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Towards a more equitable access of Developing Countries to health technologies: the impact of the international system of Intellectual Property Rights protection

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CONTENTS

ABBREVIATIONS

ABSA	Access and Benefit Sharing Agreement
AGCM	Agenzia Garante della Concorrenza e del Mercato
ALP	AIDS Law Project
AZT	azidothymidine
BMC	Biodiversity Management Committee
CAA	Clean Air Act
CAMR	Canada's Access to Medicines Regime
CBD	Convention on Biological Diversity
CGen	Genetic Heritage Management Council
CIPC	Company and Intellectual Property Commission
CPC	Community Patent Convention
DC	Developing Countries
DSB	Dispute Settlement Body
EEC	European Economic Community
EMRs	Exclusive Marketing Rights
EPC	European Patent Convention
FDI	Foreign Direct Investments
FTAs	Free Trade Agreements
FTC	Federal Trade Commission
GATT	General Agreement for Tariffs and Trade
GR	Genetic Resource
GSK	GlaxoSmithKline
GSP	Generalized System of Preferences
HIV	Human Immunodeficiency Virus
INPI	Instituto Nacional de Propriedade Industrial
IP	Intellectual Property
IPRs	Intellectual Property Rights
J&J	Johnson & Johnson
LDC	Least Developed Countries
LMICs	Law and Middle-Income Countries
MCC	Medicines Control Council
MPP	Medicines for Patent Pool
MSD	Merck Sharp and Dohme Limited
NBA	National Biodiversity Authority
NDP	National Drug Policy
NEMBA	National Environmental Management Biodiversity Act
NHS	National Health Service
NIST	National Institute of Standards and Technology
NOC	Notice of Compliance
OI	Open Innovation
PIC	Prior Informed Consent
PMA	Pharmaceutical Manufacturers Association

R&D	Research & Development
SBB	State Biodiversity Board
SPC	Supplementary Protection Certificate
TAC	Treatment Action Campaign
TK	Traditional Knowledge
TKDL	Traditional Knowledge Digital Library
TRIPS	Agreement on Trade-Related aspects of Intellectual Property Rights
UK	United Kingdom
UNIMED	Unit of Medicines and Health Technology
US	United States
UTT	Universal Test and Treat
WHO	World Health Organization
WIPO	World Intellectual Property Organization
WTO	World Trade Organization

Introduction

This dissertation addresses the topic of the international legal framework of Intellectual Property Rights (IPRs) and its impact on access to pharmaceuticals in Developing Countries (DCs). More specifically, its objective is to analyse the adoption and evolution of the patent norms at the international level, i.e. in the main international treaties governing patent rights, and in a selected group of countries which are generally included in the category of DCs.

In the middle of the nineties, with the creation of the World Trade Organization (WTO) and the consolidation of a system of rules aimed at liberalizing global trade, DCs were facing the problem of being obliged to implement normative standards on Intellectual Property (IP) which were generally more rigid than those present in their legal systems. IP regulation was strategically linked to the multilateral trade framework[1], first represented by the General Agreement for Tariffs and Trade[2] (GATT) and then by the WTO, whose main and original objective is – despite being currently deadlocked – to abolish tariff barriers in international trade, and not to regulate IP issues.

Actually, long before the creation of the GATT-based multilateral trading system, the international patent regulatory framework derived from the Paris Convention for the Protection of Industrial Property of 1883[3], was mainly the expression of the European and North American perspectives and can be considered as the precursor of the current patent system; a system which is often criticized because of the global asymmetries it has generated as the majority of IP holders has been centred in Developed Countries for a long time[4]. In particular, Developed Countries have traditionally opted for strong patent protection in order to protect the ability of their well-established technological base to generate revenue and as a way to promote technological investments[5].

[1] On the strategic linking of IP to trade, realised by representatives of some of the most important companies of the United States see Susan K. Sell, *Private Power, Public Law. The Globalization of Intellectual Property Rights* (Cambridge: Cambridge University Press, 2003), 46.

[2] See "General Agreement for Tariffs and Trade," opened for signature October, 30, 1947, 55 United Nations Treaty Series (UNTS) 187.

[3] See "Paris Convention for the Protection of Industrial Property," opened for signature March 20, 1883, 828 UNTS 305, (hereinafter referred to as "Paris Convention).

[4] See Johannes Thumfart, "Challenging the Normative Impact of Technological Innovation," in *Intellectual Property and the Law of Nations, 1860 – 1920,* ed. P. Sean Morris (Leiden, The Netherlands: Brill | Nijhoff, 2022), 56.

[5] See Carlos Correa, *Integrating Public Health Concerns into Patent Legislation in Developing Countries* (South Centre, 2000), 5.

It is worth noting that in the pharmaceutical field insufficient patent protection carries the risk of preventing Research and Development (R&D) investments, which are extremely costly and risky, so that it is important to allow the recovery of R&D costs and the achievement of a regular profit[6]. However, strenghtened patent legislation is especially problematic in relation to the impact it has on access to medicines in the countries of the Global South. If in Developed Countries the practice of patenting pharmaceuticals represents a major incentive for investments in R&D of new medicines, especially because such investments are sustained by wealthy markets that are able to buy at supra-competitive prices, the same cannot be stated of DCs where the purchasing power of patients and of the public sector is far lower so that the patent mechanism is not able to work so well. Moreover, the functioning of the patent incentive also gets jammed with respect to the so-called "neglected diseases", diseases which specifically affect DCs, whose market is not profitable enough to trigger the private incentive to R&D. Only a very small fraction of the total global pharmaceutical R&D expenditure is allocated to neglected diseases[7]. On the other hand, as concerns global diseases, namely those generally affecting the entire world population such as for example cancer and diabetes, extending patent protection to pharmaceuticals in DCs may not be the best option because in Developed Countries' markets there already exists a strong drive to R&D for such category of diseases[8].

Even if the IPRs system is certainly not the only factor determining access to medicines, the influence it has on their price – which is in turn determined by absence of competition – is undeniably relevant and requires achieving a balance between a fair reward to innovators and the protection of the fundamental right of individuals to health[9].

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[6] See Oliver Baldus, "The 'one size fits all' problem of patent systems", *Journal of Intellectual Property Law & Practice* 5, No. 10 (2010): 726, https://doi:10.1093/jiplp/jpq099

[7] See Armand Zimmerman, Mohamed Mustafa Diab *et al.*, "Investing in a global pooled-funding mechanism for late-stage clinical trials of poverty-related and neglected diseases: an economic evaluation," *BMJ Global Health* 8 (2023): 2, https://doi:10.1136/bmjgh-2023-011842

[8] This idea was for example explored by some United States scholars who considered alternatives to the indiscriminate extension of pharmaceutical patents to DCs and particularly proposed to differentiate the protection of pharmaceuticals according to different markets. In this regard, see Adam B. Jaffe, Josh Lerner and Scott Stern, "Intellectual Property and the Availability of Pharmaceuticals in Poor Countries", in *Innovation Policy and the Economy Volume 3*, ed. Jean O. Lanjouw (MIT Press, 2003), 91-129. The adoption of a diversified approach between industrialized and non-industrialized countries in the application of patent rights in respect to public health was advocated by professor Carlos Correa as well. Moreover, he also suggested a diversified approach by sector with a more moderate level of protection in cases where local industrial and technological capabilities are low. See Correa, *Integrating Public Health Concerns,* 8.

[9] On the importance of recalibrating the international IPRs system taking human rights into greater consideration see Duncan Matthews, "Reappraising the relationship between intellectual property rights and human rights: a COVID-19 pandemic response," in *Reforming Intellectual Property,* ed. Gustavo Ghidini, Valeria Falce (Cheltenham, Northampton: Elgar, 2022), 149-163.

Part one of the dissertation explores the introduction of the first international provisions on patents as well as the instances that led to the establishment of an international patent system with particular attention to the extension of patent norms to colonies. It then focuses the analysis on three legal systems which were historically subjected to colonial rule, that are nowadays generally considered as part of the DCs group and that have stood out for having implemented and used legislative instruments able to limit patent monopolies and widen access to pharmaceutical products on some occasions; they are Brazil, India and South Africa. The analysis also takes into consideration the introduction of pharmaceutical patents and their diachronic evolution in the three case studies, emphasizing first the role of colonialism and afterwards the necessity to comply with international obligations.

In India, the legal prohibition to patent pharmaceuticals, which had been in force until 2005, gave broad impetus to the generic pharmaceutical industry making the country the largest supplier of generic medicines in the world. Moreover, Section 3 (d) of the Indian Patents Act, which prohibits to grant patents to a mere new form of a known substance unless it improves the substance's therapeutic efficacy, aims to counter the *patent evergreening*[10] phenomenon.

In Brazil compulsory licensing was especially used as a negotiation leverage in order to obtain significant price reductions on pharmaceuticals. In particular, the threat to grant compulsory licenses was effective because the country could rely on its robust production capacities in the pharmaceutical field, which had been developed when the Brazilian law prohibited to grant patents on pharmaceuticals. Moreover, the effective granting of a compulsory license for the production of *Efavirenz* led to a drastic reduction of its price. Another peculiarity of the Brazilian system was the submission of patent applications regarding some specific pharmaceuticals deemed to be of special interest for public health, to the consent of the national regulatory agency.

In South Africa, the legalization of parallel importation of pharmaceuticals allowed to treat twice as many HIV patients for free. Moreover, a particular trend towards proactive enforcement of competition law in the pharmaceutical sector has been noticed until recently.

The second part of the dissertation focuses on the compulsory license provision, which gives the power to a public authority to limit the exclusive rights conferred by patents when certain circumstances are present and to entitle a third party to produce or import a patented invention without the consent of the patentee. On several occasions the compulsory license

[10] *Patent evergreening* refers to the practice of patenting minimum modifications of a product that has already been patented (e.g. modifications to dosage or formulation) so as to obtain a new patent which artificially extends the patent term related to the original invention.

instrument has been capable to lead to significant price reductions of pharmaceutical products[11]. The instrument has also significantly re-entered into the debate during the Covid-19 pandemic as possible option to achieve a more equitable distribution of medical treatments and vaccines against the virus. The analysis will in the first place particularly explore the effective use of compulsory licensing in the three case studies, then it will give an overview of its use in the global south and in some Developed Countries, and will conclude by attempting to give a contribution to the debate concerning the effects of compulsory licenses on R&D investments of pharmaceutical companies.

The third part of the dissertation will discuss the system created by the Agreement on Trade-related aspects of Intellectual Property Rights[12] (TRIPS) with particular regard to its peculiar negotiation, and to specific norms of the Agreement, that more than others, appear to be tailored on the instances of industrialized countries to the detriment of the needs of DCs. The examination of such norms offers the opportunity to explore their incorporation into the national legislations of the three legal systems representing the case studies of the present research. Within such discussion, emphasis will be also placed on the so-called "TRIPS-plus standards", normative standards extending protection of IP beyond the levels of protection already provided by the TRIPS Agreement, and whose introduction has been achieved by means of bilateral or regional Free Trade Agreements (FTAs) promoted especially by the United States and the European Community. It would be essential for DCs to carefully assess the introduction of TRIPS-plus standards into their national legislation with particular regard to the effects of such measures on wider societal interests[13].

Lastly, the study will conclude by briefly delving into the so-called Open Innovation (OI) approach and its possible application to the distribution of affordable pharmaceuticals in DCs. In this respect, the patent pool named Medicines for Patent Pool (MPP) has stood out for being able to make available essential medicines recommended by the World Health

[11] On the effectiveness of compulsory licensing in leading to price reductions of pharmaceuticals see Eduardo Urias and Shyama V. Ramani, "Access to medicines after TRIPS: Is compulsory licensing an effective mechanism to lower drug prices? A review of the existing evidence," *Journal of International Business Policy* 3, (2020): 367-384, https://doi.org/10.1057/s42214-020-00068-4

[12] See "Agreement on Trade-Related Aspects of Intellectual Property Rights," signed on 15th April 1994, Marrakesh Agreement Establishing the World Trade Organization, Annex 1C, 1869 UNTS 299. (Hereinafter referred to as "TRIPS Agreement" or "TRIPS").

[13] On the importance of implementing clear patent policies to avoid the introduction of TRIPS-plus standards without evaluating their societal effects, see Bryan Mercurio, "Challenging Coerced Conformity in Pharmaceutical Patent Law: Promoting a Holistic Review," *International Review of Intellectual Property and Competition Law (IIC)* 51 (2020): 330, https://doi.org/10.1007/s40319-020-00924-z

Organization (WHO) with a positive sanitary and economic impact in Low and Middle-Income Countries (LMICs)[14].

[14] See Sébastien Morin *et al.*, "The economic and public health impact of intellectual property licensing of medicines for low-income and middle-income countries: a modelling study," *The Lancet Public Health* 7, no. 2 (February 2022): 7, https://doi.org/10.1016/S2468-2667(21)00202-4

Chapter 1

1. Patent law legal "transplants": from colonialism to the TRIPS Agreement

1.1 International patent law standard-setting in the XIX century

The earliest form of patent protection having the force of law is historically traced in the so-called «Parte Veneziana sulle Invenzioni», a law which was passed by the Senate of the Republic of Venice in March 1474. This was the result of an effort to codify and regulate a custom that already existed in the Venetian Republic and that consisted in granting rights for the exclusive use of an invention for a certain number of years to those introducing new technological knowledge into the State[15]. What led to the approval of the law was the necessity to acquire knowledge without burdening the State budget in a historical contingency characterised by the need to build new arsenals to face the advance of the Turks. After the Venetian law another legislation having great historical importance was the English Statute of Monopolies of 1623, which arose from the opposition of the British parliament to the widespread system of monopoly privileges granted by the Crown at the time. The Statute represents the basis of the current patent law of the United Kingdom (UK) and of many other countries, and codified the principle according to which only the first and true inventor must be granted the exclusive right[16].

Patent protection spread more extensively among the nations during the nineteenth century, even if national legislations varied greatly as for the rules and procedures to obtain patents as well as for the object of protection and the protectable subject-matters.

The second industrial revolution was a crucial historical period for the development of international patent protection as it originated groundbreaking discoveries in the scientific, technological, and industrial fields transforming western Europe in the second half of the nineteenth century. The industrial class that had already emerged during the first phase of the revolution[17], was seeking outlets and opportunities for its investments and trades abroad. This is interestingly connected to the desire to start constructing an international patent

[15] See Helmut Schippel, *La storia delle privative industriali nella Venezia del '400* (Venezia: Centro Tedesco di Studi Veneziani, 1987), 22.

[16] Such principle was enshrined in the section 6 of the Statute.

[17] Here reference is made to the first industrial revolution which took place in the second half of the eighteenth century and that especially concerned the textile and metallurgical sectors.

system and was one of the factors leading to convene the 1873 Vienna Congress, a first unofficial international gathering to discuss the international harmonization of industrial property protection rules. Pressure for the introduction of international agreements making easier to obtain patent protection in foreign countries was mounting and the idea that it was favourable to promote the national interest through international conventions was spreading. Moreover, the Austro-Hungarian government wanted to address the concerns of inventors from the United States (US), who feared to have their ideas stolen ahead of the 1873 Vienna international exposition. That ferment led to the Vienna Congress, which can also be considered as the precursor of the following and more influential Paris Conference of 1878, and that was entirely financed by the German association for patents protection, the "Deutsche Patentschutz-Verein"[18]. Moreover, the congress was strongly influenced by the presence of the German Siemens brothers, with Charles William Siemens as president.

The Vienna Congress of 1873 was aimed at discussing patent protection rules and was participated by the representatives of a dozen countries, with Germany in the lead, followed by the Austro-Hungarian Empire, the United States, and the United Kingdom (UK). The participation of such limited number of countries was evidently due to the fact that not in all nations patent protection represented a pillar of the national development, as it can conversely be said about the mentioned countries. Therefore, presumably, there were a large number of states which were either not interested in participating or that were not involved in the project. The language of the resolutions that were adopted indicates in different points the "civilised nations" as the recipients of such conclusions.

It can be affirmed that the main result of the congress was the strong affirmation of the need of patent protection at a moment when the debate between supporters and critics of patents was quite heated. However, the nature and content of the debate about the necessity of patent legislations was far more political than technical[19] and saw the prevalence of the concept that patent law had to be equally reformed in all industrialized countries in order to accelerate technological progress[20].

The pressure towards the unification of national patent legislations animated, if possibly, even to a greater extent the subsequent Paris Conference of 1878. It gave birth to some of the principles that form the basis of the Paris Convention for the Protection of Industrial

[18] See Louise J. Duncan, "The Key Historical Influences Leading to the Paris Convention for the Protection of Industrial Property of 1883," in *Intellectual Property and the Law of Nations, 1860 – 1920*, ed. P. Sean Morris (Leiden, The Netherlands: Brill | Nijhoff, 2022), 26.

[19] Insight into the core of the political debate which characterized the 1873 Vienna Congress can be found in Thumfart, "Technological Innovation," 55-93.

[20] *Ibid.* Thumfart specifically delves into the normative character of the concept of Technology recalling of how it decisively influenced the debate on patents.

Property of 1883 and that still represent some of the main principles of the multilateral trading system, such as the National Treatment principle contained in the Article 2 of the Convention. Moreover, one of the 1878 Paris Conference resolutions stated that national patent legislations should be applied to colonies too[21], and in fact the Article 16bis of the 1911 Washington Revision of the Paris Convention for the Protection of Industrial Property established the right of contracting States to let their colonies access to the Convention through a written declaration to be notified to the government of the Swiss Federation[22]. The same provision was reproduced in the consecutive revisions[23] of the Convention, except for the latest Stockholm revision of 1967 where the article disappeared, reasonably because the decolonization process had come to an end so that having rules about colonies did not make sense anymore.

During the conference it soon became clear that the stated objective of achieving a uniform patent legislation was too ambitious, since every national legislation addressed national peculiarities, their different interests and legal structures, their history and ideology. The union originating from Paris Convention did not indeed lead to an actual unification of national industrial property legislations, as in the case of the Paris Postal Conference and the International Telegraph Conference. The assembly had to downsize its initial purpose so that the main concern became writing provisions that would have helped patentees to implement their property title abroad. Here is where the *priority right,* ex Article 4 of the Paris Convention, originates, establishing that who applies for a patent application in one of the countries of the Union and applies for a second patent application for the same invention as the first one in another country of the Union, has the right to maintain the same priority date as the first application, provided that the second application is submitted within one year of the first one. This allows patent applicants to avoid the risk that third parties can illegitimately profit from the publicity related to the first application. At the same time, the Convention mitigated the protectionist working requirement that was in force in some jurisdictions, where the protection of patent rights was conditional to the production of patented inventions on the national territory. Hence the Article 5 established that the importation by the patentee of the patented articles produced in one of the countries parties of the Union, would not cause the patent forfeiture.

