412]

[411] TRIPS Agreement, Article 73, Security Exceptions "Nothing in this Agreement shall be construed: (a) to require a Member to furnish any information the disclosure of which it considers contrary to its essential security interests; or (b) to prevent a Member from taking any action which it considers necessary for the protection of its essential security interests; (i) relating to fissionable materials or the materials from which they are derived; (ii) relating to the traffic in arms, ammunition and implements of war and to such traffic in other goods and materials as is carried on directly or indirectly for the purpose of supplying a military establishment; (iii) taken in time of war or other emergency in international relations; or (c) to prevent a Member from taking any action in pursuance of its obligations under the United Nations Charter for the maintenance of international peace and security."

[412] The General Agreement on Tariffs and Trade, Article XXI, Security Exceptions "Nothing in this Agreement shall be construed (a) to require any contracting party to furnish any information the disclosure of which it considers contrary to its essential security interests; or (b) to prevent any contracting party from taking any action which it considers necessary for the protection of its essential security interests (i) relating to fissionable materials or the materials from which they are derived; (ii) relating to the traffic in arms, ammunition and implements of war and to such traffic in other goods and materials as is carried on directly or indirectly for the purpose of supplying a military establishment; (iii) taken in time of war or other emergency in international relations; or (c) to prevent any contracting party from taking any action in

The provisions however need elucidations over some terms and implications. Two disputes settlement panels have succeeded in clarifying some aspects of article XXI(b)(iii) of GATT 1994 and of TRIPS article 73(b)(iii): the Russia-Measures Concerning Traffic in Transit in 2019[413], and the Saudi Arabia-Measures Concerning the Protection of Intellectual Property Rights in 2020[414].

Prior to these WTO Panel reports, many members considered both the GATT and TRIPS article a *self-judging* provision, meaning that it is a single member's prerogative to assess what is necessary to preserve its own security interests and therefore decide when to invoke the exceptions.[415] Moreover, some states claimed that the employment of these security exceptions could neither be reviewed by other members nor be subjected to a dispute settlement panel.[416]

Thus, a fundamental issue that both WTO panels dealt with is whether the reasons that led to the application of security exceptions can be disputed and reviewed by the Dispute Settlement Body. In the Russia-Transit case Russia and the US, as a third party, claimed that the motivations behind national security exceptions are *nonjusticiable*.

The case involved a complaint of Ukraine against the Russian Federation over measures implemented by the latter to restrict the transit of goods from Ukraine through Russia to other countries.[417] The US argued that the WTO Panel lacked "the authority to review the invocation of Article XXI" and that the dispute is therefore nonjusticiable due to the

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pursuance of its obligations under the United Nations Charter for the maintenance of international peace and security."

[413] WTO, Russia – Measures Concerning Traffic in Transit, Panel Report, WT/DS512/R (5 April 2019) (interpreting Article XXI of the GATT).

[414] WTO, Saudi Arabia – Measures Concerning the Protection of Intellectual Property Rights, Report of The Panel, WT/DS567/R, (16 June 2020).

[415] GATT, Contracting Parties Nineteenth Session, 'Summary Record of the Twelfth Session' SR.19/12 (21 December 1961). 196. Available at https://docs.wto.org/gattdocs/q/GG/SR/19-12.PDF.

[416] Oke, E. K. (2021). *COVID-19, pandemics, and the national security exception in the TRIPS agreement*. J. Intell. Prop. Info. Tech. & Elec. Com. L., *12*, 400.

[417] The transit restrictions were: 2016 Belarus Transit Requirements; the 2016 Transit Bans on Non-Zero Duty and Resolution No. 778 Goods; and the 2014 Belarus-Russia Bans on Transit of Resolution No. 778 Goods. See Summary of the WTO dispute WT/DS512/7, 8 May 2019. Available at https://www.wto.org/english/tratop_e/dispu_e/cases_e/1pagesum_e/ds512sum_e.pdf.

absence of legal criteria able to define what would constitute essential security interests.[418]

A similar claim was supported by Saudi Arabia and the US in the Saudi Arabia-IPRs case of 2020. Saudi Arabia invoked the security exception of article 73(b)(iii) in relation to piracy carried on by BeoutQ, a broadcasting entity owned by the Qatar company beIN.[419] In neither dispute, the Panel embraced the claims over the non-justiciability on national security reasons. The Panel for the Russia-Transit proceedings, after the interpretation of the terms of article XXI of GATT and its negotiating history, concluded that the motivations behind the invocation of the security exceptions are not totally self-judging.[420]

This conclusion clarifies once and for all that the employment of article XXI of GATT is subject to the judgement of the DSB, even if members keep a good level of discretion on the matter. The Panel also specified that the review needs to assess four elements in order to verify the legitimacy of the invoked security exception: if the threat to internal security comes from a war or an *emergency in international relations,* as worded in paragraph (b)(iii); which are the *essential security interests* at stake; whether the measures taken are contingent to the time frame of the emergency and if they are a direct solution for the protection of the security interests from that emergency.[421]

The Russia-Transit specified that the assessment on the presence of a *war or other emergency in international relations* shall be subject to objective evaluations beyond the discretion of the member invoking the article exceptions.[422]The Panel gave a precise interpretation to the terms, specifying that "political or economic differences between Members are not sufficient, of themselves, to constitute an emergency in international relations for purposes of subparagraph(iii)." An *emergency in international relations* according to the Panel's conclusions refers to "armed conflicts", explicit or latent,

[418] *Supra*, note 413. [7.51-7.52].
[419] Summary of the WTO dispute WT/DS567/11, 12 September 2022. Available at https://www.wto.org/english/tratop_e/dispu_e/cases_e/1pagesum_e/ds567sum_e.pdf.
[420] Abbott, F. M. (2020). *The TRIPs agreement article 73 security exceptions and the COVID-19 pandemic*. Research Paper, 116, 20-16; Saudi Arabia – Measures Concerning the Protection of Intellectual Property Rights, Report of The Panel, WT/DS567/R, 16 June 2020 [7.242].
[421] *Ibid*.
[422] *Supra*, note 413. [7.71; 7.100].

situations of "heightened tension or crisis" or "general instability" regarding the member state.[423]

In addition, the Panel recommended to assess that the actions resulting from the security exceptions invoked by the member are "taken in time of" the acknowledged emergency. The assessment of this obligation must as well be objective and subject to the Panel's judgement.[424]

A relevant clarification was given on what would make a national security interest *essential*. *Essential security interests* are to be considered the interests related to the "quintessential functions of the state, namely, the protection of its territory and its population from external threats, and the maintenance of law and public order internally." The Panel however left the determination of this parameter to the subjective discretion of member states, which can determine what constitutes an essential security interest while interpreting *in good faith* the obligations under article XXI(b)(iii).[425]

Regarding the assessment of the correlation between the emergency and the measures taken to protect security interests, the Panel suggested the application of a minimum plausibility requirement. This implies that the measures that the member implemented as a response to the emergency must not be remote from or unrelated to that emergency up to a point that such implemented measures are *implausibly* linked to the security interests directly threatened by that emergency.[426]

The Saudi Arabia-IPRs Panel explicitly relied on the conclusions of the Russia-Transit panel recognising that the interpretation given to article XXI(b)(iii) of GATT created an *analytical framework* for the interpretation of article 73(b)(iii) of TRIPS.[427]

Article 73(b)(iii) would be potentially applicable in cases of public health crisis, however members willing to use this option need to make some considerations. The security exceptions of article 73(b)(iii), if applied to the importation of patented pharmaceuticals, do not allow to disregard the mechanisms of article 31bis of TRIPS. Article 73(b)(iii) is

[423] *Ibid*. [7.75; 7.76].
[424] *Ibid*. [7.70].
[425] *Ibid*. [7.130; 7.131].
[426] *Ibid*. [7.138; 7.139].
[427] *Supra*, note 414. [7.241].

designed to enable states to address national emergencies and cannot be invoked to safeguard essential security interests of another country, substituting the import-export system of compulsory licenses of article 31. A state therefore cannot invoke the exception of article 73 in order to suspend IP protection in its territory over a patented pharmaceutical, that would be then produced and exported to another country. Only countries that possess national manufacturing capacity can potentially invoke security exceptions to justify patent rights suspension for specific pharmaceutical products necessary to deal with an internal public health threat.[428]

This specific matter takes on some importance in the debate over the measures available to WTO members to face the COVID-19 pandemic, as furtherly analysed in the next chapter.