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[21] See Edith Penrose, *The Economics of the International Patent System,* (Baltimore: Johns Hopkins Press, 1951), 53.

[22] The government of the Swiss Federation was in charge of hosting the "Bureau international de l'Union pour la protection de la Propriété industrielle*",* which was created by the Paris Union Convention.

[23] The Paris Convention for the Protection of Industrial Property was the object of several revisions: Brussels 1900, Washington 1911, the Hague 1925, London 1934, Lisbon 1958 and Stockholm 1967.

The patentability of pharmaceutical preparations, chemicals and foodstuffs was heatedly debated during the Paris Conference and eventually prevailed over the opinion of those who opposed to granting patents for the abovementioned subject-matters. Contracting States were let free by the Convention to regulate such aspect and to decide which exactly were the patentable and unpatentable entities and in fact the earliest versions of the Paris Convention lack a specific provision on the matter; however, during the 1934 London revision of the Convention, the scope of application of industrial property was conceptually extended to include the field of agricultural industry and of manufactured or natural products such as for example wine, grain, tobacco leaves, fruit, livestock, minerals, mineral water, beer, flowers, flour[24].

1.2 Patent law and colonialism

Among the first signatories of the Paris Convention there were some countries that are generally defined today as DCs, such as Brazil, Guatemala and El Salvador. Differently from the countries which promoted the Convention[25], their economy was mainly based on agricultural production. The protection of machinery inventors could hardly be considered as a priority in their national development policies. If we consider the period when the first rules on patents were first introduced in some DCs, it can be noticed that patents were established during colonial domination, as showed in table 1 below, and it is therefore considered that their introduction was not the result of an autonomous policy choice in such cases.

As it is known, the Paris Convention established a union whose states parties are compelled to apply all the dispositions contained therein. The institution of a union represented a useful instrument for countries that had already reached an enough homogenous level of economic-industrial development as it was aimed at harmonizing rules in the area of industrial property protection, ensuring that patent holders did not receive discriminatory treatment[26] if they were willing to exploit their inventions abroad or that they did not risk to have their idea for the invention patented by someone else[27]. However, it is questionable whether there were

[24] See Article 1(3) of London 1934 revision of the Paris Convention for the Protection of Industrial Property.
[25] As mentioned above, the countries that can be considered as the promoting States of the Paris Convention are France, the Austro-Hungarian Empire, the United States and the United Kingdom.
[26] The Article 2 of the Convention, incorporating the principle of National Treatment, established that citizens of a country member of the Union must be subject in all the other countries of the Union to the same advantages that the national legislations grant to their own citizens.
[27] The Article 4 of the Paris Convention legally created the priority right, which was illustrated in the paragraph 1.1

advantages for DCs in transplanting industrial property institutions of structurally different countries. The balance between costs and benefits resulting from the adoption of patents and other industrial property norms varied according to the economic characteristics of the State. Developing countries were net importers of patented inventions and the concession of the patent monopoly to foreign rights holders at the time did not produce nationally any benefits that could outweigh the cost connected with granting patents for inventions developed abroad[28]. On the one hand, by granting patent protection to foreign right holders, DCs were giving them the opportunity to enter in their markets with supra-competitive prices, but on the other hand such countries were not gaining equivalent benefits for their citizens in foreign markets because there were no industrialists involved in the production of mechanical inventions. This means that if through the institution of a union, countries which were already industrialized were gaining the chance to protect the inventions of their citizens and companies from competition abroad, non-industrialized countries were not achieving the same result as they were not exporters of inventions and they generally exported agricultural products.

[28] For an analysis of costs and benefits deriving from patent protection from the different perspectives of technology exporting and technology importing countries, see Edith Penrose, "The economics of the international protection of patentees: the balance of costs and gains," in The *Economics of the International Patent System*, ed. Edith Penrose (Baltimore: Johns Hopkins Press, 1951), 110-136.

Tab 1[29]

Country	Colonial power	Colonization period	Law introducing the first patent system
Mexico	Kingdom of Spain	1521 – 1821	Decreto de las Cortes Españolas de 2 de octubre de 1820
Tunisia	France	1881-1956	Décret du 26 décembre 1888
Indonesia	The Netherlands	1602 – 1945	Patent law 1910
Indian Empire	United Kingdom	1757 -1947	Act VI of 1856
Cuba	Kingdom of Spain	1511 – 1898	Real Cédula de 30 de julio de 1883
Algeria	France	1830-1962	Decret du 5 juillet 1850 portant promulgation de la loi française du 5 juillet 1844 sur les brevets d'invention
Morocco	France	1912 – 1956	Dahir du 23 juin 1916
Brazil	Kingdom of Portugal	1530 – 1822*[30]	Lei de 28 de agosto de 1830

1.3 The evolution of patent rules in Brazil and their adjustment to international provisions

1.3.1 The patent term

In Brazil the first legal form of patent protection was introduced in 1809 by João VI of Portugal as part of a wider provision of law[31] which contained several provisions aimed at encouraging industrial development on the national territory. Paragraph VI of the law prescribed that inventors shall have a fourteen-years exclusive privilege provided that they presented their invention to the royal administration in charge of trade. A law enacted in 1830[32] established that the patent term could vary within a range between five and twenty years, depending on the quality of the invention, without prejudice to a longer term granted by law. Afterwards, the 1882 patent law[33] fixed the patent duration at fifteen years removing

[29] Table 1 contains a selection of countries that were subject to colonial domination and that would today be classified as Developing Countries. It is showed that the first legislation on patent protection was introduced and imposed by colonizing powers in each of them. Also importantly, all of them were signatories of the Paris Convention for the protection of industrial property.
[30] Brazil represents a particular case in that it was the same Portoguese royal ruling family to proclaim independence of the colony in 1822, crowning Pedro I, son of the king João VI of Portugal.
[31] See "Alvará de 28 de abril 1809".
[32] See "Lei de 28 de agosto de 1830".
[33] See "Lei 3129 de 14 de outubro de 1882".

the variable terms previously set. The patent term remained fifteen years for over a century, having been extended to twenty years only in 1996 when the Brazilian patent legislation had to be adjusted to the provisions of the TRIPS Agreement. After about twenty years, in May 2021 a ruling[34] of the Brazilian Federal Supreme Court has affected the patent term related to pharmaceutical and health inventions, by declaring a part of the patent term rule unconstitutional. In particular, the sole paragraph of Article 40 of the law n. 9279 of May 14th 1996 established that the patent term shall not be less than ten years from the granting of the patent. As a result, if the patent examination had lasted for more than ten years, the effective term of the patent[35] would have extended beyond twenty years. As a matter of fact, Article 44[36] of the 1996 law ensures that the holder of the patent application can enforce his exclusive rights since before the granting of the patent. The combination of Article 40 sole paragraph and Article 44 could determine an "automatic" extension of the patent term even beyond twenty years, as it seems to have happened several times in Brazil, where the average effective patent term has been said to exceed twenty-four years[37]. According to the Brazilian Federal Supreme Court, the norm contrasts with Article 5 XXIV of the Brazilian Constitution, which underlines the temporary character of privileges granted to authors of inventions. On April 7th 2021[38] the Court suspended the effects of Article 40 for pharmaceutical patents and patented medical equipment as damages arising from an unconstitutional and undue exclusivity would have been particularly problematic in the case of medicinal products. The Judge-Rapporteur underlined that Brazil is the only Developing Country included in the set of countries with the patent term highest averages, as results from a study conducted by the University of São Paulo[39], and that the automatic extension of patents when the examination lasts for long confers an excessive advantage to patentees and prevents access to the market by competitors, keeping high prices and harming consumers, especially in the health sector.

[34] Supreme Federal Court of Brazil, 7th May 2021, Direct Action of Unconstitutionality (ADI 5529).
[35] It is here recalled that the patent term begins from the date of filing the patent application.
[36] The article establishes that the patentee shall have the right to obtain compensation for the illegal exploitation of the patent object, including exploitation having occurred between the date of the patent publication and the date of grating of the patent.
[37] See Mário André Machado Cabral, "Automatic Patent Term Extensions Ruled Unconstitutional in Brazil: Better Late Than Never?," *IIC International Review of Intellectual Property and Competition Law* 53, no. 1 (2022): 160-168, https://doi:10.1007/s40319-021-01145-8
[38] The court decision became final on May 6th 2021.
[39] See Cynthia M. Santos Bezerra et al., "A Inconstitucionalidade do Artigo 40, Parágrafo Único, da Lei de Propriedade Industrial sob uma Perspectiva Comparada," posted: 12 Feb. 2021, https://papers.ssrn.com/sol3/papers.cfm?abstract_id=3745372

1.3.2 Failure to work, patent forfeiture and compulsory license

Interpretation and meaning of "failure to work"

Failure to work is one of the legal grounds that historically legitimise the granting of compulsory licenses or of other measures aimed at limiting the patent monopoly of patentees. As a first approximation, it can be affirmed that it is currently intended as the situation in which the patented invention is not commercially exploited on the national territory and it is not available in the internal market of a given State, as presently emerges from the normative provisions of most national legal systems. However, in the history of the patent systems of some countries the definition of failure to work appeared to be broader than the one which has just been mentioned. In particular, it appeared to include the *production* of the patented invention on the national territory[40]. In a few juridical systems, failure to work still indicates the absence of production of the patented invention on the national territory or/and its availability on the domestic market at a reasonably affordable price[41].

The following table contains a sample of twenty-six States which are divided according to their interpretation of failure to work.

Table 2

Failure to work as absence of production in the country	**Failure to work as:** - **absence of commercial exploitation** - **absence of the product on the domestic market**	**There is no clear definition or none definition of failure to work**
Brazil (art. 68 (1) Lei 9279/1996)	Colombia (art. 558 decree 410 1971, Chapter VI, decision 486/2000)	Argentina (art. 43, act n. 24481 of 1995)
Thailand (Sec. 46 Patent Act 1999)	India (Sec. 84 patent act 1970 as amended in 2005)	China (art. 48 (1) Patent law of PRC)
Egypt (Act 82/2002)	Azerbaijan (art. 20 (2.6) Patents Act)	Chile (ley 19039 de 2022)
Indonesia (art. 82 act 13/2016)	Bangladesh (art. 21 (d) Patents Act 2022)	Japan (artt. 83, 93 Patent Act)
Ireland (Sec. 70 (2) (B) patent act 1992)	Italy (art. 70 CPI)	Spain (art. 92 ley 24/2015)
	Botswana (Sec. 33 (1) Industrial Property Act 2010)	Cyprus (Sec. 49 (c)(iii) 1998 Patent Act)

[40] To make an example, as will be seen in the following paragraph, the Brazilian decree 254 of February 28, 1967 established that the importation of the patented invention by the patentee was not sufficient to constitute the effective working of the same.

[41] As in the case of the Indian provision contained in Sec. 84 of the 1970 Indian Patents Act.

	Costa Rica (art. 18 of law n. 6867 of 1983, as amended by law n. 8686 of 2008)	
	France (art. L 613-11 code de la propriété industrielle)	
	Germany (Patentgesetz – patent act, sec. 24 (5)	
	Autriche (art. 36 (4) Patentgesetz 1970)	
	Saudi Arabia (art. 24 Law of Patents, Layout Designs of Integrated Circuits, Plant Varieties, and Industrial Designs)	
	Australia (Sec. 133 (3) (a) 1990 Patent Act	
	Belgium (art. XI.37 Code de Droit Economique)	
	Czech Republic (Sec. 20, act n. 527/1990 as amended in 2021)	
	Estonia (Sec. 47 (1) 1994 Patent Act 1994 as amended in 2023)	

Considering that one of the historical justifications for the patent monopoly is its function of incentivizing technical progress and dissemination of inventions within the State[42], it can be thus reasonably argued that the concept of "working a patent" does not merely refer to the availability of the patented article on the domestic market but also to its production on the national territory; by adopting such perspective, the original rationale of compulsory license seems to be allowing production of inventions on the national territory and, indirectly, developing the related productive capacities therein.

However, there seems to be a general trend of national patent legislations to interpret failure to work as absence of the patented product on the domestic market or its insufficient presence. In particular, there has been a shift of focus in the purpose of compulsory licenses for failure to work: the *ratio* is no longer stimulating innovation and technological development within the State territory but ensuring the protection of the patentee and the supply on the domestic market[43].

This shift could serve international trade policies of the States that are fully industrialized, which no longer have any interest in promoting the creation of basic productive-industrial

[42] See Adriano Vanzetti, Vincenzio Di Cataldo and Marco S. Spolidoro, *Manuale di Diritto Industriale* (Milano: Giuffrè, 2021), 379.

[43] See Hanns Ullrich, "Mandatory Licensing Under Patent Law and Competition Law: Different Concerns, Complementary Roles," in *Compulsory Licensing. Practical Experiences and Ways Forward,* ed. Reto M. Hilty and Kung-Chung Liu (Springer, 2015), 343-344.

capacity within the State since they have already reached a high industrial development level.

The provision contained in the Article 5 (A) (2) of the Paris Convention, stating that "Every Union country shall have the right to undertake legislative measures providing for granting compulsory licences with the purpose of preventing abuses that could derive from the exercise of patent exclusive rights, such as for example, failure to work[44]", intended failure to work as absence of production of the patented invention on the national territory[45]. The insufficient supply of the patented product would therefore be just an additional aspect of the concept of failure to work. Even if Article 31 TRIPS does not mention failure to work, paragraph (f) states that compulsory licenses must be granted predominantly for the supply of the domestic market. The TRIPS' drafters therefore leant towards the interpretation according to which failure to work meant absence of supply on the domestic market and not absence of production on the national territory. In the agreement, such interpretation is also supported by that part of Article 27 (1) providing that patents rights must be enjoyable without discrimination whether products are imported or locally produced.

The Paris Convention legal framework and the Brazilian system

The first international provision on the matter of failure to work appeared in the Washington revision of the Paris Convention (1911). The Article 5 provided that the patent revocation for failure to work could only occur after three years from the patent application and only when the patentee was not able to justify his inaction. Recourse to patent revocation was then mitigated by the Hague revision of 1925, which circumscribed the measure to cases where a compulsory license had not proved sufficient to prevent abuses deriving from exclusive patent rights, such as failure to work. The article, in any case, provided that such measure could not be implemented before three years from the date of granting the patent and only when, again, the patentee was not able to not justify his inaction. Afterwards, the London revision of 1934 inserted the further limitation according to which two years had to elapse from the granting of compulsory license before the patent revocation could take place. In Brazil, the act 28th August of 1830[46] established the patent forfeiture when the patentee did not put the invention into practice within two years from the granting of the patent.

[44] In the French version of the Paris Convention the expression that is used is "faute d'exploitation".
[45] See *supra note 43.*
[46] And in particular, Article 10 (3).

Similarly, the ensuing 1882[47] patent act stated that if the patentee did not make an effective use of the patent within three years from its granting, the patent would have become ineffective and specified that "effective use" meant effective exercise of the privileged industry and the supply of products proportionally to their use or consumption[48]. Lastly, the act provided that if the offer of the patented product was insufficient to meet the need of use or consumption, the exclusive right could be limited to a certain area.

In the meantime, the Paris Convention, which was signed the following year, provided that the importation of patented products by the related patentee in a contracting State where the patent was granted would have not caused the patent forfeiture[49]. This provision was aimed to avoid that a patentee who had produced the invention abroad in one of the Union countries and had imported it in another Union country without producing it there would be subject to the patent forfeiture. As a matter of fact, similar provisions existed in some legal systems. In Mexico, for instance, patentees had to prove to the Ministry of Development that the invention they patented was produced or exploited within the country, otherwise they would have been subject to the patent forfeiture[50].

Compulsory licences were introduced for the first time in Brazil by the decree 7903/1945. More specifically, the Article 53 provided for the obligation to grant compulsory licenses to third parties who requested it, when the patented invention was not effectively exploited on the national territory within two years from the granting of the patent or when use of the invention was interrupted for more than two consecutive years without justification. It is interesting to note that Brazilian legislators were concerned with regulating in detail the procedure culminating in the granting of compulsory license[51], how it can for example be seen in the regulation of the terms related to submitting objections on the part of patentees and in those related to the submission of appeal by both parties[52]. The patent forfeiture was instead regulated by the Article 77 (1), which did not introduce major changes compared to the previous provisions. However, in spite of the detailed definition of "effective use" mentioned above and already given by act 3129/1882, paragraph 2 only specified that "effective use is demonstrated through the regular functioning of the activity to which the

[47] *Supra note 33.*

[48] See Article 5 (2), 1882 act.

[49] See Article 5 of Paris Convention.

[50] See the combination of articles 33 and 37 (III), "Ley de Patentes de Invención o Perfeccionamiento, del 7 de junio de 1890" of Mexico.

[51] See Article from 54 to 63 of decree 7903/1945.

[52] The point seems particularly relevant if we consider that current rules on compulsory licensing are generally characterized by the absence of a defined term for completing the procedure. This is also considered as a shortcoming of such regulations because they tend to delay the procedure in favour of patentees.

patent relates". Thus, the previous reference to the requirement of proportionality of the supply to the need of consumption disappeared, as did the possible restriction of the territorial scope of effectiveness of the patent. Afterwards, in order to comply with the Paris Convention, Article 39 of the decree law 254 of February 28th 1967 extended to three years the period that had to elapse from the grant of the patent before a compulsory license could be granted. Then, it introduced a second type of compulsory licence named as "special", which could be granted for public interest reasons. Significantly, paragraph 2 established that the importation of the patented invention by the patentee would not constitute its effective exploitation. In order to satisfy the requirement of effective exploitation of the patent it was thus necessary that the patented invention was indeed produced on the national territory. In this law the definition of "effective use" is specified similarly to the definition given in the law 3129/1882, the reference to the satisfaction of consumption needs still being present. In particular, according to the Article 63 "it is considered as effective use the continuous and regular exploitation of the invention on an industrial scale which satisfies the consumption needs of the country (…)". Verification of effective use of the patented invention was assigned to the national department for the industrial property. Lastly, Article 61 of the same law provided for the patent forfeiture when the invention was not effectively exploited in the country for more than three consecutive years. On the point, this norm contrasted with the Paris Convention, according to which patent forfeiture could only take place when abuses deriving from the exercise of the patent exclusive rights were not eliminated as a consequence of compulsory license[53]. Compulsory license was indeed considered by the Convention as a possible remedy against abuses deriving from the exercise of patent exclusive rights and could be granted only after three years from the grant of the patent and if the patentee had not justified his inaction[54].

The decree 1005/1969 introduced an interesting definition of *effective use* of the patent, which emphasized the *production* of patented articles within the country. More specifically, by effective use was meant "the proven, continuous and regular exploitation of the invention on an industrial scale, both through production by the patentee and through production by means of licenses for exploitation to third parties (…)"[55]. Moreover, under the Article 42, the lack of effective use within the country by the patentee within two years from the grant of the patent would have entailed the obligation to grant a license to applicants, under penalty of patent forfeiture. Effective use had, again, to be demonstrated to the national department

[53] See Article 5 (A), Paris Convention.
[54] See Article 5 (A) (2), Paris Convention
[55] See Article 62 Lei 1005 de 21 de Outubro de 1969.

of industrial property[56]. Lastly, Article 43 reduced the time limit within which patentees could challenge the grant of compulsory license from ninety to sixty days.

In conclusion, the law n. 9279/1996 which is still in force today, introduced major changes to compulsory licenses: firstly, the importation of patented articles from abroad was admitted in cases in which it was not feasible to effectively exploit the patent object on the national territory[57]; furthermore, two additional restrictions were added to the grant of compulsory licenses: (i) the licensee had to demonstrate to have the technical and economic capacity to effectively exploit the patented invention and (ii) he had to allocate the articles produced under license to the domestic market[58], in compliance with Article 31 (f) TRIPS. Lastly, the law eliminated the provision on patent expropriation[59], which was present in the Brazilian system until then.

1.3.3 Patentable subject-matters

The most significant change brought by the 1996 law, which incorporated the TRIPS standards, was the introduction of patentability of pharmaceutical and food products and processes, and of all chemical processes. Previously, Brazilian patent laws had prohibited to grant patents to medicinal and food products and substances and to materials and substances obtained through chemical processes[60] since 1945. Furthermore, the decree 1005/1969 had extended the prohibition to processes for obtaining food, chemical-pharmaceutical and medicinal substances, materials and products and to mixtures and metal alloys[61]. After all, the Paris Convention left the contracting parties free to establish patentable and unpatentable subject-matters and the exclusion decided by Brazilian legislators derived from their clear choice to protect the local industry in some of the most strategic sectors for the national development.

The inclusion of pharmaceutical products among patentable subject-matters, introduced by the 1996 law, and the resulting price increase had a negative impact on public health policies, particularly on the distribution of pharmaceuticals to the public by the Brazilian healthcare

[56] See Article 42 (3) *ibid*.
[57] See Article 68 (1) law 9279/1996.
[58] See Article 68 (2) *ibid.*
[59] See Article 48, decree n. 254 of 28 February 1967.
[60] See art. 8, decree 7903/1945
[61] See art. 8 decree 1005/1969

system[62]. In an attempt to balance the introduction of patentability for pharmaceuticals with the protection of public health, the law 10196 of 2001[63] subordinated the grant of patents for some pharmaceuticals products and processes, which were considered of special interest for the healthcare assistance provided by "Sistema Unico de Saude"[64], to the consent of the national agency for the health surveillance, called "ANVISA".

The ordinance 3089 of December 11, 2013 defined and divided pharmaceuticals that needed the ANVISA consent in order to be patented in nine groups: (I) antivirals and antiretrovirals, (II) neglected diseases, (III) degenerative diseases (Alzheimer, Parkinson, etc.), (IV) immunosuppressants, (V) mental diseases (antipsychotics and anticonvulsants), (VI) biologically obtained products, (VII) vaccines and serums, (VIII) blood derivatives, (IX) oncology products. Moreover, the ordinance included groups related to health support devices, such as equipment used for producing anatomical images of the human body for the purpose of diagnosing, identifying and monitoring diseases.

In essence, the Brazilian national authority in charge of granting patents and other intellectual property rights, named "Insituto Nacional de Propriedade Industrial" (INPI), had to transmit to ANVISA patent applications related to pharmaceutical products of special interest for public health. The agency could then deny consent to grant patents to the product in question or consent to it.

The screening activity carried out by ANVISA had a concrete impact on the percentage of patent applications that could move on to the stage of the exam of INPI and it has been estimated that the agency gave consent to approximately 70% of patent applications between 2012 and 2017, with such consensus rate then increasing to 82% between January and July 2018[65].

The whole procedure was then abrogated by the law 14195 of 2021 but Brazil seems not to be the only State having implemented a similar system. Bolivia, for instance, provided for a procedure requiring prior consent of the Unit of Medicines and Health Technology (UNIMED) for patenting pharmaceutical products and processes[66].

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[62] See Marília Cunha Silva, Jefferson Holliver Motta, and Sandra Mara Maciel-Lima, "A atuação da ANVISA na questão do acesso populacional aos medicamentos," *Revista Jurídica Unicuritiba* 2, no. 80 (2016): 279-291.

[63] The norm is contained in the Article 229-C.

[64] This is the name of the Brazilian national healthcare system.

[65] See Gabriel Di Blasi, "Reaching a milestone in pharmaceutical patenting in Brazil," *Pharmaceutical Patent Analyst* 7, No. 6 (2018): 229-233, https://doi.org/10.4155/ppa-2018-0025

[66] See art. 3 of Supreme Decree No. 29004.

The so-called "Pipelines system"

The 1996 law also introduced the so-called "Pipelines" system, regulated by the Articles 230-231, which allowed those who had applied for a food, pharmaceutical or chemical patent outside Brazil[67] to submit a patent application for the same invention in Brazil as well, within one year from the publication of the law, with the possibility to maintain the same priority date as the one of the first application abroad. The patentee was ensured a term of protection equal to the residual term of protection in the country where the first application was submitted, departing from the date of application in Brazil. Secondly, Article 231 allowed those who had Brazilian citizenship or were domiciled in Brazil to submit patent applications for the above-mentioned types which had already been made available to the public, within one year from the publication of the law, and ensuring to patentees a protection term equal to the residual term calculated from the date of disclosure, departing from the date of application in Brazil.

The mechanism embedded in these two norms allowed, in essence, to apply and obtain patents for products and processes which were previously unpatentable in the country, due to the prohibition to patent pharmaceutical and food-related inventions. It is important to underline that, implementing such mechanism meant foregoing the possibility to benefit from the transitional periods regulated by Article 65 TRIPS, which allowed DCs not to implement the TRIPS standards before five years from the entry into force of the agreement. The five years were increased by an additional five years for those countries which prohibited to grant patents to certain categories of invention. Brazil could basically have begun to grant patents to pharmaceuticals only in 2005, but it began in 1996 instead. This negatively affected public health, the State budget and the domestic industry development. Furthermore, the "pipelines system" was allowing the granting of patents to inventions lacking the novelty requirement that had already been disclosed abroad or in the country before the 1996 law entered into force.

[67] The provision was addressed to both product and process patent applications.

1.4 The evolution of patent rules in India and their adjustment to international provisions

In the early stages of formation of the patent system the power to grant exclusive privileges on inventions in the Indian territory was considered as a prerogative of the British crown. The first laws on patents approved in India were shaped on the corresponding British laws and changes in British regulations directly influenced Indian ones. These were passed despite a discordance of opinions as to whether those laws should be implemented and notwithstanding even the crown representatives in India advised against their application due to the country's industrial backwardness[68].

On the relation between Indian patent law and its British counterpart it was pointed out[69] that while the latter evolved through in-depth assessments being made in every stage of its evolution by expert committees, the Indian one tented to evolve by blindly and faithfully following British law without any assessment about the effectiveness of standards or their adaptation to the national context.

The first law on the protection of inventions was the 1856 Act VI which conferred to inventors a fourteen-year *exclusive privilege* but was soon repealed as it entered into force without the approval of the Court of Directors, the governing body of the East India Company. It was first replaced by Act IX of 1857 and then by Act XV of 1859 that among other things, prohibited the granting of exclusive privileges to inventions of "no utility" with the purpose of preventing applications related to futile inventions that did not represent a real innovation.

In India the Act V of 1888 abrogated the previous laws and was adopted in order to conform the Indian legislation to the modifications that had been introduced in the United Kingdom through the 1883 law. The Indian empire was among the first nations to sign the Paris Convention for the protection of Industrial Property in 1883 but its adhesion was imposed by the British coloniser. It is significant that after having gained independence, India waited for approximately 50 years before adhering again to the Convention and signed the treaty only in September 1998. It can be assumed that the Indian legislators were aware of the fact that the number of foreign patentees that would have benefitted in India from the priority right set by the Convention would have been significantly higher than the number of Indian patentees that would have made use of the priority right abroad in the other contracting

[68] See Ministry of Industry and Supply of government of India, *Report of the patents enquiry committee (1948-1950)* (Government of India Press, 1950), 12.

[69] See Ministry of Industry and Supply of government of India, *Report of the patents enquiry,* 164-222.

States. Such hypothesis can be deduced by comparing data on patent applications submitted in India by Indian applicants and those submitted in the country by foreign applicants. Since the introduction of patent protection in India, the ratio between foreign and local patent applicants had been disproportionately in favour of the former and how it can be seen by the following table[70], approximately 90% of patent applications submitted in India from 1856 to 1949 belonged to foreign applicants. Such data were extracted from the "Report of the patents enquiry committee (1948-1950)", which was drafted by a commission appointed in October 1948 by the Ministry of Industry and Supply of the Indian government. The report also contains further data[71] concerning the countries of origin of most of the patent applications that were submitted in India in the studied period, which mainly were the UK, the United States, Germany, France, Australia, the Netherlands and Switzerland.

Table 3

97. The number of applications for "exclusive privileges" or "patents" under the various enactments referred to above, and the number of such applications filed by Indians are as given below:—

	Total Number	From Indians
Under the Act of 1856	33	Nil
Under the Act of 1859	3417	234
Under the Act of 1888	11727	1131
Under the Act of 1911 (up to the end of 1949) . . .	42498	5899

Source: *Report of the Patents Enquiry Committee, (1948-1950),* p. 48

[70] See Table 3 below.

[71] The tables reporting data on the countries of origin of patent applicants can be consulted in the Appendix I, pp. 123-124

1.4.1 Failure to work, patent forfeiture and compulsory license

The 1911 Indian Patent Act

In India a provision on compulsory licenses was first introduced by the Indian Patents and Designs Act of 1911, a law that renewed and made significant changes to the domestic patent legislation. First of all, the terminology "exclusive privilege" disappeared and gave way to the term "patent"; secondly, the first patent office[72] was introduced and was tasked with granting patents, which were before then within the competence of the Secretary to the Government of India in the Home Department; lastly, the law introduced the figure of Controller, entrusted with powers comparable to those of a civil court[73] and that included the refusal to grant patents when this was contrary to the law or morality[74].

Section 22, which was inspired by the corresponding provision in force in the UK[75], established that the application for compulsory license had to be addressed to the Governor General in Council, which was a representative of the British crown, and submitted to the patent office when "the reasonable requirements of the public with respect to a patented invention have not been satisfied (…)".

During the early 1960s the Controller of patents and Designs decided to grant a compulsory license for two process patents which were held by the company Farbenfabriken Bayer. One of the patents concerned the production process of new intermediate synthesis products of the chemical compound phthalocyanine, the other covered the dyeing and printing process related to such products[76]. The decision to grant a compulsory license to the applicant, Arlabs Private Limited, was taken on the ground that the intermediate products had not been manufactured in India by the patentee but were imported by him from Germany. As a consequence, the three legal grounds prescribed by Section 22 (2) and adduced by Arlabs existed. They were the following: a) the patented invention was not commercially worked in India; b) that the domestic demand for the patented invention in India was being met to a substantial extent by importation from other countries; c) that the commercial working of

[72] See Section 25 of the Indian Patents and Designs Act of 1911.
[73] See Section 65 *ibid.*
[74] See Section 69 *ibid.*
[75] See Section 24 British Patents and Designs Act of 28th August 1907.
[76] See Calcutta High Court, February 20, 1963, *Farbenfabriken Bayer, AG v. The Joint Controller of Patents and Designs.*

the invention in India was being hindered by the importation from other countries. With respect to the third ground, Arlabs had previously attempted to obtain a voluntary license from the patentee but it was unsuccessful.

Section 25 was devoted to the patent revocation on public grounds and established that a patent could be revoked if the central government declared that the patent itself or the manner in which it was exercised was "mischievous to the state" or "prejudicial to the public"[77], but the lack of case law on such subject makes it difficult to imagine what specific situations the provision could pertain to.

The 1970 Indian Patents act

After gaining independence in 1947, the Indian government formed two commissions and entrusted them with the task of conducting a review of the domestic law on patents in order to provide indications and recommendations for drafting and passing a new law which better suited the development needs of the country. They were the Tek Chand Committee[78] (1948) and the Ayyangar Committee (1957).

Compared to the previous law, the regulation of compulsory licenses which was introduced by the Patents Act 39 of 19th September 1970[79], significantly widened the number and extent of the grounds justifying the grant of such instrument and clearly emphasized the element of production of the patented invention on the national territory. The new grounds that could be demonstrated by applicants in order to receive the grant of compulsory license were the following:

- the patented invention was not available to the public at a reasonable price[80];
- the demand related to the patented invention was not being met to an adequate extent or on reasonable terms from manufacture in India[81];
- a market for the export of the patented article manufactured in India is not being supplied or developed[82];

[77] See Section 25 Indian Patents and Designs act, 1911.
[78] The Tek Chand Committee drafted the report which was mentioned in the previous paragraph.
[79] From here onwards it will be referred to as "1970 Indian Patents Act".
[80] See Section 84 (1) of 1970 Indian Patents Act.
[81] See Section 90 (a) (ii) *ibid.*
[82] See Section 90 (a) (iii) *ibid.*

- the patented invention was not being worked in India on a commercial scale to an adequate extent or was not being so worked to the fullest extent that was reasonably practicable[83];
- the demand for the patented article in India was being met to a substantial extent by importation from abroad by (i) the patentee or persons claiming under him; or (ii) persons directly or indirectly purchasing from him; or (iii) other persons against whom the patentee was not taking or had not taken proceedings for infringement[84];
- the working of the patented invention in India on a commercial scale was being prevented or hindered by the importation from abroad of the patented article by the patentee or the other persons referred to in the preceding clause[85].

Another innovation brought by the 1970 Indian Patents act was the introduction of the so-called *Licences of right,* governed by Sections 86, 87, 88. On the basis of such discipline, it was possible to request to the Controller to endorse a patent with the words "licences of right" when the reasonable requirements of the public with respect to the patented invention were not satisfied or the invention was not available to the public at a reasonable price. Inventions related to food and medicinal products as well as processes and methods for their manufacture and production processes related to chemical substances automatically acquired such endorsement after three years from the patent date[86]. As for the legal effect of this instrument, the endorsement of license of right implied the concession of licenses to anyone applying to the controller. As for the terms of the license, they were either mutually agreed from the parties or decided by the Controller; in any case, the royalty to be paid to the patentee could not exceed 4% of the net ex-factory sale price in bulk of the patented article. As concerns the patent revocation, the main change in the legislation was represented by the strong mitigation of the requirement that the applicant for revocation had to be ready and able to work the invention, contained in Section 23 of the 1911 act, and it was replaced by the condition that the application of revocation must "set out the nature of the applicant's interest[87]".

[83] See Section 90 (c) *ibid.*
[84] See Section 90 (d) *ibid.*
[85] See Section 90 (e) *ibid.*
[86] See Section 87 *ibid*.
[87] See Section 89 (2).

Amendments to the patent act

The 1970 Indian Patents Act was the object of three subsequent amendments in 1999, 2002 and 2005 that were approved and implemented in order to align the Indian legislation on patents with the statutory standards contained in the TRIPS agreement, entered into force in 1995. At the same time such amendments dismantled what was considered as the most "generics-friendly" legislations in the world.

As will be seen further on in this work, the 1999 amendment implemented one of the most substantial changes in the legislation, particularly relating to patentable subject-matters; moreover, it introduced exclusive marketing rights. There were also significant alterations to the Compulsory Licensing provisions which were brought about by the 2002 amendment. It incorporated the requirement set by the Article 31 (b) TRIPS and established that a Compulsory License could only be granted by the Controller if the applicant tried earlier to obtain a voluntary license from the patentee on reasonable terms and conditions. In this respect, it was pointed out that not setting a time limit by which negotiations must take place would lead patentees to intentionally extend bargaining with the purpose of delaying the potential granting of the compulsory license. In order to limit such risk Indian legislators have specifically regulated such time limit by providing for a maximum limit of six months, as established in the "explanation" in the Section 84 of the Indian act.

As for the legal grounds justifying granting Compulsory Licenses, the 2002 amendment cancels the reference to "the default of the patentee to manufacture in India to an adequate extent and supply on reasonable terms the patented article or a part of the patented article which is necessary for its efficient working", as previously established by the Section 90 (a). All the other references[88] to manufacturing the patented invention on the Indian territory as condition for the public interest satisfaction were equally cut off. It is a significant change that had repercussions on case law as well. To make an example, in *Novartis v. Cipla*, decided in 2015 by the High Court of Delhi, the Court held that "the requirement of law is limited to working the patent in India so that the same is available to public at large. It is not essential that the patent must be worked by manufacturing the patented product in India".

The 2002 amendment repealed all the provisions concerning the endorsement of patents with the words Licences of Rights and incorporated clauses on non-exclusivity and non-assignability of compulsory licenses which were transposed from the Article 31 (d) and (e) TRIPS. Moreover, Section 97 which provided for the possibility to grant compulsory license

[88] I am here referring to the references to manufacturing the patented invention in India of section 90 (a) (ii) and 90 (d).

at any time on public interest grounds after an *ad hoc* declaration of the central government was replaced by the Section 92 that, by transposing Article 31 (b) TRIPS, provides for granting compulsory license after the government declaration in cases of a "national emergency, or other circumstances of extreme urgency or in case of public non-commercial use".

The provision[89] that expressly provided for the importation from or on behalf of the central government of a medicinal product for the purpose of its distribution in hospitals or other medical institutions was repealed.