[428] *Supra*, note 416. 405-406.

CHAPTER 4

The TRIPS Agreement and the COVID-19 Pandemics

4.1 Covid-19 and Intellectual Property

The global outbreak of SARS-CoV-2 virus, also known as the COVID-19 pandemic, originated in China in December 2019. The virus spread rapidly across countries and in January 2020 the WHO declared a Public Health Emergency of International Concern (PHEIC), and two months later labelled it as a pandemic.[429]

Coronavirus disease is an infectious disease that affects the respiratory system and particularly threatens older people and individuals with previously diagnosed medical conditions such as cardiovascular diseases, diabetes, and respiratory conditions.[430] Initially labelled as respiratory disease, COVID-19 has then been understood to be responsible for long-term secondary effects on cardiovascular, neuromuscular and endocrine levels, leading some scholars to recognize it as a vascular disorder.[431] Since December 2019, over 760 million cases have been registered worldwide and almost 7 million Covid-19-related deaths have been recorded.[432]

The pandemic quickly became a global crisis impacting the political and economic spheres of our society. The hyperconnected and globalized modern world facilitated the spread of the disease and of its social impacts, calling for a global cooperative intervention.

The crisis also exposed the weakness of the global health system due to its reliance on intellectual property to develop and distribute medical technologies necessary to face health emergencies. Intellectual property incentives and market influences may not be

[429] *Coronavirus disease (COVID-19) pandemic*. Retrieved 1 September 2023, from https://www.who.int/europe/emergencies/situations/covid-19.
[430] *Ibid*.
[431] Lopez-Leon, S., Wegman-Ostrosky, T., C. Perelman, R. Sepulveda, P.A. Rebolledo, A. Cuapio et al. (2021). *More than 50 long-term effects of COVID-19: A systematic review and meta-analysis*. Scientific Reports, 11, 16144.; Siddiqi, H.K., P. Libby and P.M. Ridker (2021). *COVID-19 – A vascular disease*. Trends in Cardiovascular Medicine, 31, 1–5.
[432] *Coronavirus disease (COVID-19)*. Retrieved 1 September 2023, from https://www.who.int/news-room/fact-sheets/detail/coronavirus-disease-(covid-19).

enough to grant the development of the medical technologies needed in the case of a wide public health crisis. IP strongly influences the direction of R&D investments, however if the public health value of the pharmaceutical cannot be easily estimated and the return on investment does not result appealing enough, necessary medicines or technologies may stay undeveloped. This is usually the case for vaccines regarding emerging pathogens. The prospect of patenting vaccines does not seem a strong enough catalyser for R&D, however crisis as pandemics or epidemics usually lessen this disequilibrium between pharmaceutical supply and demand. COVID-19 confirmed this dynamic given the huge investments that were channelled towards Sars-Cov-2 treatments.[433]

In March 2020 the government of Costa Rica advanced the proposal of a Covid-19 patent pool, the COVID-19 Technology Access Pool (C-TAP).[434] According to WIPO a patent pool is "an agreement between two or more patent owners to license one or more of their patents to one another or to third parties".[435] The general purpose of patent pools is to reduce the transaction costs of the negotiations that lead to licensing agreements. The C-TAP has the goal to facilitate and speed up the public disclosure of information fundamental for the R&D of COVID-19 treatments. Moreover, it promotes the licensing of pharmaceutical products essential to tackle the pandemic.[436]

Another voluntary mechanism implemented with the aim of favouring the use of patented pharmaceuticals in the context of the Covid-19 pandemic has been the Open Covid-19 Pledge launched in March 2020.[437] The Pledge is born as "a commitment by holders of intellectual property to share some or all of their intellectual property for the purposes of ending and mitigating the COVID-19 Pandemic."[438] Some of the early members of the Covid-19 pledge have been Facebook, Amazon and IBM. For example, NASA pledged a patent protecting 3D-printed respirators while Fujitsu pledged its patent

[433] Santos Rutschman, A. (2020). *The Intellectual Property of COVID-19* (SSRN Scholarly Paper 3691239), 3-5.
[434] *Ibid*. 12-14.
[435] WIPO - Patent Pools And Antitrust- A Comparative Analysis (2014), https://www.wipo.int/export/sites/www/ip-competition/en/studies/patent_pools_report.pdf.
[436] *Supra*, note 433. 12-14.
[437] *Supra*, note 433.
[438] OPEN COVID-19 PLEDGE, Frequently Asked Questions, Retrieved 3 September 2023 https://opencovidpledge.org/faqs/.

over an automated software for disease diagnosis. The Pledge operates to collect the commitment of pledgors and provides different kinds of licensing terms that allow pledgors to choose the contract that they deem to be the most appropriate according to their interests.[439]

In April 2020 the General Assembly of the United Nations, given the clear severity of the health crisis, adopted Resolution 74/274 which acknowledged the importance of the World Health Organization to coordinate the response globally. The resolution was followed by the introduction of the Access to COVID-19 Tools (ACT) Accelerator, a platform for raising funds and sharing resources to tackle the health emergency. The platform, promoted by the WHO, is made of four pillars: diagnostics, therapeutics, health system strengthening and vaccines. [440] The last pillar, also referred to as COVAX, has been designed to coordinate the effort to develop and equally distribute COVID-19 vaccines. Other than the WHO, that is the general coordinator of the COVAX activities, the pillar also includes the Coalition for Epidemic Preparedness Innovations (CEPI), which deals with the phase of vaccines development and manufacturing, and Gavi, which operates for the procurement and distribution. Any country is free to join the platform with the condition of committing to purchase a given amount of vaccine doses and after contributing financially to the program. Participating countries would in exchange receive COVID-19 vaccines directly from COVAX once they are accessible.[441]

The three specific objectives of COVAX were to speed up the development of COVID-19 vaccines by directly financing a series of promising developers, to boost at-risk investments in manufacturing capacity and to grant equitable access to vaccines globally. The worldwide distribution of the vaccines is regulated by the COVAX Facility which tries to facilitate multilateral cooperation and particularly to make sure that poorer countries do not rely on bilaterally donated vaccines only.[442]

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[439] *Supra*, note 433.
[440] Eccleston-Turner, M., & Upton, H. (2021). *International Collaboration to Ensure Equitable Access to Vaccines for COVID-19: The ACT-Accelerator and the COVAX Facility*. The Milbank Quarterly, *99*(2), 426–449.
[441] *Supra*, note 433.
[442] *Supra*, note 440. 429-430.