Another alteration concerned the royalty amount to be paid to the patentee in case of use of a patented food or medicinal product by the government. While Section 100 (3) provided that the amount of the royalty shall not exceed 4% of net ex-factory sale price in bulk of the patented article, the amended version of the disposition, by following the formulation of Article 31 (h) TRIPS on compulsory licenses, mandates that "the patentee shall be paid not more than adequate remuneration in the circumstances of each case, taking into account the economic value of the use of the patent[90]".

Lastly, the 2005 amendment brought about the incorporation of the Section 92A that provides for the granting of compulsory license with the purpose of manufacturing and exporting patented pharmaceutical products in countries lacking sufficient manufacturing capabilities with respect to certain pharmaceutical products. The introduction of such provision is directly linked to the Doha Declaration on the TRIPS agreement and public health, adopted in November 2001 in the context of the World Trade Organization (WTO) ministerial conference. The main result of the Doha Declaration was the insertion of the Article 31*bis* in the agreement, which provides for the possibility to use a compulsory license with the purpose of exporting pharmaceutical products to eligible importing members and not only to supply the domestic market, as established by Article 31(f). As will be seen, this provision entails a system which is complex to activate and implement to the point of dissuading its use, as also evidenced by the fact that it was used only once since its existence.

Lastly, the 2002 amendment also introduced in Section 83 a number of general clauses[91] on transfer and dissemination of technology, economic and social welfare, public health and public interest, which were included in the attempt to balance in some way the restrictive standards of TRIPS, but which were not intended to have significative concrete effect.

[89] See Section 99 (2) of the first version of the Indian Patents Act of 1970.
[90] See Section 100 (3).
[91] See clauses c, d, e, f, g of Section 83 of 1970 Indian Patents Act.

1.4.2 The patent term and patentable subject-matters

As it was mentioned above, the first form of patent protection in India conferred a fourteen-year term of protection to the privilege owner. Afterwards, the Act V of 1888 established that the patent term could be extended by the Governor general in council to an additional seven-year period in ordinary cases and to a fourteen-year period under exceptional circumstances. Duration of the privilege was then extended to sixteen years by the 1930 amendment act, which could be furtherly extended to additional five years in ordinary cases and to ten years in exceptional cases. Such extensions could be requested by the patentee to the central government or to the High Court division in case the patent had not been sufficiently profitable during its natural term. The patent term lastly reached twenty years following the approval of the 2002 Patents Amendment Act, which was one of the legislative changes passed in the country in order to align the domestic Intellectual Property Rights legislation to the TRIPS' standards.

As for patentable subject-matters, the exclusion from patentability of food, medicine and drug products and of products produced by chemical processes was one of the main results of the two committees of inquiry on the patent legislation appointed by the government. Section 5 of the 1970 Indian patents act excluded such categories of product from the possibility to receive exclusive patent protection, while at the same time allowing to grant patents for methods and processes of production of such inventions. These provisions formed the backbone of the generic industry in India, leading the country to deserve the epithet "pharmacy of the third world". The exclusion of pharmaceutical products from patent protection will be definitively abrogated only in 2005 when an amendment of the same year made pharmaceutical products patentable in accordance with Article 27 TRIPS.

As a matter of fact, after having been in force for about thirty years, the 1970 Indian Patents Act became the object of a number of subsequent changes that were approved in order to make the Indian legislation compliant with the TRIPS Agreement. The 1999 amendment act caused the introduction of paragraph 2 in the section 5 of the 1970 Indian Patents act and made possible granting *exclusive marketing rights* for pharmaceutical products which were the subject of a patent application. This was the result of incorporation of Article 70 (9) TRIPS after India was brought before the WTO Dispute Settlement Body (DSB)[92] for not having complied with the norm.

[92] In July 1996 the United State filed a complaint before the DSB of the WTO against India for failing to comply with Articles 27, 65 and 70 TRIPs. The panel was instituted in November 1996 and established violations of Articles 70 (8) (a) and (9), as well as of Article 63 (1) and (2). On appeal in December 1997 the DSB appellate body confirmed the panel's conclusions concerning Articles 70 (8) (a) and (9) but dismissed

But before getting into the detail of the exclusive marketing rights provision, it is appropriate to dwell on two TRIPS' norms: the transitional periods of Article 65 on the one hand, and Article 70 (8) (a) and (9), on the other. Transitional periods were introduced in order to allow to certain States parties some time before providing for patent protection for categories of invention that were previously excluded from patentability in their legislations. In other words, in order to be compliant with the TRIPS Agreement, these States found themselves having to implement patent protection for categories of invention they had excluded from patentability, traditionally pharmaceutical and food products. Article 27 (1) TRIPS in fact required to grant patent protection for all types of invention, whether products or processes, in every field of technology, provided that they satisfied patentability requirements. In particular, the Article 65 allowed Developing Countries and countries which were transitioning from a centrally-planned economy to a free-market one to abstain from complying with the agreement for a four-year period after the entry into force of the TRIPS Agreement. Moreover, States parties that at the date of application of the agreement, did not provide for patent protection for certain areas of technology could benefit from a further waiver of five years that were added to the four years already mentioned and provided by paragraph 2. Lastly, the subgroup of developing countries represented by Least-Developed Countries (LDCs) were initially given ten years by Article 66 (1) to comply with the provision of the TRIPS Agreement. Over time, a number of decisions of the TRIPS Council have furtherly extended this term[93].

On the other hand, the Article 70 (8) (a), as already mentioned, required that the States parties not having yet implemented patent protection for pharmaceuticals and chemical products at the date of entry into force of the agreement, make however possible to file patent applications. These would have been accepted or refused only when the country implemented patent protection.

Article 70 (9) TRIPS established that exclusive marketing rights shall be granted to pharmaceutical inventions even when a member country was availing itself of the transitional periods provided by Article 65. As a result, even if the State was not immediately obliged to provide for patent protection for categories of subject-matter that were excluded,

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breach of Article 63. See Report of the Appellate Body, *India – Patent protection for pharmaceutical and agricultural chemical products,* WTO Doc. WT/DS50/AB/R (adopted Dec. 19, 1997).

[93] On 27 June 2002, to give effect to the Doha Declaration on the TRIPS Agreement and public health, the TRIPS Council adopted a decision extending the transition period for LDCs until 1st January 2016 with respect to the TRIPS' provisions related to patents and to the protection of undisclosed information applicable to pharmaceutical products (IP/C/25). This term was furtherly extended by another decision of the TRIPS Council adopted on 6 November 2015 until 1 January 2033 or until the country in question ceases to be a LDC (IP/C/73). Moreover, as for the general transition period provided by Article 66 (1), it was first extended to 1 July 2021 (IP/C/64) and then to 1 July 2034 (IP/C/88).

it had to provide for exclusive marketing rights for who was filing patent applications. Protection was therefore been given to applicants whose applications could also have been refused at a later time.

In the Indian legal system Section 24 A – B, introduced by the 1999 amendment act to the patent act, incorporated the TRIPS' exclusive marketing rights rule and in addition to it, it also made possible to file a patent application in India for who had already filed for patent for the same invention abroad in a country member of the Convention after the 1st day of January 1995. This appears to represent a derogation from the novelty requirement to obtain patents that was introduced with the aim to compensate the impossibility of applying and obtaining patent protection on pharmaceutical products until then. The provision on exclusive marketing rights was lastly abrogated in 2005, when it ceased to be necessary due to the introduction of patent protection for pharmaceuticals.

In any case, Section 24D which was also part of the 1999 amendment, gave the power to the central government to sell or distribute the invention in question independently or through third parties authorized by it, when deemed necessary and expedient in the public interest and established the government right to determine the selling price of such inventions when justified by the public interest.

An important change brought by the Patent Amendment Act 2002 was the inclusion of microorganisms among patentable subject-matters. In particular, clause j in Section 3 excluded from patentability "plants and animals in whole or any part thereof *other than microorganisms* (…)". For the first time microorganisms were mentioned in the Indian patent legislation as patentable subject-matters in order to make the legislation compliant with Article 27 TRIPS, which requires patent protection for every field of technology. Just before such amendment was approved, the High Court of Calcutta asserted the patentability of a process of preparation of an attenuated live vaccine against bursitis of poultry in the context of *Dimminaco AG v. Controller of patents*[94]. The related patent application had been refused by the Controller of patents on the ground that, in order to be patentable, a process must always result in an *article* or *substance*, and not in a living matter, as in the case in question. Moreover, according to the Controller such process could not be considered as a process of manufacture because in his opinion it was a natural process. By reversing this decision, the High Court of Calcutta held that there was no rule that excluded a living end-

[94] *Dimminaco v. Controller of patents*, High Court of Calcutta, 15th January 2002, *Intellectual Property Law Reports* (IPLR), July 2002, p. 255.

product from the definition of manufacture and that the process in question was a process of manufacture in all respects because it resulted in a product saleable on the market.

Clear similarities can be found between such judgment and that given in *Diamond v. Chakrabarty*[95] by the United States Supreme Court about twenty years before, in 1980. The latter arose from the refusal to grant a patent for *Pseudomonas Putida*, a bacterium developed in laboratory and able to degrade crude oil. In both cases patentability was refused due to the living nature of the object for which patent protection was sought and in both cases the judges were able to propose an extensive interpretation of the notion of patentable invention that was necessary because neither jurisdiction expressly envisaged patentability of microorganisms.

As a matter of fact, in *Diamond v. Chakrabarty*, a living and human-made microorganism was considered to constitute a "manufacture" or "composition of matter" within the meaning of Section 101, Title 35 of the United States Code, and as such it was considered patentable even if such provision did not expressly refer to microorganisms. Moreover, the living nature of the bacterium was considered to be irrelevant for the purpose of its patentability. Similarly, in *Dimminaco v. Controller of patents*, the living nature of the end-product was considered not to compromise its patentability, which in turn was based on the fact that the live vaccine was the saleable object of a process of manufacture.

Another disposition that is worth mentioning is Section 3 of the Indian Patent Act which enlists subject-matters that are not considered as inventions and that, as a consequence, cannot be patented. In particular, the clause (d) before the 2005 amendment excluded from the concept of invention and from patentability "the mere discovery of any new property or new use of a known substance or of the mere use of a known process, machine or apparatus unless such known process, machine or apparatus results in a new product or employs at least one new reactant". The 2005 amendment on the one hand, softened such disposition but at the same time, it made it more incisive, especially as for pharmaceutical inventions. In particular, apart from preserving the exclusion from patentability of the mere use of a known process, machine or apparatus unless it results in a new product or employs at least one new reactant, the new disposition excluded from patentability 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. According to Correa[96], it was possible for India to include such disposition thanks to the lack of definition of the inventive step patentability requirement in

[95] *Diamond v. Chakrabarty,* Supreme Court of the United States, 17th March 1980, 447 U.S. 303 (1980).
[96] See Carlos M. Correa, "Is Section 3(d) Consistent with TRIPS?" *Economic and Political Weekly* 48, no. 32, (2013): 49-51.

the TRIPS agreement (as a matter of fact, neither the novelty and industrial application requirements are defined in the agreement). The Indian parliament was thus able to take advantage of such empty space and approved a disposition whose relevance lies in its ability to prevent the evergreening of pharmaceutical patents, namely, the practice to request and obtain patents on minor developments of pharmaceuticals, ensuring extensions of the normal patent term, in order to delay or bloc competition from generic products. The provision was also the object of the case *Novartis v. Union of India & others*[97], which was decided by the Indian Supreme Court in April 2013 and where the Court confirmed the refusal to grant a patent for a form of an already known compound which did not present any significative enhancement in its therapeutic efficacy.

1.5 The evolution of patent rules in South Africa and their adjustment to international provisions

1.5.1 The patent term and patentable subject-matter

The first law on patent protection in the South Africa united under the British colonial domination was the Patents Designs Trademarks and Copyright Act of 1916. Before then, the different colonies that made up the South African territory had their own patent legislations: the 1860 Cape Patents Act, the 1870 Act of the colony of Natal, the 1887 "De Octrooi Wet" of the Transvaal Colony and the 1907 law on letters patent of the Orange Free State. These legislations were modelled on the laws of the respective colonising powers, the United Kingdom and the kingdom of the Netherlands, and are generally known as "Provincial Patents Acts".

The 1916 Patents Designs Trademarks and Copyright Act, which was based on the 1907 British Patents Act, established a fourteen-year patent term, without prejudice to the possibility to obtain an extension equal to a maximum of seven years or fourteen in exceptional cases, when the court held that the patentee had not been sufficiently remunerated. Afterwards, the natural patent term was brought to sixteen years by the Patents Act 37 of 1952, before being definitively fixed at twenty years by the Patent Act 57 of 1978, which is the law currently in force.

[97] *Novartis v. Union of India & others,* Supreme Court of India, 1st April 2013, 6 Supreme Court Cases (SCC) 1.

The 1916 Patents Designs Trademarks and Copyright Act seems to include from the outset pharmaceutical products among patentable subject-matters. The definition of invention in Section 6 encompassed "composition of matter" along with new and useful art, process, machine and manufacture. Secondly, the Section 25 of the South African Patents Act established patentability of microorganisms similarly to the above analysed Indian provision[98], that is to say by excluding from patent protection "(…) any variety of animal or plant or any essentially biological process for the production of animals or plants, *not being a micro-biological process or the products of such a process."* South Africa is also one of the very few African countries[99] to be part of the Budapest Treaty on the international recognition of the deposit of microorganisms through which the States parties commit themselves to recognize microorganisms deposited in any international depositary authority established by the treaty.

There are two further characteristics of the South African patent system which ultimately deserve attention. In the first place, the South African patent office does not carry out any substantial examination of patent applications, meaning that before granting patents the Company and Intellectual Property Commission[100] (CIPC) does not examine in detail the nature of the invention which is disclosed in the patent application to verify if the invention satisfies patentability requirements such as novelty and inventive step. This actually happens[101] notwithstanding Section 34[102] of the South African Patent Act prescribes examination of patent application. It follows that, even though the South African law mandates substantial patent examination, the exam which is actually carried out does not go beyond the assessment of applications' formal requirements. This would make the South African system a depository patent system, a feature which is often criticized as capable of leading to flawed patents[103].

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[98] Reference is here made to the Section 3 of the Indian Patents Act 1970.

[99] The others are Morocco, Rwanda, Senegal and Tunisia.

[100] The Company and Intellectual Property Commission is the South African patent office.

[101] On the website of the Company and Intellectual Property Commission itself it can be read that "(…) the patent office is not officially performing substantive examination of patent applications, the Office does have limited capacity to identify patent applications that patently do not meet intrinsic and/or extrinsic patentability requirements (…)". See https://www.cipc.co.za/?p=17839 accessed on 15th February 2025.

[102] The provision reads as follows: "*The registrar shall examine in the prescribed manner every application for a patent and every complete specification accompanying such application or lodged at the patent office in pursuance of such application and if it complies with the requirements of this Act, he shall accept it*."

[103] Among the others see Ndlovu, *Why South Africa should introduce patent searches and substantive examinations to improve access to essential medicines,* in *WIPO-WTO Colloquium Papers*, Volume 6, 2015. https://www.wto.org/english/tratop_e/trips_e/colloquium_papers_e/2015/chapter_9_2015_e.pdf

Lastly, the South African patent legislation completely lacks a provision to combat the patent evergreening phenomenon[104] on the model of Section 3(d) of the Indian patent act, that could improve access to critical generic pharmaceutical products.

1.5.2 Working of patents, compulsory licenses and patent revocation

The legal regulation governing compulsory licenses and established by the Section 59 of the 1916 Patents Designs Trademarks and Copyright Act is practically identical substantially, formally and procedurally to the discipline defined by the 1907 British Patents Act (Section 24), with the only significant difference that the South African norm allowed to apply for compulsory license only after two years[105] from the grant of the related patent. Both the South African and the British rule provided that any person could submit an application for compulsory license, or for the patent revocation, by claiming that the public interest with respect to the patented invention was not satisfied. The application would have been either referred to the court by the registrar or the board of trade in case it was well-founded, or if this was not the case, it would have been rejected. Both laws provided for the establishment of two identical legal grounds legitimising granting compulsory licenses for public interest reasons: on the one hand, when failure to manufacture adequately or carry on the patented invention caused prejudice to any new or existing trade or industry in the State or the demand related to the patented invention was not reasonably met; on the other hand, when the conditions imposed by the patentee to the use, purchase or hire of the patented invention caused prejudice to any trade or industry in the State. The practically identical conformity of the two norms on compulsory license was not followed by the adoption of the same standard on patent revocation: in particular, the South African law was completely lacking of a provision on revocation of patents worked outside the territory of the State, which was instead present in the corresponding British law. As a matter of fact, the Section 27 of the British law established that it was possible to apply for the patent revocation after four years from the grant of the patent, when the patented invention was being produced or carried out exclusively or mainly outside the British territory. Such provision was for instance used in March 1909 when the chancery division of the UK High Court of Justice confirmed

[104] See paragraph 1.4.2 *supra.*
[105] Afterwards such term was extended to three years.

revocation of two patents related to the production process of artificial stone slabs that the patentee, named Hatschek[106], commercially exploited in Germany, France and Belgium but not in the United Kingdom. It was held that he used his patents not to establish a new industry in the British territory but to ensure himself a sale monopoly on the articles produced abroad. According to the Court, a new industry could have been established in the United Kingdom if Hatschek had not exercised its rights in the way he did. He particularly granted an exclusive production license to a Belgian company to import in the British territory the articles produced in Belgium. Such exclusive license precluded the possibility of having other licensees directly in the UK.

Since the South African legislation on patents was based on the corresponding British legislation to the point that the discipline of compulsory license was basically the same in both States, the question arises about the reason why the 1916 South African act did not have a provision on the revocation of patents worked outside the territory of the State that recalled the British one. In this respect, it seems interesting the perspective according to which, for the British empire it was desirable to leave foreign patent holders, including the British ones, free to commercially exploit their patents in South Africa without constraints of producing on the territory of the State or of licensing the production to local actors.

The discipline of compulsory license which is currently in force in South Africa was introduced by the Patents Act 57 of 1978, then amended by the Intellectual Property Laws Amendment Act 38 of 1997. It is significantly different both in substantial and procedural terms compared to the 1916 act. Specifically, jurisdiction to decide on the grant of compulsory license passes to the commissioner of patents; secondly, the possibility to order patent revocation in case the compulsory license did not remedy to the patent abuse was removed[107] and the right to oppose the grant of the license was introduced[108]. Not less significantly, the current discipline, in addition to providing for compulsory license in the case of dependent patents[109], bases the grant of compulsory license on evidence of abuse of patent rights which was declined in five types of abuse, then become four after the 1997 amendment. Before outlining such typologies, it seems important to stress that evidence of the abuse must be provided by the applicant of compulsory license.

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[106] See *Hatschek v. Comptroller general,* High Court of Justice of England and Wales (EWHC) – Chancery Division, March 3rd, 4th, and 26th, 1909.

[107] Such possibility was formerly provided by Section 59 (3) of the 1916 Patents Designs Trademarks and Copyright Act.

[108] See Section 56 (3) Patents Act 57 of 1978.

[109] Compulsory licensing for dependent patents is typically applied when it is not possible to use a new invention without infringing a former patent.

Section 56 (2) lists the abuse types, which can be outlined as follows: (a) the failure of the patentee to work the patent in South Africa on a commercial scale or to an adequate extent, after four years from the patent application or three years from the grant and no satisfactory reasons are adduced to justify such failure; (b) the prevention or hindrance to adequate commercial working of the invention due to importation from abroad; (c) the demand related to the patented article is not met to an adequate extent or on reasonable terms; (d) prejudice to an existing or new trade, industry or agriculture due to the patentee refusal to grant voluntary license, and the ensuing need to grant license in the public interest[110]; (e) the demand related to the patented article is satisfied by means of importation and the article price is excessive compared to the price charged by the patentee in other countries.

Judicial interpretation of Section 56 (2) is especially owed to the case *Sanachem (Pty) Ltd v British Technology Group PLC 1992,* which was decided by the Supreme Court of South Africa and in which the South African chemicals company Sanachem was denied compulsory license for a product which had been patented by the multinational British Technology Group. The Supreme Court particularly interpreted the expression "worked" in the Section 56 (2) to mean "exploited" and not "manufactured" so that the working requirement could be met even only through importation and not necessarily through local production. Moreover, as concern the interpretation of paragraph (c) of the section, the Court held that if the patented product was sold by the patentee at an excessive price, the demand was not considered to be met on reasonable terms but the applicant had to provide evidence of public dissatisfaction with the price.

Of significant importance was the interpretation of the expression "public interest", drawn from the British case law in the *Brownie Wireless* case[111], where the expression was interpreted in its widest meaning, including not only the purchasing public but also the community as a whole, which was intended to comprise traders, producers, patentees and licensees as well.

Brownie Wireless was taken as a reference also with regard to the interpretation of the term "prejudice" within the meaning of clause (d) of the Section 56 (2); in particular, the Court stressed that it was not enough to establish that a given entrepreneur was unfairly prejudiced, it must be proved that the trade or industry in question is being affected as a whole.

[110] This was the clause abrogated by the 1997 amendment.

[111] See *Brownie Wireless* (1929) EWHC, 46 RPC 457.

It seems that, rather than adapting the interpretation of such provisions to the local context, the South African judges took the British jurisprudence as a reference and a benchmark from which they did not detach.

1.5.3 Parallel importation: the Medicines and related Substances Control Act

The medicines and related substances control act, enacted in December 1997 by then President of the South African republic, Nelson Mandela, institutionalized and legalized parallel importations of pharmaceuticals. In particular, Section 15C (a) of the act prescribed that the Minister of Health could establish the conditions aimed at providing more affordable medicines in order to protect public health and specifically:

"*(...) determine that the rights with regard to any medicine under a patent granted in the Republic shall not extend to acts in respect of such medicine which has been put onto the market by the owner of the medicine or with his or her consent*"[112];

clause (b) then prescribed that the Minister:

"(…) *may prescribe the conditions on which any medicine which is identical in composition, meets the same quality standard and is intended to have the same proprietary name as that of another medicine already registered in the Republic, but which is imported by a person other than the person who is the holder of the registration certificate of the medicine already registered and which originates from any site of manufacture of the original manufacturer as approved by the council in the prescribed manner, may be imported*.[113]".

The two provisions introduced parallel importations of pharmaceuticals with the purpose of making more affordable pharmaceuticals available to the public in the South African republic at a time when South Africa was the country with the highest percentage of the Human Immunodeficiency Virus (HIV) cases in the world.

The provisions were compliant with Article 6 TRIPS, which let the contracting countries free to regulate autonomously the exhaustion of IPRs issue. In other words, individual states can decide whether to adopt a national exhaustion regime allowing patentees to retain control over the resale of the patented products outside the country's borders, or they can conversely

[112] See Sec. 15C (a) of Medicines and related Substances Control Act 1997.
[113] See Sec. 15(C) (b) *ibid*.

adopt an international exhaustion regime in which the patented product can be freely resold once it is put for the first time on the market in any part of the world.

Since the introduction of Section 15C (a) and (b), the Ministry of Health would have been able to rely on parallel importation determining which pharmaceuticals could be imported, who could import them and the conditions on which importation could occur. The general regulations made in terms of the medicines and related substances act enacted in April 2003 defined how the measures contained in the main act[114] were to be put into practice and particularly established that the importer had to be authorized by a regulatory agency recognised by the Medicines Control Council (MCC)[115] and had to be in possession of a two-year permit issued by the Ministry of Health. Moreover, the importer had to provide the Ministry with documentary proof as to the price at which the medicine would have been sold in South Africa and as to the lowest price at which the medicine was already available in the republic. Lastly, the imported products would have been sold exclusively to the State or to persons authorized to sell medicines under the law[116].

After the introduction of the parallel importation act in 1997, some dozens of pharmaceutical manufacturers which were part of the association of South African pharmaceuticals appealed to the High Court of Pretoria by claiming that the regulation was illegal and unconstitutional. In addition to this, South Africa was inserted by the US in its "watch list"[117] dedicated to countries which were considered not to be in line with their Intellectual Property (IP) protection standards.

The legal dispute initiated by pharmaceutical producers was eventually interrupted in April 2001 and the US criticism weakened after negotiations between the two countries and thanks to the vigourous activist organization Treatment Action Campaign (TAC).

The generic versions of antiretrovirals imported in South African allowed the government to treat twice as many patients[118] for free in public health structures. In the same period two pharmaceutical companies who held patents on a number of antiretrovirals[119] were

[114] "Main act" still means Medicines and related Substances Control Act 1997.

[115] MCC was the regulatory agency of South Africa, which was afterwards replaced by the South African Health Products Regulatory Authority (SAHPRA).

[116] Such provisions were formulated in the Sec. 7 of the 2003 general regulations.

[117] It was established by Sec. 301 of the US Trade Act of 1974.

[118] See Toby Kasper, Davis Coetzee, Francoise Louis, Andrew Boulle, and Katherine Hilderbrand, "Demystifying antiretroviral therapy in resource-poor settings," *Essential Drugs Monitor Issue,* No. 32*,* 2003: 20-21*,* https://core.ac.uk/download/pdf/9416789.pdf

[119] In particular, GlaxoSmithKline held patents on AZT, branded as Retrovir, Lamivudine, branded as 3TC and AZT/Lamivudine branded as Combivir, while Boehringer Ingelheim held patents on Nevirapine, branded as Viramune

successfully accused of abuse of dominant position[120] in front of the South Africa Competition Commission and had to license their patents to local generic manufacturers.

In 2016 the Universal Test and Treat (UTT) was implemented and it consists in providing antiretroviral treatment on a universal basis to anyone having contracted the virus irrespective of the CD4 cells[121] count which was previously used to administer the therapeutic treatment[122].

To conclude, parallel importation of pharmaceuticals was part of a wider project initiated in South Africa in 1994 and known as National Drug Policy (NDP). The policy was aimed, among the other things, at promoting the availability of safe and effective medicines at the lowest possible cost through the promotion and use of generic medicines[123] and more transparency and equity of the pricing system. Another objective was the promotion of local production of pharmaceuticals and their exportation to neighbour countries.

[120] See *Hazel Tau & others v. GlaxoSmithKline, Boehringer Ingelheim & others.* (2002) South African Competition Commission

[121] HIV typically attacks and destroys CD4 cells in the human body, which are essential to combat bacteria, viruses and other organisms.

[122] Before UTT was implemented, antiretroviral therapy was administered to who had a number of CD4 lower than 200 cells/ml, increased to 350 cells/ml and extended to pregnant women in 2010.

[123] As a matter of fact, the 1997 medicines and related substances control act introduced compulsory generic substitution as well. Sec. 22 (F) established the obligation for pharmacists to dispense the equivalent generic drug instead of the drug prescribed by the doctor, unless expressly prohibited.

Chapter 2

2. Compulsory Licenses: the international framework and use of the instrument across world countries

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2.1 Origin and structure of compulsory license in international law

Exclusive rights conferred by patents normally give to their owners a twenty-year monopoly on the use of the patented invention. At the European level, such rights have been defined in the articles 29 and 30 of the Community Patent Convention (CPC)[124] and include the exclusive right of "making, offering, putting on the market or using a product which is the subject-matter of the patent, or importing or stocking the product for these purposes[125]". In this framework, compulsory licenses represent one of the instruments in theory aimed at mitigating the impact of the patent monopoly, when necessary, e.g. when the price of pharmaceuticals hinders medicine supplies in countries having limited economic and financial resources. More practically, a compulsory license can be defined as an authorization given by a national authority, to produce, import and sell a patented invention during the patent term without the patentee's consent. One of the first examples of such norm appeared in the 1883 Patents, Designs and Trade Marks Act of the United Kingdom, whose Section 22 provided for the granting of a mandatory license when the patent was not worked in the UK, or it impeded to satisfy the reasonable needs of the public, or when anyone was hindered to work its own invention or to make the best use of it. The "ratio" of the rule lay in the protection of the national industry to avoid that foreign inventors could damage the British market related to a certain industrial sector[126] by refusing to grant license to someone operating in UK.

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[124] Although it was never ratified, the Community Patent Convention (CPC), represents a significant document as the norms and principles contained therein are applied in the European patent law and form part of important international agreements, such as for example, the Unified Patent Court Agreement (UPCA).

[125] See Article 29 (a) CPC.

[126] See J. E. Crawford Munro, *The Patents, Designs, and Trade Marks Act, 1883 (46 & 47 Vict. C. 57) with the Rules and Instructions together with pleadings, orders, and precedents,* (London: Stevens and Sons, 1884), 33-34. The author specifies that when the second reading of the bill was introduced by the chairman of the Board of Trade, it was explained that the purpose of Section 22 was to protect the national industry. More specifically, the chairman referred to a memorial by representatives of the chemical sector stressing that before the Section's adoption, it would have been possible for a foreign inventor to destroy an entire industrial sector in UK by simply refusing to license, as it happened to a certain manufacture of coal products which was completely brought from UK to Germany.

As it has been mentioned in paragraph 1.3.2, at the international level a provision on compulsory licensing was for the first time introduced in the Hague 1925 revision of the Paris Union Convention for the protection of industrial property. Here, the norm on compulsory license replaced the more severe measure of "patent forfeiture" to remedy to the abuse of patent rights, such as in the case of failure to work the invention. The rule[127] established that compulsory license, as well as other legislative measures aimed at preventing patent abuses, could not be issued earlier than three years from the patent date and only if the patentee had not justified its inaction. *Patent forfeiture* was not totally cancelled but was limited to cases in which a compulsory license had not proved sufficient to prevent a patent abuse. Lastly, the 1958 Lisbon revision of the convention provided that compulsory licenses had to be non-exclusive and that they could not be transferred without the undertaking transfer.

Gradually, provisions on compulsory licensing began to be adopted in a growing number of countries and on an increasing number of grounds. In fact, other than failure to work, such grounds began to include the public interest protection and the need to remedy to anticompetitive practices. Entered into force in 1995, the TRIPS Agreement introduced a new range of constraints to be met when granting a compulsory license. Such constraints represent the normative content of Article 31 which is leant toward the restriction of the instrument use rather than its facilitation and has been drafted with the purpose of conferring a solid protection to patent holders. Delving into the norm structure, firstly the use of the license is subordinated to a prior attempt by the license applicant to obtain a voluntary license from the patentee "on reasonable commercial terms"[128]. The meaning of such formulation is not defined in the agreement but a derogation from the prior attempt is established for cases of national emergency or other circumstances of extreme urgency, for cases of public non-commercial use[129] and finally, in the circumstance in which compulsory license is granted to remedy to an anticompetitive practice[130]. A further limitation to compulsory licensing was inserted for the semiconductor sector in order to protect patent holders in such a strategic area for the national interest of many advanced countries. In fact, paragraph (c) of Article 31 limits the granting of the license for semiconductors only to cases of public non-commercial use and to remedies in competition law cases.

[127] See Article 5 of Paris Convention.
[128] See Article 31 (b) TRIPS.
[129] *Ibid.*
[130] See Article 31 (k) *ibid*.

Significantly, paragraph (f) of Article 31 restricts the use of compulsory licensing for the purpose of supplying the domestic market of the country where the license is granted. Such normative decision was due to the willingness to protect patentees from unfair competition that could result from massive exports aimed at obtaining competitive advantages on international markets. Paragraph (g) states that compulsory license is subjected to its termination as soon as the circumstances that have led to its granting cease. According to Correa[131], this represents a heavy burden upon the licensee, that can see its right to use the invention terminated at any time and especially when the company efficiency in the invention production increases. As a result, companies can be discouraged in applying for the license. Furthermore, each granting of compulsory license shall be considered on its individual merits, its scope and duration shall be limited to the purpose for which the license was granted and the patentee shall receive an adequate remuneration considering the economic value of the authorization[132]. Lastly, paragraphs (i) and (j) provide for the possibility to subject the license and the related remuneration to judicial review.

2.1.2 The Doha Declaration on the TRIPS Agreement and Public Health and Article 31 bis

The restriction on the use of compulsory licensing exclusively for supplying the domestic market, which is set out in the paragraph (f) of Article 31, even though necessary to avoid the uncontrolled diversion of the products to other markets, was also considered as the denial of an opportunity from which LMICs could benefit in order to provide their citizens with health care otherwise unaffordable. In this respect, on the occasion of the Doha Declaration on the TRIPS Agreement and public health of 2001, the WTO Ministerial Conference acknowledged the difficulty of using effectively the compulsory license instrument under the TRIPS terms and instructed the Council for TRIPS to find an expeditious solution to such issue. As a result, a derogation to the paragraph (f) constraint was introduced through the insertion of article 31 *bis,* which essentially established that compulsory licenses could be granted with the purpose of producing and exporting pharmaceuticals products to countries with insufficient productive capacities in the pharmaceutical sector, denominated *eligible importing members*[133]. In other words, article 31 *bis* introduced a new system for granting

[131] See Carlos Maria Correa, *Intellectual Property Rights and the use of compulsory licenses: options for developing countries* (South Centre, 1999): 8.
[132] See paragraphs (a), (c), (h) of Article 31 TRIPS.
[133] Paragraph 1 (b) of the Annex to the TRIPS Agreement defines *eligible importing members* as any Least-Developed Country (LDC) member and any other member that has made a notification to the Council for

compulsory licenses in the special circumstance described above. The system is linked to a specific procedure which is often described as complex and burdensome and that is expressed in the paragraph two of the agreement's annex. Such procedure involves a notification to the Council for TRIPS by the importing country specifying the quantity of product needed and confirming not to have sufficient manufacturing capacity in relation to the product in question. The notification must also indicate that the State has granted, or is willing to grant, a compulsory license in the case that there are valid patents covering the product in the State[134]. On the other hand, the exporting country must establish the compulsory license only to be valid for the quantity of product sufficient to satisfy the importing country's need[135]. The exporting country must also ensure that the products are identified through specific labelling and packaging that clarify the purpose of such exportation[136], in order to avoid that the products are exported for other purposes. Furthermore, before the shipping takes place the licensee must publish on-line a series of information, among which there are the quantities supplied to each destination and the distinctive characteristics of the products[137]. Lastly, the exporting country must notify to the Council for TRIPS the compulsory license granting, specifying the licensee's name and address, the name and quantity of the licensed product and the countries that will be supplied during the validity period of the license[138].

Article 31 *bis* was used only once between 2007 and 2009 for the exportation from Canada to Rwanda of Apo-Triavir, a generic antiretroviral against HIV/AIDS, which was produced by the Canadian generic company Apotex. More specifically, in July 2007 Rwanda notified the Council for TRIPs its intention to import 260.000 packs of Apo-Triavir from Canada, retaining the option of modifying the needed quantity at a later stage. Afterwards, Apotex applied to the Canadian government for a compulsory license under the terms of Canada's Access to Medicines Regime (CAMR)[139] so that the exportation could occur within the

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TRIPs of its intention to use the system as an importer, except for those members which have stated that they will not use the system such as Australia, Canada, those belonging to the European Community, Iceland, Japan, New Zealand, Norway, Switzerland and the United States, and members which have stated that if they use the system it would be no more than in situations of national emergency or other circumstances of extreme urgency.

[134] See sub-paragraphs (i), (ii), (iii) of paragraph 2 (a) Annex to the TRIPS agreement.

[135] See sub-para. (i) of para. 2 (b) *ibid.*

[136] See sub-para. (ii) of para. 2 (b) *ibid.*

[137] See sub-para. (iii) of para. 2 (b) *ibid.*

[138] See para. 2 (c) *ibid.*

[139] Passed in May 2004, the act denominated "An Act to amend the Patent Act and the Food and Drugs Act (The Jean Chrétien Pledge to Africa*"* established the legal framework for the so-called CAMR, which by incorporating article 31 *bis* TRIPs, introduced a special regime for the exportation from Canada of generic versions of pharmaceuticals and medical devices in Developing and Least-Developed Countries lacking

framework of article 31 bis TRIPS. The Canadian government rapidly notified to the Council for TRIPS its intention to use article 31 *bis* and granted compulsory license within two weeks of Apotex's application[140]. With the purpose of winning the tender for the antiretroviral procurement and in order to prevail over the more advantageous offer of Indian generic companies, Apotex had to lower the price that it initially planned[141]. The first shipment took place in May 2008 and was eventually supplemented by two further shipments in September 2008 and September 2009[142].