The COVAX pillar has acted as a pooling system to coordinate the resources of the participating countries and to share vaccines-related risks and advantages. The pillar invested $2.4 billion in R&D, with the aim of reducing the four years period usually necessary to develop a vaccine. The investment was made "at-risk" because prior to the proven efficacy of vaccine candidates. The investment was based on a strategy of push and pull financing. Push financing refers to the direct at-risk financial disbursement to vaccine manufacturers, pull financing instead is backed by the commitments made in advance to purchase the doses in case of vaccine efficacy.[443]

According to Eccleston et al., the main obstacle for the success of the COVAX Facility has been the presence of "vaccine nationalism" that leads countries to prefer direct negotiations with pharmaceutical companies that manufacture vaccines, rather than entering multilateral agreements such as the COVAX Facility. As a proof of the countries' nationalistic attitude towards the matter, the European Union behaviour has been quite significative. EU officials initially warned member countries that joining the facility would have led to higher prices and delays in the supply. Despite this, in September 2020 the EU finally joined the facility, just after making sure to benefit from previous purchase agreements negotiated by the EU Commission. Moreover, France, Germany, Italy, and the Netherlands constituted the Inclusive Vaccine Alliance (IVA) through which they secured an agreement with the pharmaceutical company AstraZeneca. The EU scenario showed the willingness to cooperate in order to grant internal equal distribution in the EU, rather than securing equal access worldwide.[444]

In June 2021 a remarkable initiative, VaxPaL, was launched by Medicines Patent Pool (MPP). VaxPaL is a free source of information on the progresses in the patenting of COVID-19 vaccines. In December 2021 the platform became a proper online database which allows users to do patent searches on COVID-19 vaccines, with the aim to increase global transparency on the development of these products.[445] MPP is an organisation for public health backed by the United Nations trying to increase availability and development of life-saving pharmaceuticals for low and middle-income countries,

[443] *Supra*, note 440. 430-432.
[444] *Ibid*. 438.
[445] VaxPaL - COVID-19 vaccines patent database MPP. (n.d.). *MPP*. Retrieved 5 September 2023, from https://medicinespatentpool.org/what-we-do/vaxpal.

whose priorities are therefore aligned with the efforts to grant global access to COVID-19 treatments and vaccines.[446]

In order to get the maximum health benefit from vaccines, they shall be evenly distributed across countries to equalise the national morbidity and mortality rates and to prevent further mutations of the virus. Low-income and middle-income countries however find it difficult to access vaccines due to their financial constrictions and the lack of technological knowledge and manufacturing capacity. These countries also lack negotiating power, and they usually rely on multilateral agreements or bilateral donations to reach new technologies.[447]

Further difficulties for vaccines distribution, vaccines licensing or the extension of their manufacturing capacity come from the inherent complexity of the product and process in object. Being vaccines biological products, they rely on specific knowledge for their manufacturing, this makes it difficult to expand the production further than the original pharmaceutical company. Even if the patent has been licensed through the C-TAP or other voluntary mechanisms, many crucial information on how to manufacture the vaccine may not be included in the patent itself.[448] Even when patentees are willing to transfer their technology, Rutschman observes the presence of practical drawbacks as infrastructural limitations, the scarcity of raw materials and the consequent difficulties licensees may encounter to actually produce the vaccines.[449]

Patents protect both products and processes and in the field of vaccines the former include vaccine components, antigens, adjuvants, or stabilizers; the latter regard the manufacturing process of the vaccines.[450] In 2022, WIPO published a patent landscape report on COVID-19-related pharmaceuticals. The report analysed patent filing activity from the start of 2020 to the end of September 2021. 1,465 patent applications were

[446] Medicines Patent Pool. Retrieved 3 September 2023, from https://medicinespatentpool.org/.
[447] Peacocke, E. F., Heupink, L. F., Frønsdal, K., Dahl, E. H., & Chola, L. (2021). *Global access to COVID-19 vaccines: A scoping review of factors that may influence equitable access for low and middle-income countries.* BMJ Open.
[448] Santos Rutschman, A., & Barnes-Weise, J. (2021). *The COVID-19 vaccine patent waiver: the wrong tool for the right goal*. Bill of Health.
[449] *Ibid*. 3.
[450] *Ibid*. 2.

filed for COVID-19-related therapeutics, 417 for vaccines and a total of 5,293 patents were filed on general technologies regarding COVID-19.[451]

According to the WIPO patent research, the most common patent applicants' locations are China, the US, the Russian Federation, the UK, and India. The filing strategy adopted varies from domestic IP protection to European Patent and PCT applications.

The number of patent filings for COVID-19 therapeutics significantly surpasses the one of vaccines' patents. Both categories of patents applications peaked in March 2020.[452]

Moreover, considering the patent offices that received the highest number of publications and comparing the time necessary for COVID-19-related patents to be published with the time necessary for patents filed in the fields of general chemistry and biosciences in the same period, the analysis shows that the former category have been published between 7 and 30 percent faster. These shorter examination periods may be directly linked to the efforts that patent offices worldwide made to contribute to the solution of the health crisis.[453]

The report also explores the data on the vaccines' platforms recorded in the patents. Vaccines' platforms range from conventional, including live attenuated or inactivated virus vaccines, protein subunit vaccines and virus-like particles, to novel platforms such as adenovirus-vector-based or DNA and mRNA vaccines. Almost half of the patents filed, according to the data up to September 2022, refers to protein subunit vaccines, viral vector vaccines represent the 23% and RNA the 12% of the dataset.[454]

The remarkable and unprecedented speed for the development of COVID-19 vaccines and medicines has been the result of catalysed global efforts responding to the catastrophic impact of the pandemic. Moreover, intense worldwide cooperation in the scientific community and the emergence of a global market for COVID-19

[451] World Intellectual Property Organization. (2022). *Patent Landscape Report: COVID-19-related vaccines and therapeutics. Preliminary insights on related patenting activity during the pandemic*. Available at https://www.wipo.int/publications/en/details.jsp?id=4589.
[452] *Ibid*.
[453] *Ibid*. 13-15.
[454] *Ibid*.

pharmaceuticals surely influenced the development and innovation efficiency of these products.[455]

4.2 The Proposal of a Waiver of Certain Provisions under The Trips Agreement

In October 2020 the Governments of India and South Africa advanced a proposal before the TRIPS Council to waive the implementation, application, and enforcement of some of the provisions included in the TRIPS Agreement. The goal of the waiver was primarily to address the COVID-19 pandemic.

In their communication to the Council the two members emphasized the context of global crisis that led them to table the proposal.[456] They directly cited the WTO statement which described the pandemic as "an unprecedented disruption to global economy and world trade".[457] They highlighted that to effectively face the pandemic, *rapid access to affordable medical products* is crucial. The communication refers to protective equipment, vaccines, and medical treatments.[458]

According to the document, the pandemic has led to an increasing demand of medical supplies that resulted in many countries experiencing shortages which put at risk national public health and led to *avoidable deaths*. The communication points out how threatening it is to let the COVID-19 outbreak last longer given its socio-economic impacts.[459] It expresses the concern around the accessibility and affordability of newly developed diagnostics, therapeutics, and vaccines for COVID-19, suggesting that scaling up the manufacturing capacity of medical products is the *obvious solution* to face the crisis.[460]

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[455] *Supra*, note 451. 51.
[456] Waiver From Certain Provisions Of The Trips Agreement For The Prevention, Containment And Treatment Of Covid-19, Communication From India And South Africa (2020), (IP/C/W/669), Available at https://docs.wto.org/dol2fe/Pages/SS/directdoc.aspx?filename=q:/IP/C/W669R1.pdf.
[457] Covid-19 and World Trade, Available at https://www.wto.org/english/tratop_e/covid19_e/covid19_e.htm.
[458] *Supra*, note 456. Paragraph 5.
[459] *Ibid*. Paragraph 6.
[460] *Ibid*. Paragraph 8.