The article 31 *bis* system has generally been criticized for the length and complexity of its underlying procedure. On the side of the exporting country, the obligation to attempt to negotiate a voluntary license before applying for the compulsory one has been considered as the reason of delays that could otherwise be avoided and, in addition to it, the need to differentiate the exported products through specific labelling and packaging would make the burden borne by the licensee quite heavy[143]. What seems to be even more relevant is the economic sustainability of the whole transaction from the point of view of the exporting pharmaceutical company. As a matter of fact, the price level of the product has to be low in order to match the financial capacity of the importing country. For this reason, the system seems to be more suitable in circumstances of high sales volumes, where in spite of reduced margins on each unit sold, profit would still be significant thanks to the large quantity of product being sold[144]. On the other hand, from the importing country's point of view, the obligation to specify the needed product quantity *ex ante* and the absence from the framework of article 31 *bis* of a mechanism to modify such quantity at a later stage would

pharmaceutical manufacturing capacity, especially with respect to medicines for the treatment of HIV/AIDS, malaria and tuberculosis.

[140] For a detailed reconstruction of the Canadian use of article 31 *bis* in the context of the exportation of antiretrovirals to Rwanda see Tolulope Anthony Adekola, "Has the Doha Paragraph 6 system reached its limits?," *Journal of Intellectual Property Law & Practice* 15, No.7 (2020), https://doi.org/10.1093/jiplp/jpaa058

[141] *Ibid.*

[142] *Ibid.*

[143] For a complete overview on the weaknesses of the article 31 *bis* system see Ezinne Miriam Igbokwe & Andrea Tosato, "Access To Medicines and Pharmaceutical Patents: Fulfilling the Promise of TRIPs Article 31bis," (faculty publication, University of Pennsylvania, 2022), https://scholarship.law.upenn.edu/faculty_scholarship/2802/

[144] In this respect, in order to harness economies of scale paragraph 3 of article 31 *bis* allows to derogate from paragraph (f) and use compulsory licensing to export a pharmaceutical product in more Developing or Least-Developed Countries which are part of the same regional free-trade agreement concluded within the WTO framework. Igbokwe & Tosato (*ibid.)* suggest that such provision should trigger pooled procurement strategies for satisfying collective needs of Developing Countries being part of the same regional free-trade agreement. In particular, importing states might aggregate their demand to make their request more attractive for pharmaceutical companies, which could in turn benefit from high-volume low-margin orders.

require to make an assessment which could subsequently change if the needed quantity increases[145].

Notwithstanding the article 31 *bis* system is an undoubtedly complex apparatus which entails a burdensome bureaucratic procedure, which can be economically unfeasible and that needs to be supported from a strong political willingness to be implemented, it has been underlined that it remains a viable option[146] to improve access to essential medicines, especially after the TRIPS Agreement undermined the possibility to produce and export generics even from historic generic supplying countries such as India[147]. Significantly, many diseases still lack generic alternative medicines from which poor countries could benefit[148].

Still on the subject of the Doha Declaration, in addition to having led to the introduction of article 31*bis,* it was also important because it clarified that each WTO member State has the right to determine freely the grounds upon which compulsory license shall be granted[149]. Similarly, it specified that each member has the right to determine what constitutes a national emergency or other circumstances of extreme urgency, it being understood that public health crisis such as HIV/AIDS may fall under this definition[150].

The freedom of the TRIPS' contracting States to autonomously determine the grounds on which compulsory licenses can be granted is in theory limited by article 27 (1)[151] TRIPS. This in fact provides that patents shall be granted irrespective of whether they are locally produced or imported. As a consequence, failure to work the patented invention, when intended as production on the national territory[152], would not be a sufficient ground to derogate from the exclusive rights conferred by a patent through the granting of a compulsory license. Such interpretation is however not unanimous, Correa[153], for instance, highlighted that the reading of the provision is debatable, especially because article 27 is counterbalanced by articles 7 and 8 of the TRIPS Agreement. Such articles establish that the

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[145] *Ibid.*

[146] Adekola, "Doha Paragraph 6 system," 527.

[147] Even though India remains one of the major exporters of generic medicines, there is some evidence of a shifting trend of the country's pharmaceutical industry from the production of generics to the production of innovative pharmaceuticals. On this recent observed trend of the Indian industry to focus on innovative pharmaceuticals see Varun Mahajan, D.K. Nauriyal, and S.P. Singh, "Domestic market competitiveness of Indian drug and pharmaceutical industry," *Review of Managerial Science* 14, (2020): 519-559, https://doi.org/10.1007/s11846-018-0299-7

[148] Adekola, "Doha Paragraph 6 system," 528.

[149] See paragraph 5 (b) of the Doha Declaration on the TRIPs agreement and public health.

[150] See paragraph 5 (c) *ibid*.

[151] Article 27 (1) TRIPS reads as follows: "(…) *patents shall be available for any inventions, whether products or processes, in all fields of technology, provided that they are new, involve an inventive step and are capable of industrial application* (…)"

[152] For a discussion about the interpretation of "failure to work" refer to the para. 1.3.2 in Chapter I of the present work.

[153] Correa, *Intellectual Property Rights*, 9.

protection of intellectual property has to take into consideration the transfer and dissemination of technology "in a manner conducive to social and economic welfare[154]" and that contracting States can adopt the measures that are necessary to protect public health and promote the public interest in the most vital sectors for their development[155]. Bearing this in mind, failure to work would be legitimate ground for granting compulsory licenses.

2.2 Implementation and use of compulsory license in the three case-studies

2.2.1 Compulsory licensing in Brazil: a leveraging tool and the Efavirenz case

In Brazil the threat to grant compulsory license has been an effective mean of exerting pressure over pharmaceutical companies in order to obtain price reductions on antiretroviral medicines against HIV/AIDS. Exhausted the means of threat, Brazil granted its first compulsory license in May 2007 for the antiretroviral active ingredient Efavirenz. As early as the late 1990s Brazil began to express dissatisfaction for the pricing policies applied by pharmaceutical multination companies. Article 71 of the 9279/1996 act[156], combined with Brazilian industrial manufacturing capacity, allowed the country to use credibly the threat to issue compulsory licenses. In particular, article 71 provided for the possibility to grant *ex-officio* a provisional non-exclusive license for the exploitation of a patented invention without the patentee's consent, in cases of national emergency or public interest, declared by act of the federal executive power. Secondly, Brazil had a solid industrial production capacity in the pharmaceutical sector, which was developed in the years before 1996, before that the prohibition to grant patents for pharmaceutical products was revoked. Before then, the country was already active in the production of antiretroviral generic medicines against HIV/AIDS[157]. Moreover, the national pharmaceutical laboratory Farmanguinhos had been able to provide the government with reliable estimates about the acceptable and economically viable scale of prices of antiretrovirals[158], thanks to which it was possible to make admissible price reduction requests. In August 2001 the minister of health José Serra

[154] See Article 7 TRIPS.
[155] See Article 8 TRIPS.
[156] The act 9279/1996 was examined in paragraph 1.3 of the present dissertation.
[157] See Juana Kweitel & Renata Reis, "A primeira licença compulsória de medicamento na américa Latina" *PONTES* 3, No. 3 (June 2007): 26-28.
[158] William C.V. Rodrigues and Orenzio Soler, "Licença compulsória do efavirenz no Brasil em 2007: contextualização," *Revista Panamericana de Salud Pública* 26, No. 6 (2009): 554.

announced that Brazil was going to grant compulsory license for Nelfavir, an antiretroviral against HIV/AIDS which had been patented by the multinational pharmaceutical company Roche. After such announcement, the company accepted to offer the medicine at a price reduced by 40% compared to the original price. In December 2003 another threat to issue compulsory license on the same medicine caused a further price reduction. Moreover, the price of other four antiretrovirals was reduced as well, they were Tenofovir, Atazanavir, Lopinavir and Efavirenz[159]. In June 2005 the Brazilian president announced its intention to grant compulsory license for the pharmaceutical combination Lopinavir/Ritonavir, which was patented by the pharmaceutical multinational company Abbot with the trade name *Kaletra*. The announcement led to subsequent negotiations between the two parties and to a price reduction which satisfied the government, as a consequence the compulsory license was not granted[160].

Eventually, the first compulsory license was granted with decree number 6108 of May 4th 2007, after unsuccessful negotiations for obtaining from Merck a price reduction of the antiretroviral Efavirenz. More specifically, the decree established the granting of a non-exclusive compulsory license for government use and for the public and non-commercials use of the patents covering Efavirenz. It further provided that the medicine would have been used in the context of the national AIDS programme which consisted in the provision free of charge[161] by the health national system of antiretroviral medicines to HIV patients, under the terms of the act number 9313 of November 13th 1996. Significantly, article 3 of the license decree stated the patentee's obligation to put at the disposal of the Ministry of Health the information necessary to the effective reproduction of the medicine. Efavirenz was eventually imported from India at a cost of $0,45 per 600 mg pill and with a royalty of 1,5% of the value of the imported generic medicine to be paid to the patentee[162]. The Indian exporting generic companies were Aurobindo e Ranbaxy and it was estimated that the purchase of Efavirenz generic versions led to a price reduction between 65,6% to 71,3% of the total annual cost incurred for the treatment of patients[163]. As of March 2009, the national laboratory Farmanguinhos started to produce Efavirenz and to supply the Health Ministery determining Brazil's self-sufficiency. The compulsory license was renewed in May 2012 for a further five years.

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[159] See Regina Ferro do Lago & Nilson do Rosário Costa, "Dilemas da política de distribuição de medicamentos antirretrovirais no Brasil," *Ciência & Saúde Coletiva* 15, No. 3 (2010): 3533.
[160] *Ibid.*
[161] See art. 1, law n. 9313 of 13th November 1996.
[162] Ferro do Lago & do Rosário Costa, "Dilemas da política", 3533.
[163] Rodrigues & Soler, "Licença compulsória", 556.

2.2.2 The Indian Nexavar case: the importance of availability and affordability of medicines on the territory

The only case which involved a compulsory license granted for a pharmaceutical product in India concerns the medicine Sorafenib for the treatment of kidney and liver cancer, patented by the German multinational pharmaceutical company Bayer in March 2008 and marketed under the name Nexavar.

In June 2010 the Indian generic pharmaceutical company Natco Pharma unsuccessfully approached Bayer for a voluntary license for the production of Sorafenib. After the six months period required by Indian law[164] before it is possible to apply for a compulsory license expired, Natco applied to the Controller of patents[165] for a compulsory license for Sorafenib. It legitimised its application on the ground of Section 84 (1) (a), (b) and (c) of the Indian patent act, according to which a compulsory license can be requested when (a) the reasonable public demand related to a patented invention is not satisfied; (b) the patented invention is not available to the public at a reasonably affordable price; and (c) the patented invention is not worked on the Indian territory. On 9th March 2011 the Controller of Patents accepted the application and granted compulsory license with a royalty rate of 6% of Natco's net sales value to be paid quarterly to the patentee. As a consequence, Bayer challenged the license before the High Court of Judicature of Bombay which dismissed the writ petition. Then, again Bayer challenged the compulsory license before the High Court of Delhi which refused the appeal. Afterwards, Bayer filed a notice of opposition under Section 87 (2) of the Indian Patent Act to the Controller, that however refused its argument[166]. More specifically, Bayer claimed that the public demand related to Sorafenib was satisfied by the company itself and by the Indian generic producer Cipla, that in the meantime had been sued by Bayer for patent infringement. According to the Controller, the uncertain supply of Sorafenib by Cipla, which among the other things was an alleged infringer at the time, could not be considered in the decision on the granting of Sorafenib compulsory license as such

[164] Section 84 of the Indian Patent Act states that the Controller of patents shall take into consideration efforts made by the license applicant to obtain a voluntary license from the patentee on reasonable terms and particularly clarifies that a reasonable period of time for such negotiations shall not exceed six months. The Indian jurisdiction is one of the few having regulated how long such period shall last, an aspect which is particularly important to regulate with the purpose of avoiding that patentees can strategically prolong negotiations to delay the compulsory license process.

[165] Within the meaning of Section 84 (1) of the 1970 Indian Patent Act, compulsory license applications have to be submitted to the Controller of Patents.

[166] See the decision of the Controller of Patents related to the Compulsory License application n. 1 of 2011, p. 20, https://patentdocs.typepad.com/files/compulsory-license-application.pdf

decision "*involves the lives of cancer patients, which in my opinion cannot be left to the uncertainties of legal proceedings*"[167].

Furthermore, among the points underlined in the Controller's decision, there was the fact that from data related to the years 2009 and 2010, just an insignificant quantity of the medicine had been made available to the public. During those years in India there were 20.000 liver cancer patients and about 8.900 kidney cancer patients, according to the estimates mentioned in the decision. In the controller's opinion, Bayer unjustifiably made Sorafenib available to the public through importation to little more than 2% of the Indian patients[168] and notwithstanding it was active in selling the medicine in other parts of the world starting from 2006. Moreover, the Controller found that the provision referred to in the Section 84 (7) (a) (ii) according to which the reasonable requirements of the public are not satisfied when the demand related to a patented invention has not been met to an adequate extent or on reasonable terms was undoubtedly applicable to the case in question.

The above-mentioned facts would have been sufficient to lead to the granting of a compulsory license for Sorafenib but there was a further issue contributing to the effective granting: the price issue. In fact, pursuant to Section 84 (1) (b), as recalled above, one of the grounds on which a compulsory license request can be legitimate is the situation in which the patented invention is not available to the public at a reasonably affordable price. In particular, the price at which Bayer was selling Nexavar[169] amounted to approximately 280.000 rupees[170] per treatment per month, which clearly was not considered as an affordable price by the controller. Lastly, as concerns the ground that the patented invention was not worked on the Indian territory referred to in Section 84 (1) (c), after careful consideration the Controller concluded that Sorafenib was not effectively worked on the Indian territory so that the above-mentioned compulsory license requirement was satisfied. Since the Indian patent act did not provide for a definition of the expression "worked on the Indian territory", the Controller decided to refer to the international patent treaties and conventions in force.

In his argument a precise interpretation of article 5 (A) (1) and (2) of the Paris Convention can be observed. The first paragraph of the article states that importation of a patented invention by the patentee from one to another of the Union countries where the invention is patented shall not entail the patent revocation. Then, the second paragraph establishes that

[167] *Ibid.* p. *21*
[168] *Ibid.* p. 22
[169] It is here recalled that Nexavar is the trade name for the active ingredient Sorafenib.
[170] 280.000 rupees are equivalent to little more than 3.000 euros.

each Union country is free to adopt legislative measures providing for compulsory licensing in order to prevent patent abuses, such as for example "failure to work". It follows that importation of the patented invention can legitimise the granting of a compulsory license, a measure which is slighter and less severe than the patent revocation. On closer examination, the Indian national provision contained in Section 83 (b) of the Indian Patent Act provides that patents are not granted merely to allow patentees to benefit from importation monopolies for patented products[171]. It leaves no room for doubt and supports the Controller's decision in this compulsory license case, that the mere importation of the patented article cannot be considered as its working on the Indian territory. Among other things, the entire Section 83 of the Indian Patent Act is dedicated to principles and objectives of technologic innovation promotion and of technology transfer and dissemination. Objectives that cannot be reached, in the Controller's opinion, without the production of inventions on the Indian territory. In conclusion, the expression "to work the invention" does not indicate its importation but the patentee has to produce it on the Indian territory so that the invention can be truly worked in India.

In granting the license, the Controller also established that the price of the product of the licensee Natco did not have to exceed the price of 8.880 rupees for a 120 pills pack and that the company had to supply the medicine free of charge to at least 600 needy patients annually.

2.2.3 South Africa: effective patent licensing within the competition law framework

In South Africa the compulsory licensing provisions which are part of the national patent law have never been used[172]. Instead, patent licenses have been granted several times as

[171] The provision specifically reads as follows: "Without prejudice to the other provisions contained in this Act, in exercising the powers conferred by this chapter, regard shall be had to the following general considerations, namely (…) that they (patents) are not granted merely to enable patentees to enjoy a monopoly for the importation of the patented article; (…)".

[172] Hostility of the international pharmaceutical industry as well as coercive actions by the United States can be considered among the main reasons why such patent law provisions have never been used in the country. In this respect, it should be remembered that in April 1997 the United States Trade Representative (USTR) sent a missive to the South African United Nations representative in order to investigate about the use of compulsory licensing in South Africa and on the implementation of the TRIPS Agreement by the country. Shortly afterwards, on 1st May 1998 the United States government, prompted by the Pharmaceutical Research and Manufacturers of America (PhRMA), placed South Africa in its Special 301 Watch List, as retaliation against amendments contained in the South African *Medicines and Related Substances Amendment Act, 1997 (Act No. 90 of 1997),* which among other things established measures for the supply of more affordable medicines and for the licensing to compound, dispense or manufacture medicines.
For a more detailed overview on the subject, see Heinz Klug, "Access to Medicines and the Transformation of the South African State: Exploring the Interactions of Legal and Policy Changes in Health, Intellectual

judicial remedy against anti-competitive practices in order to protect the public interest with respect to pharmaceuticals. Such cases represent an eminent example of how competition law can be used to defend the right to health and improve access to medicines. One of the most important is *Hazel Tau & others v GlaxoSmithKline, Boehringer Ingelheim & others* decided in 2002, it originated from a complaint before the South African Competition Commission, filed by a group of HIV/AIDS patients, doctors and several organizations. The group accused two pharmaceutical companies GlaxoSmithKline (GSK) and Boehringer Ingelheim to charge an excessive price on the antiretroviral medicine that they produced and by doing so to abuse of their dominant position in breach of section 8 (a) of the South African Competition Act[173]. The two pharmaceutical companies held patents respectively on azidothymidine (AZT), lamivudine, AZT/lamivudine and on nevirapine and were also accused of causing premature and preventable death of people living with AIDS by way of the high prices they charged. The companies' dominant position was determined as in the South African market there were not alternatives to the branded versions of the above-mentioned medicines produced by GSK and Boehringer Ingelheim, nor they could be substituted by other typologies of antiretrovirals. The two companies had previously refused to grant voluntary licenses to local generic producers for the production of antiretrovirals intended for the local market. The Competition Commission decided that GSK and Boehringer Ingelheim had abused of their dominant position for charging an excessive price pursuant to Section 8 (a) of the Competition Act, for refusing to grant access to an essential facility to competitors in according with paragraph (b) of the section, and lastly for having engaged in an exclusionary conduct, pursuant to paragraph (c). As a consequence, the Commission referred the case to the Competition Tribunal, requesting to authorize any person to the use of the patents in question with the purpose of making available on the market generic versions of the medicines in question in exchange for the payment of reasonable royalties. The case did not eventually arrive to the Competition Tribunal because the two companies concluded two different settlement agreements with the Competition Commission in which they committed to grant licenses to generic producers with a royalty not exceeding 5% of net sales of the medicines. Moreover, the two agreements also provided that generic producers could export the antiretrovirals generic versions in other countries of Sub-Saharan Africa and to import the generic versions for distribution within the State whether they had not the necessary manufacturing capacity to produce them in South Africa.

Property, Trade, and Competition Law in the Context of South Africa's HIV/AIDS Pandemic," *Law & Social Inquiry* 37, No. 2 (2012), https://doi.org/10.1111/j.1747-4469.2011.01268.x

[173] The norm prohibits excessive pricing to the detriment of consumers by undertakings in dominant position.

Even if the licenses deriving from such settlement agreements are technically voluntary licenses, it should be considered that the two pharmaceutical companies would have never accepted to grant them in the absence of the Competition Commission's decision. For this reason, such licenses could certainly be considered as non-voluntary licenses[174].

This case does not only represent an effective example of the way in which competition law can contribute to the improvement and expansion of access to medicines but it also affirmed the important principle that even when considering high production costs, high R&D costs and an adequate profit rate for the pharmaceutical industry, prices charged for antiretrovirals can be unjustified. In fact, the group of complainants was able to prove the excessive level of the charged prices through the cost-based approach used other times by the Competition Commission. Such approach takes into consideration production costs with the addition of a normal profit margin for the sector.

A few years later, in 2007 the TAC activist organization[175] filed a complaint before the Competition Commission against the multinational company Merck and its South African subsidiary MSD which held a patent on the antiretroviral Efavirenz. Starting from 2001 and for a significantly long period Merck negotiated with the human rights organization "AIDS Law Project" (ALP), which was trying to obtain licenses on reasonable terms for the local production and importation of Efavirenz. In such period, the company refused to grant a license to two generic producers but actually decided to license some local companies[176] on unreasonable conditions, they in fact either failed or were not able to bring the product to the market before 2008. In the meantime, notwithstanding several pharmaceutical companies around the world were able to produce Efavirenz at a significant lower price, in South Africa its price was still far higher than the price of the other two medicines composing the therapy for AIDS. The complainants accused Merck of abuse of dominant position before the Competition Commission because of its refusal to grant license to generic producers on reasonable terms. As a matter of fact, the Efavirenz generic versions as well as combination products containing Efavirenz and at least one additional active ingredient, could not accede the market. During the proceeding, the TAC organization clarified that the complaint would have been withdraw if licensing agreements along the lines of those reached in *Hazel Tau*

[174] See Atangcho N Akonumbo, *Intellectual Property, Trade, Human Rights and Access to medicines in Africa: A reader* (Pretoria University Law Press – PULP, 2022), 267.

[175] See paragraph 1.5.3 in the first chapter of the present work.

[176] They were the Joint-Venture Thembalami Pharmaceuticals which failed before trading Efavirenz, the local producer Aspen Pharmaceuticals that started to market the product only in 2008 and of the local company Adcock Ingram. For more detailed information, see the quarterly magazine published by the Office of the Commissioner of the South African Competition Commission "*Competition news"* edition 49, June 2014, p. 18, available at: https://www.compcom.co.za/wp-content/uploads/2020/02/Competition-News-Edition-49.pdf

had been concluded; and indeed, the case was closed when Merck granted a license to four generic companies for marketing Efavirenz and co-packaged products including Efavirenz in South Africa and other countries of southern Africa. Given this development, the Competition Commission announced that the case had not been referred to the Competition Tribunal. The licenses had a major impact on the price of Efavirenz and the State was able to procure the medicine for half the price at which it bought it before the complaint was filed. Other cases in which the application of competition law led to the granting of production and importation licenses to generic companies, and therefore to reductions on the price of medicines, concerned conditions set by the Competition Commission and the Competition Tribunal for the approval of some mergers. In July 2000 the Competition Tribunal approved[177] a merger between Glaxo Wellcome Plc and SmithKline Beecham Plc, on the condition that the two merging parties would grant license for some of the medicines produced by them. The merger had previously been prohibited by the Competition Commission because of the high market shares that the new resulting merged entity GlaxoSmithKline would have held in respect of three therapeutic categories: antiretrovirals, topic antibiotics and anti-ematics. In order for the merger to be approved, the Competition Tribunal requested the granting by the merged entity of licenses for one pharmaceutical product for each of the therapeutic categories of anti-ematics and antiretrovirals and of three pharmaceutical products in the topic antibiotics category[178].

A similar case regarded the conditions established by the Competition Commission for the approval of the merger between GSK and the South African generic producer Aspen Pharmacare. In February 2009 Aspen notified to the Competition Commission its intention to absorb the South African subsidiary of GSK, pursuant to the Section 13 of the Competition Act. In turn, the multinational GSK would have become the largest shareholder of Aspen, owing 16% of its share capital. Overall, the Commission's assessment on the merger did not detect the risk of anticompetitive market alteration, with the only exception of the production and marketing of the antiretroviral Abacavir, which was supplied exclusively by GSK on the South African market. As a consequence, GSK concluded licensing agreements with five generic companies[179] for the production and importation of Abacavir. Once satisfied for GSK's commitments, the Competition Commission approved the merger provided that the licensing agreements were effectively implemented and that the use of Abacavir was

[177] See Competition Tribunal of the Republic of South Africa, 28th July 2000, Case Number: 58/AM/May00.
[178] In particular, Granisetron for the anti-ematics therapeutic category, Famciclovir for the antiretrovirals category and Polysporin, Cicatrin and Neosporin in the topic antibiotics category.
[179] They were Adcock Ingram, Biotech Laboratories, Cipla Medpro, Feza Pharmaceuticals and Ranbaxy.

possibly licensed also to other interested companies on terms no less favourable than those granted to the five generic companies.

The enforcement of competition law in South Africa has continued to have a positive effect on access to pharmaceuticals over the last few years. On September, 15th 2023 the Competition Commission announced[180] to initiate a complaint against the multinational pharmaceutical company Johnson & Johnson (J&J) and its South African subsidiary Janssen Pharmaceutica on the ground that they may have engaged in abuses of dominant position in the form of exclusionary practices and excessive pricing, in respect of Bedaquiline, commercialized as Sirturo ®, a medicine used in the treatment of tuberculosis. As a matter of fact, J&J had tried to extend the lifespan of its patent to 2027 on Bedaquiline by filing for a secondary patent[181] to the CIPC[182], risking to impede the access of generic medications in the market and charging an excessive price. Only a few days after the initiation of the complaint and in particular on 29th September 2023, J&J publicly announced[183] that it would have not enforced its patents on Bedaquiline in 134 middle and low-income countries, including of course South Africa. After this change of conduct, the Competition Commission announced[184] that it would have not prosecuted the complaint as the last J&J's decision opened the way to the entry of generic medications into the market. In addition to this, the multinational company reduced by 40% the price charged to the South African National Department of Health for Bedaquiline.

[180] The Commission's press statement can be read here: https://www.spotlightnsp.co.za/wp-content/uploads/2024/08/media-statement-commission-investigates-johnson-johnson-15-september-2023.pdf accessed on February, 16th 2025.

[181] Secondary patents are patents granted to additional aspects of an invention after the main patent has been granted. In the pharmaceutical field, secondary patents may be granted for specific dosages, forms, formulations of a known substance and since they often concern minor variations of inventions, they are at the heart of a debate on their adequacy. More specifically, it has been stressed that pharmaceutical companies often engage in the practice of applying for secondary patents with the purpose of extending the lifespan of their patents, such as in the case in question, leading to the phenomenon of "patent evergreening". See, among the others, Bhaven N. Sampat and Kenneth C. Shadlen, *Secondary pharmaceutical patenting: a global perspective*, (National Bureau of Economic Research, 2017), http://www.nber.org/papers/w23114

[182] CIPC is the South African patent office, as it was mentioned in the first chapter.

[183] J&J's public statement can be read on its website at the following link: https://www.jnj.com/media-center/press-releases/johnson-johnson-confirms-intent-not-to-enforce-patents-for-sirturo-bedaquiline-for-the-treatment-of-multidrug-resistant-tuberculosis-in-134-low-and-middle-income-countries accessed on February, 16th 2025.

[184] See the media statement released by the Competition Commission on 5th July 2024, https://www.compcom.co.za/wp-content/uploads/2024/07/TUBERCULOSIS-PATENT-COMPLAINT-AGAINST-JOHNSON-JOHNSON.pdf accessed on 16th February 2025.

2.3 The use of compulsory licensing in the global south: a useful instrument to increase medicines availability

One of the countries of the "global south" that have used compulsory licensing on pharmaceutical patents most is Ecuador. Since 2010 the Ecuadorian State has granted a number of compulsory licenses for a decent variety of active ingredients, such as Ritonavir, Abacavir/Lamivudine, Etoricoxib, Mycophenolate Sodium, Sunitinib, Certolizumab, Raltegravir. Most of the licensees have been private Ecuadorian pharmaceutical companies and one pharmaceutical company funded by the government of Ecuador. They either produced or imported the active ingredients from abroad, as it happened in 2010 in the case of the antiretroviral Ritonavir, on which the multinational Company Abbott held a patent. It was distributed by Eskegroup, the Ecuadorian distributor of the Indian generic producer Cipla. Another case dates back to 2021 and concerns the antiretroviral against HIV/AIDS Raltegravir, which was patented by MSD and imported from India by the Ecuadorian licensee Soulpharma.

In South-east Asia there has been a significant utilization of compulsory licensing, particularly in Malaysia, Indonesia and Thailand. More specifically, in the Indonesian archipelago, compulsory licensing was first used in 2004, granted by the presidential decree number 83 which authorized the government use of the antiretrovirals against HIV Nevirapine and Lamivudine, which were patented respectively by Boehringer Ingelheim and Biochem Pharma. For their production Indonesia extensively relied on importation of raw materials from India and on the manufacturing capacity of the two state-owned companies Kimia Farma and Indofarma. In particular, Kimia Farma could count on its wide distribution network all over the country. Afterwards the government use of patents was authorized in 2007 for the antiretroviral Efavirenz and in 2012 for the antiretrovirals Abacavir, Didanosin, Tenofovir and of the combination compounds Lopinavir/Ritonavir and Tenofovir/Emtrisitabin/Efavirenz. In more recent times, the government use of patent was used in 2021 for the antiretroviral against Covid-19 Remdesivir.

In Malaysia the government use of patent was used for the first time in 2004 with the purpose of importing from the Indian generic producer Cipla the antiretrovirals against HIV Didanosine and Zidovudine and the combination Lamivudine/Zidovudine. The authorization was limited to the dispensing of the medicines in hospitals[185]. Afterwards in 2017 after some

[185] For more information on the 2004 Malaysian license, see the Consumer Project on Technology, funded among the others by the Rockefeller Foundation, which focused on access and production of knowledge, including medical inventions. The project, also known as Knowledge Ecology International, extensively documents data on compulsory licenses and government use of patents with regard to pharmaceuticals in

attempts to obtain a price reduction from Gilead on the antiretroviral against hepatitis C Sofosbuvir, the Malaysian government used again the provision on government use of patents with the purpose of importing from Egypt the generic version of Sofosbuvir. Having done so, the government could start to collaborate with the non-profit research centre DNDi for developing the new combination compound Ravidasvir/Sofosbuvir that turned out to be more effective than the other already existing therapies[186].

As concerns Thailand, the provision on the government use of patent was used for the antriretrovirals Efavirenz and Lopinavir/Ritonavir and for Clopidrogrel, a medicine treating cardiovascular diseases, respectively in November 2006, January 2007 and February 2007[187].

Moreover, in January 2008 further licenses for government use were granted for Letrozole, Docetaxel, Elotinib and Imatinib, medicines for the treatment of different kinds of cancer. As a result, the price of such medicines dropped and the Thailand health system could increase the number of patients that it was able to treat[188]. The license for Efavirenz was granted to the pharmaceutical State company Government Pharmaceutical Organization (GPO), which imported the necessary amount from the Indian generic producer Ranbaxy. The GPO started to produce the generic version for Lopinavir/Ritonavir which had been developed by the Indian generic company Mylan, thanks to a technological transfer cooperation between the two.

As instead concerns the African continent, compulsory licensing has been used more occasionally if compared to the States mentioned above. Nevertheless, even here compulsory licensing had a significant impact in a number of cases. Eritrea used the instrument to import generic antiretrovirals in 2005; in the same year Ghana used the provision on the government use of patent with the purpose of importing antiretrovirals against HIV from India and after declaring the national emergency. Since 2000 Mozambique had lived a public health crisis due to the spread of HIV, which was worsened by the absence of available antiretroviral medicines and by the lack of the manufacturing capacity needed to produce them. At the beginning the country relied on humanitarian programs and donations, with international

several countries. Such data has been gathered and can be viewed by connecting to the following web-page: http://www.cptech.org/ip/health/cl/recent-examples.html#Malaysia

[186] See "South-South Collaboration & Compulsory License Can Benefit Public Health," Third World Network (TWN) February 22, 2023, https://www.twn.my/title2/intellectual_property/info.service/2023/ip230202.htm

[187] The related acts can be consulted at the following link: http://www.cptech.org/ip/health/c/thailand/thai-cl-white-paper.pdf accessed on February, 26th 2025.

[188] See Adun Mohara *et al*., "Impact of the Introduction of Government Use Licenses on the Drug Expenditure on Seven Medicines in Thailand", *Value in Health* 15, No. 1 (2012): S98.

donors actually funding the purchase of antiretrovirals. To make an example, generics from the Indian Cipla were purchased not by the country itself but the Italian Non-Governmental Organization "Comunità di Sant'Egidio" and successively by the United States program President's Emergency Plan for AIDS relief, which ensured more extensive funding. In 2004 the Mozambique government granted a compulsory license for a triple antiretroviral combination including Lamivudine/Stavudine/Nevirapine. The license was granted to the local company Pharco Moçambique Lda, which however abandoned the project as it turned out to be unfeasible[189]. In November 2003 Mozambique had signed a memorandum of understanding for technological and scientific cooperation with Brazil, which was aimed to the technological transfer of resources and knowledge for the production of generic antiretrovirals, the medical staff training and the creation of a public pharmaceutical laboratory in Mozambique. In 2009 this was incorporated as a private company with 100% state-owned capital and was called "Sociedade Moçambicana de Medicamentos". It was officially inaugurated in 2012[190].

In 2004 Zambia, after having declared the national emergency due to the HIV/AIDS epidemics, granted a compulsory license for the antiretrovirals combination Lamivudine/Stavudine/Nevirapine to the Egyptian pharmaceutical company operating in the country PHARCO ltd with a royalty rate of 2.5% of the annual total turnover[191].

Lastly, in Zimbabwe a compulsory license was granted in 2002 for antiretroviral medicines. Among the licensees there were the local company Varichem that undertook to produce the medicines locally and other two local companies that imported from the Indian generic producers Cipla and Ranbaxy[192]. The implementation of such compulsory license combined with the intense activity of Varichem made possible to serve the domestic antiretroviral market with locally produced pharmaceutical products[193].

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[189] References to the case of Mozambique can be found in Patrick L. Osewe, Yvonne K. Nkrumah and Emmanuel K. Sackey, *Improving Access to HIV/AIDS Medicines in Africa. Trade-Related Aspects of Intellectual Property Rights Flexibilities* (World Bank, 2010).

[190] Extensive analysis on the South-south cooperation enacted between Brazil and Mozambique can be found in Alila Brossard Antonielli, "A transferência de tecnologia do Brasil para Moçambique para a fabricação local de medicamentos genéricos: condições historicas e práticas de uma cooperação em saúde," in *Desafios para Moçambique*, ed. Salvador Forquilha (Istituto de estudos sociais e económico – IESE, 2018): 421-444.

[191] It is possible to view the compulsory license act thanks to the work of the Consumer Project on Technology, better known as Knowledge Ecology International, to the following web page: http://www.cptech.org/ip/health/c/zambia/zcl.html

[192] See Wael Armouti, "Grounds for compulsory license with selected cases granted for pharmaceuticals," *Tulane Journal of International and Comparative Law* 26, No. 2 (2018): 402.

[193] See David Shore, "Divergence and convergence of royalty determinations between compulsory licensing under the trips agreement and ongoing royalties as an equitable remedy," *American Journal of Law & Medicine* 46, No. 1 (2020): 67, https://doi.org/10.1177/0098858820919553

2.4 Varied usage of compulsory licensing in the western world

2.4.1 The United States

In the United States, there is no specific provision authorizing for the granting of compulsory licenses in the patent legislation or in the Sherman Antitrust Act, which is the basic pillar of the US antitrust law. Nevertheless, US courts have recommended the use of compulsory licensing in cases in which the rights conferred by patents are used against the public interest[194]; actually, US courts have often used compulsory licenses as remedies to anticompetitive practices. A classic example is *United States v Glaxo Group LTD*[195] in which the US Supreme Court ruled that it is mandatory to allow third parties to sell the patented product in bulk form in order to remedy to the negative effects of the unlawful conduct enacted by the patentees. The conduct in question, which was considered as an unreasonable restriction of trade, consisted in prohibiting to licensees and sub-licensees, which had not been authorized by the patentees, to sell the patented product in bulk form. Similarly, in 1973 the Federal Trade Commission (FTC) concluded with the Xerox company a consent decree[196] which contained the obligation to grant license in order to remedy to anticompetitive practices put in place by the company in respect of its photocopier patents. Moreover, after the Supreme Court decision in *eBay v MercExchange*[197] several scholars and jurists argue that the court practice of denying permanent injunctions after finding patent infringement and establishing royalty compensation can be considered as a *de-facto* compulsory license.

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[194] See Jessica Bernardini, "Leveraging mandatory licensing under the Clean Air Act. A novel framework to domestic reduction of greenhouse gases," *Environmental Law* 51, No. 1 (2021): 314.

[195] See *United States v Glaxo Group LTD*., 410 U.S. 52 (1973).

[196] On the use of consent decrees in the United States antitrust law see Lawrence Schlam, "Compulsory royalty-free licensing as an antitrust remedy for patent fraud: law, policy, and the patent-antitrust interface revisited," *Cornell Journal of Law and Public Policy* 7, No. 2 (1998): 512.