India and South Africa furtherly argument their proposal making a reference to the existence of *several reports* that support the thesis that IP hinders the availability of affordable medical products. Moreover, paragraph 10 of the communication to TRIPS Council recalls the difficulties that countries have when implementing the flexibilities granted by the Agreement. They specifically mention Article 31bis ant the *cumbersome and lengthy* mechanism it implies.[461]

The waiver requested before the Council does not concern patents only, instead it also regards WTO provisions for copyrights, industrial designs, and undisclosed information *in relation to prevention, containment or treatment of COVID-19.* India and South Africa therefore demanded a waiver for Sections 1, 4, 5, and 7 of Part II of the TRIPS Agreement.[462] The communication recommends that the waiver shall be valid until vaccination has been distributed globally and the majority of the population has become immune.[463] The proposal came to the council with an annexed draft of the waiver that the General Council could have adopted.[464]

As the annex to the proposal states in the first paragraph, the legal framework for WTO waiver lies in Article IX of the Marrakesh Agreement Establishing the WTO.[465]

The third paragraph of Article IX of the Marrakesh Agreement states that in the event of "exceptional circumstances" the Ministerial Conference of WTO may waive a provision dictated by the WTO agreement or its related multilateral agreements. At least three quarters of the members must support the waiver proposal in order for it to be approved by the Conference.[466]

Article IX.3 (b) states that when the waiver proposal regards one of the multilateral trade agreements annexed to the Marrakesh Agreement, the request should be initially

[461] *Ibid*. Paragraph 9-10.
[462] *Ibid*. Paragraph 12
[463] *Ibid*. Paragraph 13.
[464] *Ibid*. Paragraph 14.
[465] *Ibid*. Annex, Draft Decision Text.
[466] Ranjan, P. (2021). *The Case for Waiving Intellectual Property Protection for Covid-19 Vaccines*, ORF Issue Brief No. 456, Observer Research Foundation, 5.

analysed by the respective Council. The TRIPS Agreement constitutes Annex 1C and waiver proposals must be first reviewed by the Council for TRIPS.[467]

Article IX.4 specifies that the Ministerial Conference issuing the waiver also must explain what makes the circumstances for the waiver *exceptional* and therefore justifies such decision. The waiver may be granted either to an individual WTO member or to the whole WTO community. Moreover, the Conference must outline the terms and conditions of the waiver and set an expiry date. If the decision results in a waiver longer than one year, there shall be an annual review of the provision on behalf of the Ministerial Conference.[468]

The wording of the article results as usually ambiguous, since the term exceptional circumstances has no precise definition.[469] According to Ranjan, the COVID-19 global pandemic certainly represents an *exceptional circumstance.* The waiver would have allowed countries with pharmaceutical manufacturing capability to produce and export COVID-19 vaccines thanks to the globally suspended IP obligations, increasing accessibility and affordability of medicines essential to face the outbreak.[470]

The waiver proposal was backed by many developing countries, but both the European Union and the USA rejected it. In May 2021, India, South-Africa and other countries presented a revised text for the waiver before the Council for TRIPS. The new text included some clarifications on the period for which the waiver would have been valid and implemented some changes in response to some received critiques. The revised document, IP/C/W/669/Rev.1, specifically requested a waiver of the TRIPS obligations covering enforcement in the IP fields of copyright, industrial designs, patents, and the protection of undisclosed information.

India and South Africa were able to get more countries' approval but still not enough to reach the third quarters threshold. The EU opposed the revised waiver request and

[467] *Ibid*.
[468] *Ibid*. 5-7.
[469] *Ibid*.
[470] *Ibid*. 7.

presented a counter-proposal in June 2021.[471] The EU's proposition was outlined in two documents[472] which overall claimed that a clarification over the functioning of the compulsory licensing mechanism of Article 31 and 31bis would have been a more efficient solution to the pandemic.[473]

The EU, in the first point, claims that a further clarification of article 31(b) may be needed. Article 31(b) already provides that the obligation to make effort to get a voluntary licence before resorting to compulsory licensing may be waived in case of national emergency or extreme urgency. The EU specifies - we may add unnecessarily - that the pandemic meets this condition and therefore allows for compulsory licensing procedures.

The second point aims at clarifying provision 31(h) about the remuneration to be paid to the licensor. The EU proposal states that the remuneration shall be equal to the price set by the producer of the pharmaceutical product under the circumstance of compulsory licensing. This specification however does not appear necessary given the wide flexibility that the original TRIPS provision already grants.

The last point of the EU counter-proposal has been defined by Oke as "more or less, an explicit admission of the complexities associated" with the exploitation of Article 31bis flexibilities. EU officially recognizes the inefficiency of the current formulation of the provision, whose mechanism has in fact never been used by any member to respond to the COVID-19 pandemic. The solution proposed by the EU to reduce the complexity of the article 31bis import-export mechanism is that the aspiring exporting member may list in one single notification to the TRIPS Council all the countries that wish to be supplied by the aforementioned exporting member.[474]

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[471] Oke, E. K. (2022). *The Waiver of the TRIPS Agreement for COVID-19 at the WTO: A Rhetorical Analysis* (SSRN Scholarly Paper 4205253), 9.
[472] WTO (Council for TRIPS) 'Urgent Trade Policy Responses to the Covid-19 Crisis: Intellectual Property' (4 June 2021) IP/C/W/680 (Communication from the European Union to the Council for TRIPS); WTO (Council for TRIPS) 'Draft General Council Declaration on the TRIPS Agreement and Public Health in the Circumstances of a Pandemic' (18 June 2021) IP/C/W/681 (Communication from the European Union to the Council for TRIPS).
[473] *Supra*, note 471. 9-10.
[474] *Ibid*. 10-11.

Oke argues how the complex EU counter-proposal could have been more realistic simply requesting an amendment of Article 31(h), which allows production of compulsory licensed products mainly for the domestic market.[475]

The Ministerial Conference finally took a decision in June 2022, at the twelfth session of the Conference in Geneva.[476] The Ministerial Decision on the TRIPS Agreement marked an end for the debate over the October 2020 waiver proposal and set a precedent in the WTO context for the management of future crisis.

4.2.1 The International Debate on the Proposal

The debate on whether the TRIPS waiver proposed by South Africa and India was a winning strategy mainly polarised around the aforementioned positions.

The proponents of the waiver essentially claimed that intellectual property rights represent a barrier to global access to medicines and, in a situation such as the Covid-19 pandemic, they are not necessary to regain the R&D investment thanks to the wide public financing in the pharmaceutical field disbursed to face the health emergency.[477]

They further claimed that the flexibilities existing in the TRIPS are not sufficient given the difficulties in the implementation and the lack of manufacturing capacity that characterises poorer countries. According to India and South Africa, the proposal could support these countries more than voluntary licenses would, scaling up the global production of essential pharmaceuticals.[478]

The European Union, that since the beginning directly opposed the proposal, questioned the validity of the supporters' claims. According to the EU, intellectual property rights are not proven to be a barrier to access COVID-19 treatments, instead the cause of the

[475] *Ibid*.
[476] *Ministerial Decision on The Trips Agreement Adopted on 17 June 2022*. Ministerial Conference Twelfth Session. Geneva, 12-15 June 2022. WT/MIN(22)/30, WT/l/1141.
[477] *Supra*, note 471. 13.
[478] *Ibid*. 15-16, 18.

difficulties to procure accessible medicines is claimed to be a result of a sharp increase in demand that does not match the manufacturing capacity.[479]

The European Union initially disagreed with the claims regarding the inefficiency of TRIPS flexibilities for public health, but later, in the counter-proposal, recognised the problematic nature of Article 31 and 31bis. Moreover, the EU suggested that voluntary licensing would be able to increment COVID-19 vaccines manufacturing through the transfer of technology and know-how.[480]

The sponsors of the waiver highlighted the barriers that IP creates to the access of affordable medicines but did not provide further argumentation on the issue. Moreover, the debate over the hindering role of IP for the scale up of manufacturing is subordinate to the presence of domestic manufacturing capacity in the pharmaceutical field. Patents cannot be an obstacle to access medicines and treatments in those countries where patents have not been filed. In most developing countries pharmaceutical companies did not seek patent protection, but, even if such countries are free to manufacture medicines protected elsewhere, the lack of manufacturing capacity and know-how makes this scenario impossible.[481]

It is however unclear how the waiving of IP rights could actually lead to the incrementation of global manufacturing capacity. Ana Santos Rutschman and Julia Barnes-Weise in their article appraised the effects of the proposed waiver. The exclusive rights granted by a patent may be overcome through the waiver however the information disclosed in patents are insufficient to replicate vaccines for parties different from the creators. The waiver would not be able to oblige the patentee to share the additional information and know-how needed beside the details included in the patent. Moreover, the waiver would not address the practical concerns linked to the lack of adequate manufacturing facilities and of raw materials necessary to develop COVID-19 vaccines. The analysis also highlights the issue of the unequal allocation to the Global South of vaccines' doses and labels it as a *contractual problem* since there is no existent

[479] *Ibid*. 14-16.
[480] *Supra*, note 471. 16-17.
[481] Mercurio, B. C. (2021). WTO Waiver from Intellectual Property Protection for COVID-19 Vaccines and Treatments: A Critical Review. *SSRN Electronic Journal*.

international legal framework that differentiate the negotiations for lifesaving vaccines from other tradable goods.[482]

Thambisetty et al. explicitly stated that the TRIPS waiver *could help stimulate the building of capacity in LMICs.* They argued that the development of pharmaceutical and industrial capacity has been prevented by the insufficient transfer of technologies from high-income countries. The waiver proposal highlights the multiple layers that characterize property rights and the complexity of information sharing mechanisms in the context of IP. For it to be efficient, waiving patent rights is not sufficient. The waiver shall include, as the proposal did, a system for know-how transfer and data disclosure for COVID-19 vaccines. A significant example is the statement that Moderna made about not enforcing its patent rights on its vaccine which was followed by the company admitting that replicating the vaccine without its undisclosed know-how would have been quite difficult.

Thambisetty et al. further points out the deficiencies of patent law which become relevant in the circumstance of the waiver. The first deficiency is represented by the fact that the information in the filed patent is usually not enough to replicate the invention. Second, the time lag of 18 months from filing to publication, within which the information disclosed in the patent is not accessible, is significantly long in the emergency context of the pandemic. The third issue is related to overlapping IP rights, which results from new registered patents that minimally differ from previous patents and lead to patent families and evergreening. These three issues are pointed out as the reason why a simple patent waiver would not be enough to grant the scaling up of vaccine manufacturing.

The intellectual property debate around vaccines does not only rely on patents, trade secrets are equally involved. An ordinary business framework grant to the holders of trade secrets the possibility to maintain them undisclosed if they wish. However, in the context of the COVID-19 pandemics, trade secrets could hinder the access to vaccines due to the presence of NDAs. For instance, it has been reported that non-disclosure

[482] *Supra*, note 448.

agreements have been signed by Pfizer and BioNTech and their suppliers, preventing these parties to take part in initiatives as C-TAP.

Undisclosed information also involves the concept of data exclusivity, in particular the issue of clinical trials data. Being vaccines a complex biologic, it would be difficult for a new manufacturer to demonstrate in the regulatory pathway that its version is similar enough to the original vaccine to rely on its clinical trial data. If the regulatory data were not shared, it would be difficult for a new vaccine producer to market the product even after accessing patent information and know-how.[483]

The issue of undisclosed information has been pointed out by some scholars as the core challenge to formulate an efficient TRIPS waiver proposal.[484] Moreover, the general lack of transparency and the restrictions on the sharing of information during the pandemic have negatively affected the public perception of the patent system.[485]

Despite the challenges highlighted, Thambisetty et al. conclude sustaining the universal waiver proposal developed by India and South Africa, due to its wide scope willing to waive all relevant IP besides patents. According to them the incentive to voluntary information disclosure shall be paired with national mandatory measures. The waiver should therefore be followed by other actions and domestic legislation should build a basis to facilitate the sharing of trade secrets and regulatory data.

One of the main solutions pointed out as an alternative to the waiver, encouraged primarily by the EU counter-proposal, is voluntary licensing. The pandemic scenario saw the signing of some voluntary licensing agreements. For instance, after that Gilead's drug Remdevisir was approved for COVID-19 treatment, Gilead granted non-exclusive voluntary licenses to generic manufacturers in Egypt, India, and Pakistan. Another example of voluntary cooperation from the pharmaceutical industry regards the AstraZeneca Vaccine. AstraZeneca promised to grant voluntary licensing to developing

[483] Thambisetty, S., McMahon, A., McDonagh, L., Kang, H. Y., & Dutfield, G. (2021). *The TRIPS Intellectual Property Waiver Proposal: Creating the Right Incentives in Patent Law and Politics to end the COVID-19 Pandemic* (SSRN Scholarly Paper 3851737).

[484] Houldsworth A. (20 April 2021). *TRIPS Covid Vaccine IP Waiver fails to address crucial questions*, IAM. Available at https://www.iam-media.com/article/trips-covid-vaccine-ip-waiver-proposal-fails-address-crucial-questions.

[485] Matthews, D. (2022). *The Covid-19 Pandemic: Lessons for the European Patent System*. Queen Mary Law Research Paper, (377).

countries and entered into sublicensing agreements with several generic manufacturers to scale up vaccine production.[486]

If voluntary agreements are not pursuable, Governments can resort to the mechanism of compulsory licensing but the limits of the system have been highlighted both in theory and experienced in practice. The flexibility granted by Article 31 and 31bis on this matter proved to be often inefficient and in the context of the pandemic a few drawbacks become evident.

First, compulsory licensing needs a specific examination on a case-by-case scenario, both for each product and each country involved. The TRIPS does not provide a compulsory license for COVID-19 vaccines valid worldwide. As previously pointed out, the procedures are often difficult and lengthy and countries may fear political or trade repercussions after issuing a compulsory license. Moreover, an interpretative issue arises as always around the term of the TRIPS provision, *adequate remuneration*. It is indeed not clear what could be considered *adequate* in the context of a public health emergency.[487]

Nonetheless, during the pandemic there have been some examples of either granted or filed compulsory licenses. In March 2020, a compulsory license was granted by the Health Ministry of Israel and the Attorney General to allow the importation from India of a generic version of the patented medicine Kaletra, which is traditionally used in HIV treatment but useful against COVID-19 as well. The license appointed K.S. Lim International Ltd as the importer from the Indian producer Hetero, that could already manufacture the drug in India where the patent for Kaletra had expired. The owner of the patent, AbbVie Pharmaceuticals, after this compulsory license was issued stated that it would not enforce its IP rights over Kaletra for its experimental use against COVID-19.[488]

The early 2020 witnessed the issuing of another compulsory licensing which has been highly criticized. Hungary issued a compulsory license for Remdevisir, a COVID-19

[486] *Supra*, note 481.
[487] *Supra*, note 483.
[488] Bonadio, E., & Contardi, M. (2022). *Compulsory Licences during the COVID-19 Pandemic: A European and International Perspective* (SSRN Scholarly Paper 4282886).

medicine patented by Gilead, even though the country was already receiving the drug via the European Union procurement agreements with the pharmaceutical company. The domestic licensee Richter was able to manufacture the drug for the treatment of 3,000 people by October 2020.[489]

The same drug was protagonist of a compulsory license in Russia. Pharmasyntez JSC tried to obtain a voluntary license from Gilead without success. In 2021, the Russian Government amended the article of the Civil Code regulating compulsory licensing. The amendment entitled the government to issue a compulsory licensing through an administrative order to safeguard public security and the welfare of the population. After the Government order the compulsory licensing of Remdevisir, Gilead challenged the administrative order claiming there was no national defence or security reasons behind the compulsory license of the drug. The Russian Supreme Court rejected the claims and confirmed the validity of the license.[490]

In February 2021, Bolivia attempted to implement the compulsory licensing mechanism under Article 31bis. It notified the WTO about its need to import 15 million doses of the Johnson & Johnson using the 31bis provision through an agreement with a generic producer based in Canada, Biolyse. The options for Biolyse to proceed were either to get a voluntary license from the patentee or to obtain a compulsory license for export from the Canadian Government, according to the Canada's Access to Medicines Regime (CAMR). The CAMR provides that only the medicines listed in Schedule 1[491] of the Canadian Patent Act can be subject to compulsory licensing, and the amendment of this list is a complex procedure. Biolyse's request to add the Ad26.COV2.S Johnson and Johnson patented vaccine to the list failed, once again displaying the difficulties in implementing the 31bis import-export system.[492]

Mercurio stated that the waiver is an *extreme measure* and shall be used only if the TRIPS provisions are proven to be inadequate. The difficulties encountered by developing countries in the exploitation of TRIPS flexibilities and compulsory licensing mechanisms

[489] *Ibid*.
[490] *Ibid*.
[491] Shedule 1, Canadian Patent Act, Available at https://laws-lois.justice.gc.ca/eng/acts/p-4/page-17.html#docCont.
[492] *Supra*, note 487.

are, in accordance with his vision, the result of inefficiencies at the domestic level rather than a problem in the international IP legal framework. Two additional elements are labelled as the reasons that make the waiver unnecessary. The first factor is that pharmaceutical companies allegedly set reasonable prices for the vaccines. Second, the waiver does not address the overall lack of pharmaceutical manufacturing capacity worldwide. Vaccine manufacturing is a complex process and the most relevant obstacles to its scaling up are the procurement of raw materials, the approvals, production, and distribution. IPRs are, according to Mercurio, a far from pressing issue.[493]

P. Ranjan acknowledges the need to address the lack of manufacturing and institutional capacity worldwide. According to his analysis waiving IP rights would not disincentivize pharmaceutical innovation thanks to the huge demand coming from the market. Moreover, the wide public funds devoted to COVID-19 Vaccines R&D implicitly ask pharmaceutical companies to share with the society the benefits of the resulting innovation. His conclusion is that any measure is legitimate if it contributes to alleviate the health emergency.[494]

According to J. Bacchus the wide waiving scheme derives from the widespread belief that medicines should be considered a public good, and recalling a UN statement, profitability shall not be considered when global public health is at stake. This perspective is *myopic* according to Bacchus, and would mean that any TRIPS provision and obligation shall be waived for medicines since the IP protection of these public goods would be deemed as a violation of human rights. Bacchus recalls the major role of IP as promoter of R&D and the need to strike a balance between private exclusive rights and public welfare. The solution he calls for is multilateral action, outside of the WTO context. His conclusion however appears a bit superficial, calling for a balance between global access to medicines and the maintenance of IP rights, not acknowledging the proven inefficiency of TRIPS flexibilities for public health.[495]

As any complex global challenge, COVID-19 vaccines allocation and manufacturing could not be solved with a simple solution. The debate that arose from the waiver proposal

[493] *Supra*, note 481.
[494] *Supra*, note 466. 11.
[495] Bacchus, J. (2020). *An Unnecessary Proposal: A WTO Waiver of Intellectual Property Rights for COVID-19 Vaccines* (SSRN Scholarly Paper 3775799).

was predictable given the polarized interests involved. Once again, the international community and the WTO struggled to find a solution able to accommodate both developed and developing countries. The negotiations in Geneva that led to the Ministerial Decision on the TRIPS Agreement of June 2022 did not seem an ultimate answer to the challenge of the balance between private-public interests in the context of public health, but again it gives a mild solution to a problem that has been seeking a firm assessment since the nineties.

4.3 The 12th WTO Ministerial Conference in Geneva

On the 17th of June 2022 the Ministerial Conference of the WTO came to a set of conclusions. The latest WTO efforts to face the pandemic have been collected in the Ministerial Declaration on the WTO Response to COVID-19 Pandemic and Preparedness for Future Pandemics[496] and the Ministerial Decision on the TRIPS Agreement.

The Decision on the TRIPS is the conclusion of the negotiations started with the South African and Indian waiver proposal. After the EU counter-proposal had been advanced, the negotiations for the waiver started to focus on finding a solution able to revisit TRIPS flexibilities rather than a wide general IP waiver.[497]

In December 2021, a group constituted by ministers of the European Union, India, South Africa, and US, gathered with the support of the WTO in order to reach a consensus over the text of the waiver. The result was the Quad's Outcome Document, which became the basis for the TRIPS Decision the following June. The Document focused on the patents of vaccines, postponing the negotiations over IP issues regarding COVID-19 diagnostics and treatments.[498]

The TRIPS Decision includes nine paragraphs and, as the initial waiver proposal, recalls article IX of the Marrakesh Agreement of the WTO.

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[496] *Supra*, note 476.
[497] Ma, L. (2023). *TRIPS Decision on COVID-19 Vaccine Patent Waiver: Old Wine in a New Bottle?* US-China Law Review, *20*(2), 76–90.
[498] *Ibid*.

The first paragraph clarifies that eligible members may authorize the use of patented subject matter necessary for COVID-19 vaccines' manufacturing without the patentee's consent. Eligible members include all developing countries. Developing countries that possess vaccines manufacturing capacity *are encouraged* to not take advantage of the provisions of the TRIPS Decision.

Paragraph two specifies the authorization method for this waiving mechanism. The authorization can happen *through any instrument available in the law of the Member.* Some cited examples are executive orders and emergency decrees. Further clarification is given on the term "law of a Member" used in Article 31 of the TRIPS. The wording does not refer to legislative acts only, but also to other acts such as *executive orders, emergency decrees, and judicial or administrative orders.*

Paragraph 3(a), given the premises of the first two paragraphs, waives out the provision outlined in Article 31(b) which required compulsory licenses to be preceded by an attempt to reach a consented agreement with the patentee. Paragraph 3(b) instead waives the requirement of Article 31(f) requiring production to be intended for domestic market only and allows the export of the manufactured products at *any proportion*. Export to eligible members can also happen through international or regional initiatives aimed at ensuring equitable access to COVID-19 vaccines manufactured under this authorization. Paragraph 3(c) states that eligible members shall prevent the re-exportation of the products manufactured under the conditions of this Decision and avoid the importation of the above products *diverted to their markets* against the provisions of the Decision. The last clause of the third paragraph covers instead the matter of *adequate remuneration*, which should *take account of the humanitarian and not-for-profit purpose* of vaccines' distribution initiatives and it should consider *existing good practices in instances of national emergencies.*[499]

Paragraph 4 recalls article 39 and the issue of undisclosed clinical trials data while paragraph 5 states the need for any eligible member to communicate to the Council for TRIPS any action related to the mechanism of the Decision. Paragraph 6 sets the validity

[499] *Supra*, note 476.

of the provisions of the Decision for the five years following its adoption with the possibility of the extension if deemed necessary by the General Council.

Lastly, the seventh paragraph prohibits any challenge to the measures taken in accordance with the Decision and the eighth paragraph encourages Members to decide whether to extend the provisions of the Decision to COVID-19 diagnostics and therapeutics.

The TRIPS Decision concludes by highlighting the crucial role of the TRIPS flexibilities, recalling the Doha Declaration and specifies that the Decision shall not prejudice the interpretation of TRIPS rights, obligations, and flexibilities beyond the scope of the Decision.[500]

The TRIPS Decision granted some improvements to the interpretation and consequent feasibility of the Article 31 bis system. First, the Decision allows the export of any proportion of goods granting the possibility to take advantage of economies of scale for vaccine production. The export of vaccines produced under compulsory licensing can take place as long as both importing and exporting countries are eligible. This solution finally tackles the differentiation between domestic and for export production outlined by the original article. Moreover, the vaccines manufactured under the condition of compulsory licensing in the Decision no longer need special labels or packaging, a costly requirement still present under Article 31bis.[501]

The Decision supports in paragraph 3(b) international and joint initiatives thus grants the possibility to export a great quantity of low-cost vaccines directly to programs such as COVAX.

The value criterion used to establish adequate compensation in Article 31 and 31bis is here substituted by the concept of humanitarian and not-for-profit purpose of COVID-19 vaccines.[502] Footnote four of the Decision specifies the guidelines to establish the appropriate value of the compensation fees and cites the WHO-WIPO-WTO Study on Promoting Access to Medical Technologies and Innovation and the Remuneration

[500] *Ibid*.
[501] *Supra*, note 496.
[502] *Ibid*.

Guidelines for Non-Voluntary Use of a Patent on Medical Technologies published by the WHO (WHO/TCM/2005.1).

Despite these improved aspects, the Decision raised some criticisms. The further specifications made on Articles 31 and 31bis may have facilitated the import and export of vaccines, but also generated more legal uncertainty and called for further clarification from the WTO on certain provisions of the article.[503] The matters involved in the debate over the need for a waiver persisted after the Ministerial Conference Decision and the main critiques moved against the Decision are that a patent waiver cannot be the solution to institutional and manufacturing issues and the flexibilities granted by the TRIPS originally shall be enough to address the health crisis.[504]

The supporters of the Decision state that it clarifies the application of TRIPS flexibilities beyond the extraordinary case of COVID-19, giving valuable insights on eligible members and carrying the hope to reduce the centralization of vaccine production towards a more diversified and evenly distributed production capacity.[505]

The Decision overall results more implementable than Article 31bis and, despite the outcomes and criticisms, it appears to be a fair compromise compared to the initial waiver proposal and a symbol of the multilateral efforts that contradistinguished the COVID-19 crisis.

4.4 Remarks on the Cooperation for COVID-19 Crisis and Vaccines' Allocation

The relevance of vaccines as powerful tools to face the public health crisis has been highlighted since the start of the pandemic.

Before any vaccine had been developed, the challenge of how to equally distribute their supply became evident. It was obvious that the disparity of incomes and pharmaceutical

[503] Blog of the European Journal of International Law, Watal, J. (2022). *Analysis of the 12th WTO Ministerial Conference decision on the TRIPS agreement*. Retrieved from https://www.ejiltalk.org/analysis-of-the-12th-wto-ministerial-conference-decision-on-the-trips-agreement/.
[504] *Supra*, note 496.
[505] *Ibid*.

manufacturing capacities worldwide would have called for multilateral actions. Even if global cooperation was recognised to be essential, in early 2020 nationalistic attitudes were already explicit due to the shortages of equipment for personal protection.[506] High-income countries secured direct agreements with pharmaceutical companies to access the first doses manufactured, and by the beginning of 2021 access to vaccines was already tremendously unequal and proportional to the countries' wealth.[507]

As of 5 September 2023, 13.500.135.157 vaccine doses have been administered and 5.589.920.885 people have been vaccinated with at least one dose.[508]

The Global COVID-19 Vaccination Strategy of the WHO aimed to achieve the target of the 70% of the population vaccinated. To date the percentage of low-income countries that reached that target is zero, compared to the 62% value registered in high-income countries.[509]

International cooperation attempts failed overall. COVAX did not meet the initial objectives for funding, administered vaccines and donations. The WTO was able to decide over the necessity to waive IP rights after two years from the beginning of the emergency. The World Bank acted slowly and did not use its full financial power to back up vaccines access. Multilateral cooperation failed also at regional level. The European Union restricted vaccine exports and secured bilateral agreements justifying this strategy as an attempt to grant equal distribution inside of the Union. The African Union founded the African Vaccine Acquisition Trust (AVAT) setting the goal of vaccinating the 60% of the African continent population. Vaccine delivery started in August 2021 and by December 2022 only the 25.6% of the population was registered as fully vaccinated.[510]

Brown and Rosier labelled the failure to grant equitable access to COVID-19 vaccines as political more than scientifical or economical. The adverse outcome was the result of vaccine nationalism and the lack of a binding mechanism to prevent wealthier states

[506] Moon S, Armstrong J, Hutler B, et al. (2022*) Governing the access to COVID-19 tools accelerator: Towards greater participation, transparency, and accountability*. The Lancet 399(10323): 487–494.
[507] Brown, S., & Rosier, M. (2023). *COVID-19 vaccine apartheid and the failure of global cooperation*. The British Journal of Politics and International Relations, *25*(3), 535–554.
[508] Updated data available at https://covid19.who.int/?mapFilter=vaccinations.
[509] Updated data available at https://www.covid19globaltracker.org/#vaccination.
[510] *Supra*, note 506.

from meeting their domestic needs first.[511] In order to succeed, cooperation towards complex issues such as the pandemic shall have its roots in a human-rights-based approach that naturally leads to the moral duty of securing equitable access to vaccines globally without income-based preferences.[512]

Public health disparities and crisis cannot be solved through a WTO Decision alone and international cooperation could represent the right boost to implement the necessary administrative, political, and economic reforms to improve global access to medicines. Ordinary social and economic conditions do not lead to systemic changes, crisis do. Thus, they can become the propellant to improve international political and economic frameworks towards societal welfare. The debate over the balance between public interests and private IP rights in the context of public health is far from being concluded. The matters left unsolved and the inefficiency of the international IP system will likely emerge again in the event of future crisis.

[511] *Ibid*.

[512] Gostin, L. O., Karim, S. A., & Mason Meier, B. (2020). *Facilitating access to a COVID-19 vaccine through global health law*. The Journal of Law, Medicine & Ethics, *48*(3), 622-626.

Conclusion

The first challenge for IP systems has always been to strike a balance between private and public rights, safeguarding innovators' rights and pursuing societal development in the sake of the greater good. Patents' regulation shall work as an incentive to innovate for privates and as a way for society to access technological knowledge. The regulatory framework should consider the downsides of the system such as the rising of monopolies, the consequent lack of competition, and the possible negative externalities.

Moreover, patents do not equally apply to all industrial fields. The pharmaceutical sector is one of the sectors in which they have shown to be effective mechanisms of protection. Nonetheless, the role of patents for the increase of the innovation rate in the field has been debated: the common belief is that without patents R&D investments in pharmaceuticals would decrease given the opportunity for generic producers to immediately enter the market, however first-mover advantage has a great relevance. The huge costs for a producer different from the inventor to enter the market are complementary to IP protection in granting to innovators the market monopoly necessary to recoup R&D investments.

A major issue that characterises the international IP legal framework is the lack of harmonization. Despite the many IP Conventions and Agreements that marked significant advancements, the international efforts have always been and still are characterized by profound polarized positions: supporters and opponents of IP, global North versus global South, private for-profit entities and NGO.

The international policymaking process in the context of IP has been mainly led by the World Intellectual Property Organization and the World Trade Organization.

Because of the 20th century's significant advancements in the pharmaceutical industry and the invention of numerous life-saving treatments, the right to access medicines has come to be seen as a human right that is directly related to the widely recognized universal right to health.

The international community started to act to find solutions able to embrace the development of the sector and to grant universal access to medicines, but the lack of

international guidelines led to many diverse frameworks. For instance, a group of countries did not allow neither the protection of pharmaceutical products nor processes. It was during the eighties that developed countries and pharma companies started to ask for worldwide standards of IP protection for the pharmaceutical field. Despite the opposition of developing countries which advocated for affordable access to imported medicines and generics, a significant result was obtained in 1994 with the Annex 1C to the Marrakesh Agreement, the Trade-Related Aspects of Intellectual Property Rights Agreement. The Agreement finally introduced the obligation for member countries to grant IP protection in any technological field, pharmaceutical sector included.

The objective of the agreement is to effectively protect and enforce IP rights, granting mutual advantage to IP owners and society and to reduce IP-related market distortions and impediments in international trade. The Agreement has been subject to many critiques, the first of which is the failure in the enforcement of its provisions. The lack of enforcement has been caused by different factors such as the high costs that effective enforcement implies, the need for member countries to elaborate and implement IP enforcement laws on their own to comply with the Agreement and the unclear and ambiguous wording of many TRIPS provisions. Over the past decades many disputes were brought before the WTO Dispute Settlement Body (for instance WT/DS362/1 and WT/DS86/1).

Developed countries that were looking for higher IP protection, being unsatisfied by the framework implemented by the TRIPS Agreement, started to pressure developing countries to sign Free Trade Agreements. These agreements typically aimed at implementing stricter IP standards in developing countries in exchange for preferential access to developed countries' markets. This IP provisions, that take the name of TRIPS Plus, play an important role in the debate of IP and medicines' access. Some typical TRIPS Plus indeed prohibited the use of compulsory licensing for pharmaceuticals, obviously to safeguard the interests of pharmaceutical companies in the developed countries that pressured poorer nations in the FTA.

Developed countries were not the only party whose expectations were unmet by the Agreement. The Agreement has been formulated to leave a certain degree of freedom to member countries in the national implementation phase of its provisions. These wide

standards are referred to as flexibilities and include measures such as transitional periods to comply with the obligations of the Agreement, freedom in defining the patentability criteria, compulsory licensing, and exceptions to IP rights in the event of national emergency or urgency.

The problem related to these flexibilities, whose ultimate goal is to facilitate the removal of the obstacles that IP could generate for the development of poorer countries, is that they are not self-executing provisions and they depend on the interpretation given to their wording.

Article 6 is the first relevant example. It deals with the exhaustion of IP rights and it does not specify whether countries shall adopt a national, regional, or international exhaustion regime. The way this impacts access to medicine is quite direct, given that international exhaustion allows parallel imports which grant competition and price discrimination. Articles 7 and 8 constitute the basis for the interpretation of TRIPS flexibilities in a public health-preserving manner. Article 7 encourages technological innovation and the transfer of technologies and calls for an interpretation of the TRIPS that safeguards social and economic welfare. Article 8 allows states to implement measures that safeguard public health. The central role of these two articles in the interpretation of the Agreement was confirmed in the Australia-Tobacco Plain Packaging decisions.

Exclusion from patentability due to the protection of *ordre public* and morality is granted by article 27.2, but many terms in the formulation of the article need further clarification. For instance, the ruling of the Myriad Case before the US Supreme Court, which regarded the patentability of sequences of artificially created DNA (2013), gave implicit interpretation to article 27.3. Moreover, Novartis AG vs. Union of India (2013) became a remarkable case on the issue of the "evergreening" of patented drugs, which implies the filing of previously patented inventions after applying minor modifications or improvements. The exceptions to the rights conferred dealt with in article 30 are another example of flexibility whose application is hindered by the wording of the article. Concepts like *normal exploitation* of the patent, *unreasonably prejudice* and *legitimate interests* all need to be interpreted. One exception that falls under this flexibility is for instance the Bolar exception. Article 39 on the protection of undisclosed information and

73 on security exceptions are other examples of attempts to grant flexibility to the Agreement.

It was with the HIV/AIDS crisis of the nineties that it was absolutely clear that the flexibilities present in the Agreement were not enough to grant the safeguard of public health. Therefore, a new deal was reached with the Doha Declaration on the TRIPS Agreement and Public Health. The Declaration and the consequent Decision on the Implementation of Paragraph 6 led to the amendment of TRIPS with the introduction of Article 31bis, which waived the provision of article 31(f) for pharmaceutical products.

Article 31(f) allowed the production under compulsory license only for the domestic market and therefore prevented poor countries with no manufacturing capacity from using this provision. The solution provided by 31bis showed the attention to the needs of developing countries but the mechanism did not produce the expected outcome, resulting in an ensemble of complicated bureaucratic manoeuvres.

The COVID-19 pandemic represents the last global health challenge faced in the policy making process on the issue of IP and public health. The international community was not able to cooperate efficiently towards equitable vaccines' distribution and this is in part due to the retardation of the Ministerial Decision on the TRIPS to facilitate access to the vaccines. The Decision was the compromise resulted from the debate over an IP waiver proposal tabled by India and South Africa. The waiver generated a polarized debate on the necessity of such a radical solution to the IP-related barriers to COVID-19 treatments. The Decision granted some improvements to the 31bis system, for instance removing the highly costly requirement for pharmaceuticals produced under compulsory licensing to present different labelling and packaging. Despite the overall improved applicability of the system, the critiques against the waiver persisted after the decision. The lack of institutional and manufacturing capacity could not be addressed with such a decision. The information available in a patent would not be enough for a producer different from the inventor to reproduce the vaccine or treatment, therefore waiving the patentees' rights would not directly lead to an increase of pharmaceutical manufacturing. Moreover, the inefficiencies of the IP legal framework have been highlighted to be at the domestic level thus not solvable through an international resolution.

Besides the role of IP and TRIPS, it is necessary to highlight the complexity of the interrelations involved in the management of an international health crisis and the more practical difficulties related to vaccine manufacturing processes.

To conclude, it is worth noticing the analogies between the debate over IP and public health and the growing discussion on IP and the transfer of climate change mitigation technologies or environmentally sound technologies. The debate over patents and climate change involves many of the issues that characterize the controversy between private rights and public interests.

The debated role of the IP system as incentive to innovate is still relevant and applicable in the field of climate change mitigation and adaptation technologies. The transparency granted by the public disclosure of patented technologies can help policy makers to define their strategy to mitigate and prevent the effects of the climate crisis. Compulsory and voluntary licensing will play again a fundamental role for the dissemination of these technologies and terms like patent pooling and humanitarian licensing will likely be central in the management of this crisis as well.

Waiver proposals may be presented again as necessary solutions against the emergency of climate change. The North-South dynamics and the conflicting voices of developed and developing countries will undoubtedly persist and feature in the increasing urgency of the debate.

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