[197] See *eBay Inc. v. MercExchange*, L. L. C., 547 U.S. 388 (2006). The Supreme Court ruled that there is no an automatic right of patentees to obtain an injunction in case of patent infringement but a case-by-case assessment is necessary applying a four factors test. In particular, eBay was using a particular bidding method for online auctions for which it did not manage to reach a licensing deal with the patentee. As a result, the patentee sued eBay for patent infringement. While awarding damages to the patentee, the competent district court denied permanent injunction; a decision which was then overturned by the court of appeal. In turn, the Supreme Court overturned the judgment of the court of appeal, stressing that who seeks a permanent injunction must satisfy a four-factors test according to the principles of equity law. On the topic see Jorge L. Contreras & Jessica Maupin, "Unenjoined infringment and compulsory licensing" in *Berkeley Technological Law Journal* 38, (2023), https://doi.org/10.15779/Z38GQ6R356

Provisions on compulsory licensing can be found in a few acts, such as for example the Atomic Energy Act, which allows the US government to regulate access to sensitive nuclear technologies and to ensure that strategic inventions in the atomic energy sector are used in conformity with security and public policy interests. In particular, Section 153 gives the power to the Atomic Energy Commission to grant compulsory licenses for patents affected by the public interest for inventions involving fissile material and atomic energy or which are essential in the use of such material.

Another act containing provisions on compulsory licensing is the Clean Air Act (CAA) of 1970, enacted for the purpose of controlling and reducing air pollution. In fact, Section 308 provides for the granting of compulsory license with the purpose of allowing producers in the sector an adequate availability of technology to be able to comply with obligations set by the act.

Sometimes, the expression compulsory license is used with regard to the Bayh-Dole Act[198] to indicate a non-exclusive and "royalty-free" license in favour of the government[199] in case of inventions achieved with public funds in universities, small business firms or non-profit making organizations. The expression can also be applied to the exercise of "march-in rights[200]" by the federal agency which provided funding. In fact, under certain circumstances the federal agency can request to the institution which received public funding for the invention achievement to grant an exclusive or non-exclusive licence to a third party. This can happen when the invention is not worked or when reasons of public health, safety or other public use so require[201]. Significantly, no federal agency has ever exercised this right since the act entered into force and an interesting debate on the reasons legitimizing the march-in rights exercise by the government is currently ongoing. According to some, when the price charged in the market for the invention is too high, the exercise of march-in rights by the government would be legitimate, especially in the case of pharmaceutical products developed with federal funds[202]; others argue that the requirement to work the invention is satisfied for the mere fact that the invention is available on the market and it is therefore

[198] Enacted in 1980, the Bayh-Dole act has allowed universities, small businesses and non-profit organizations to hold ownership and exclusive rights on federally-funded inventions. Its purpose was to encourage such institutions to develop and commercialize new inventions after the previous system had failed to do so discouraging innovation. As a matter of fact, before the Bayh-Dole act was passed, the exclusive rights related to inventions developed by government contractors belonged to the government, which among the other things, could grant non-exclusive licenses to anyone willing to practice the invention in question.

[199] See 35 U.S. Code § 202 (4)

[200] See 35 U.S. Code § 203

[201] See 35 U.S. Code § 203 (a) (1) (2) (3)

[202] See Congressional Research Service (CRS), "Pricing and March-In Rights Under the Bayh-Dole Act," (2024), https://crsreports.congress.gov

unnecessary to take actions of "price control"[203]. On 8th December 2023 the National Institute of Standards and Technology (NIST) issued a Request for Information for a draft guidance framework for exercising march-in rights[204] which has no the force of law but attaches some importance to the price issue in assessing the march-in rights exercise.

Ultimately, it seems appropriate to refer to the provision contained in 28 U.S. Code § 1498 on the government use of patents, of works protected by copyright and of protected plant varieties. With particular regard to the government use of patents, the provision institutionalises such use by defining it as the use or production by a contractor, sub-contractor or any other person on behalf of the government or authorized by the government, of an invention covered by a patent in the United States. It also provides that the patentee has the right to obtain reasonable and complete compensation[205]. In the first place, such provision was used especially during the two world wars for favouring competition in the aviation, aeronautics, technology and industry sectors to ensure that patent rights in force at the time did not hinder war production[206]. It was also used after September 11th on the heels of *bioterrorism* as negotiating leverage to obtain from the Bayer pharmaceutical company a price reduction on the only medicine available against anthrax, *ciprofloxacin*[207]. Lastly, the provision seems to have been used at the turn of the 1950s and 1960s to import generic medicines from abroad, especially from those countries such as Italy, where a legal prohibition to confer patent rights for medicines was in force. By way of example, in 1959 the US government issued an order for purchasing the antibiotic *tetracycline* in Italy, where the generic version used to cost 0,08 USD per pill, while the corresponding branded-version patented by the Pfizer company costed 0,17 USD per pill. As a result, when a tender was launched two years later, Pfizer reduced the price to 0,06 USD but the Italian generic producer managed to beat such price by reducing it to 0,05 USD, which continued to drop in the following years thanks to such international competition[208].

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[203] *Ibid.*

[204] National Institute of Standards and Technology (NIST), "Request for Information Regarding the Draft Interagency Guidance Framework for Considering the Exercise of March-In Rights," Federal Register/Vol. 88, No. 235 (2023).

[205] See 28 U.S. Code § 1498 (a).

[206] See Christopher J. Morten & Charles Duan, "Who's afraid of Section 1498? A case for government patent use in pandemics and other national crises," *Yale Journal of Law & Technology* 23, (2020).

[207] The quantity of ciprofloxacin produced by Bayer was not sufficient to meet the amount required by the US government. Moreover, Bayer was refusing to license generic producers that could contribute to an increase in production. By threatening to invoke Section 1498, the government eventually managed to obtain by Bayer both an increase in the quantity of ciprofloxacin produced and the reduction of its price from $1,83 per pill to less than $0,85.

[208] See Ellen F.M. 't Hoen, *The global politics of pharmaceutical monopoly power*, (Diemen: AMB Publishers, 2009), 43.

2.4.2 Germany

In Germany the legal provisions on compulsory licensing have been at the centre of two judicial proceedings. In the first proceeding the German Federal Court of Justice "*Bundesgerichtshof (BGH)*" ruled that a compulsory license having as object a pharmaceutical product cannot be granted if "the public interest can be satisfied through alternative products which are roughly equivalent[209]". In particular, the application for compulsory license concerned the production and distribution of a medicine for the treatment of rheumatoid arthritis called *Polyferon* and had been granted by the court of first instance, the Federal Patent Court "*Bundespatentgericht (BPG)",* that recognised the existence of the public interest ground[210]. Such judgment was then overturned on appeal before the Federal Court of Justice which stated that there was no evidence of significant improvements in Polyferon's therapeutic effects, compared to the other available products[211]. At a closer look, even if some technical examinations showed that Polyferon might have beneficial therapeutic effects without significant side effects for a specific subset of patients, there were no sufficient studies to prove it with certainty[212].

The second proceeding concerned a compulsory license granted by the Federal Patent Court and then confirmed by the Federal Court of Justice for the first time in the history of Germany[213]. The applicant was the US pharmaceutical company Merck Sharp and Dohme Limited (MSD) and had as object the patent on the HIV antiretroviral active ingredient Raltegravir, marketed as Isentress. MSD had been producing and selling the medicine in Germany since 2008 but the Japanese company Shionogi held a European Patent for Raltegravir which was in force on the German territory. In June 2014 Shionogi notified to MSD that the product fell within the scope of its patent. After negotiations between the two companies for a voluntary license failed, Shionogi sued MSD for patent infringement before the Düsseldorf district Court in August 2015. Afterwards, MSD initiated legal proceeding before the Federal Patent Court to request a compulsory license on the basis of Section 24

[209] Federal Court of Justice, December 5th 1995, ref: X ZR 26/92, in *GRUR 1996* – 190
[210] See Section 24 (1) German Patent Act" *Patentgesetz (PatG)".*
[211] Federal Court of Justice, December 5th 1995, ref: X ZR 26/92, *ibid.*
[212] *Ibid.*
[213] Federal Court of Justice, July 11th 2017, ref: X ZB 2/17, in *Entscheidungen des Bundesgerichtshofes in Zivilsachen [BGHZ*] 215, 214

of the German Patent Act. Moreover, MSD requested a compulsory license by way of preliminary injunction under the Section 85. On August 31st 2016 the Federal Patent Court granted a preliminary compulsory license to MSD, a decision which was then confirmed by the Federal Court of Justice on July 11th 2017. The Federal Court of Justice based its reasoning on its interpretation of the public interest ground given in *Polyferon* and claimed that the public interest ground under Section 24 can be satisfied when a pharmaceutical drug treats a serious disease which cannot be treated with an equivalent drug or that can be treated with equivalent drugs but at the cost of significant side-effects. The Court added that the same reasoning applies even when a relatively small group of patients is affected and in fact in this case there actually were specific groups of patients which heavily depended on Isentress for their treatment with significant consequences and health risks in the case of switching to other medicines. The Federal Court of Justice established that according to Section 85 of the German Patent law, a compulsory license can be granted by way of a preliminary injunction if it is urgent in the public interest.

Lastly, during the Covid-19 pandemic Germany amended the "Act on the Prevention and Control of Infectious Diseases in Humans"[214], entitling the Minister of Health to authorise third parties to use a patented pharmaceutical under Section 13 of the Patents Act[215], during a national epidemic as declared by the *Bundestag*, and with compensation to the patent holder.

2.4.3 Canada

In Canada the provision on compulsory license was introduced by the 1969 amendment to the patent law, following some studies conducted in the 1960s which highlighted the excessively high price level of medicines in the country if compared to other nations. This reform allowed for the first time compulsory licenses for importation of medicines from abroad and caused a significant increase in the number of compulsory licenses granted within the country[216]. At the same time, in order to encourage price competition, several provinces

[214] "Gesetz zur Verhütung und Bekämpfung von Infektionskrankheiten beim Menschen" (Act on the Prevention and Control of Infectious Diseases in Humans) of 20th July 2000, as amended on 27th March 2020.
[215] "Patentgesetz" (German Patents Act) of 16th December 1980, Federal Law Gazette 1981 I, p. 1.
[216] Between 1935 and 1969, before the reform entered into force, 49 applications for compulsory license were submitted, 22 of these were granted, 4 were refused and 23 were abandoned or not pursued. After the 1969 reform the number of licenses increased to 559, 306 were granted, 15 were refused and 96 were abandoned (the remaining 142 applications were still pending when the report was written). On the topic see Harry C.

passed laws allowing or requesting pharmacies to dispense specific prescription medicines with the lowest cost equivalent drug[217]. The price of medicines decreased and the reform became an important part of the "patent policy for the pharmaceutical industry"[218]. With the beginning of the adjustment process to the TRIPS Agreement's provisions, Canada modified the provision on compulsory licensing with the approval of Bill C-22[219]. According to the new provision, compulsory licenses could be granted only after 10 years from the so-called Notice Of Compliance[220] (NOC) which authorizes a pharmaceutical product to enter the market. The ten-year period was reduced to seven years in case of compulsory license for production and not importation. Interestingly, compulsory licensing for importation was made unavailable in cases in which a medicine had been realised and developed on the Canadian territory, a disposition aimed to protect the national industry. The system was however supplemented by a "patented medicines prices review board" with functions of control and reduction of prices of patented medicines in a perspective of consumer protection. More specifically, according to the Bill C-22 amendments[221], patentees of pharmaceutical patents in Canada have to provide the board with information and documents concerning the price at which a particular medicine is sold along with information about costs of making and marketing the medicine. In case the board considers that the price of a particular medicine is excessive, it may order the patentee to reduce the price, or revoke the ten-year deferral of the compulsory license. Such last power may also be used in case the patentee does not provide with the requested information and documents or it does not comply with the order of price reduction. Even if there have been cases in which the board ordered price reduction of pharmaceuticals, such as in November 2022 in the case of the pharmaceutical product Procysbi patented by Horizon Therapeutics Canada[222], according to some scholars[223] the activity of the board would have not been very effective over the years.

Eastman, *Report of the Commission of Inquiry on the Pharmaceutical Industry* (Ottawa: Minister of Supply and Services Canada, 1985).

[217] *Ibid.*

[218] *Ibid.*

[219] Bill C-22 of November 19, 1987.

[220] In Canada the Notice of Compliance (NOC) is equivalent to marketing authorizations of a pharmaceutical product whose safety, quality and efficacy parameters have been tested and approved.

[221] On the topic see Milan Chromecek, "The Amended Canadian Patent Act: General Amendments and Pharmaceutical Patents Compulsory Licensing Provisions," *Fordham International Law Journal* 11, No. 3 (1987).

[222] "PMPRB Hearing Panel issues order in Procysbi case," *Canadian Press,* November 8, 2022.

[223] See Rujun Zhang, Danielle Martin, and C. David Naylor, "Regulator or regulatory shield? The case for reforming Canada's Patented Medicine Prices Review Board," *Canadian Medical Association Journal (CMAJ)* 189, No. 14 (2017), https://doi.org/10.1503/cmaj.161355

On the contrary, it would have been used by the pharmaceutical industry as a "regulatory shield"[224] to avoid more concrete interventions to protect the public interest.
Significantly, Canada has been the only country to have used the "article 31 *bis* system"[225] so far to export generic pharmaceuticals to Rwanda.
Lastly, during the Covid-19 pandemic, through the enactment of the "Covid-19 Emergency Response Act"[226], Canada modified its patent law[227] entitling the Commissioner of Patents, upon request of the Ministry of health, to authorise the government or other authorised person, to produce, use or sell a patented invention, during a public health emergency of national interest ensuring that the patent holder receives adequate remuneration.

2.4.4 The United Kingdom

In the United Kingdom, the compulsory license instrument was used to supply the national healthcare system with generic medicines. UK imported pharmaceutical generic versions especially from Italy at the time where the prohibition to grant medicines for pharmaceuticals was in force. This for example happened in the case of the antibiotic tetracycline which was patented by Pfizer and imported in its generic version from Italy with the purpose of supplying British hospitals[228]. In particular, in 1961 the UK Minister of Health, making use of Section 46 of the 1949 patent act[229] launched a tender for supplying tetracycline the National Health Service (NHS) hospitals with the purpose of procuring the medicine at a lower price than the price charged by the patentee Pfizer. The British importer Fraser Chemicals won the tender and imported the medicine from Italy, where it had not been patented because of the prohibition of pharmaceutical patents. Tetracycline was therefore sold to the Minister of Health which dispensed it in NHS hospitals. As a consequence, Pfizer sued[230] the Minister of Health claiming that the minister was not empowered to authorize third parties to sell the patented invention with the purpose of supplying medicines to public hospitals as such use of the patent could not be considered "for the services of the Crown" as Section 46 required, but the use was actually motivated by the benefit of the patients. The

[224] Zhang, Martin, and Naylor, "Regulator or regulatory shield?," 516.
[225] See paragraph 2.1.2 of this chapter.
[226] See Statute of Canada (S.C.) 2020, c. 5 of 25 March 2020.
[227] See Sec. 19.4, Canadian Patent Act (R.S.C., 1985, c. P-4).
[228] On the topic of the use of patented inventions for *crown use* in the United Kingdom, see 't Hoen, *The global politics,* 42-43.
[229] The provision entitled any government department, or any person authorised in writing by a government department, to produce, use and work any patented invention for the services of the Crown.
[230] See *Pfizer Corporation v. Minister of Health* (1965) 2 W.L.R. 387.

pharmaceutical company was able to win on first instance but the court's decision was then overturned both in appeal and before the House of Lords.

2.4.5 Italy

In Italy the provision on compulsory licensing has been used a few times as remedy to anti-competitive practices. In 2005 the Italian competition agency "Agenzia Garante della Concorrenza e del Mercato (AGCM)" ordered[231] the pharmaceutical company Merck, which at the time was virtually the exclusive world producer of the active ingredient *Imipenem Cilastina,* to authorize the Italian pharmaceutical company Dobfar to produce in Italy such active ingredient for storage purposes. *Imipenem Cilastina* was covered in Italy by a Supplementary Protection Certificate (SPC) held by Merck. In turn, Dobfar was a supplier of generic companies and had declared to be willing to export the active ingredient only in those countries where there was no patent in force for it or it had expired, so that the exportation could not be considered as patent infringement. Dobfar unsuccessfully attempted to negotiate a voluntary license with Merck for two years. As a consequence, AGCM initiated investigation proceedings against Merck in order to ascertain the violation of competition rules ed in particular the abuse of dominant position, which at the time was regulated by article 82 of the treaty establishing the European Economic Community (EEC). It was established that Merck had abused of its dominant position because of its refusal to make available *Imipenem Cilastina* to the Dobfar company, that in turn could not meet the demand of generic companies, namely the prospective competitors of Merck in those State markets where the active ingredient was not patented. Essentially, Merck's refusal not only excluded Dobfar from the production and exportation of the active ingredient but it also impeded to generic companies to enter and compete in the market. The license ordered by AGCM had as object only the production of the active ingredient for storage purposes because the related SPC would have anyway expired in the following months and in particular on January 30th 2006. If, conversely, Dobfar had to wait until the expiration of the SPC, even just for starting to produce *Imipenem,* its marketing would have significantly been delayed. In the end, the production license for storage purposes was considered as a

[231] See AGCM, 15th June 2005, n. 14388.

"temporary corrective to a refusal that seems abusive for a production license for exportation purposes"[232].

In March 2007, in the context of an investigation proceeding which saw again the multinational Merck involved in an abusive conduct, AGCM[233] accepted Merck's mandatory commitment to grant a free license for the production and sale of the active ingredient *Finasteride* and the related generic versions two years before the expiration of the SPC.

2.5 Does Compulsory Patent Licensing in Developing Countries harm the innovation activity of pharmaceutical companies?

First of all, it is necessary to specify how difficult is to answer this question in a definitive manner, both for its technical complexity and for the scarce amount of recent literature and studies dedicated to such issue. It is nevertheless not difficult to distinguish between two main lines of thought. On the one hand, there is the idea according to which the risks involved in the use of compulsory licenses outweigh its beneficial aspects, in that extensive compulsory licensing may reduce the investments in R&D of multinational pharmaceutical companies considering the considerable costs implied in the development of new products in the pharmaceutical sector and given the high risk deriving from such kind of investment[234]. More specifically, among the contributions that relate to the first trend, Bird[235] while recognizing the severity of the lack of available and affordable life-saving medicines in the developing world and considering the compulsory license instrument as a powerful option to allow DCs to make medicines available to their citizens, warns the same countries on the risks that may derive from an indiscriminate use of the instrument. In particular, he underlined the risk of reduced incentives to innovate for multinational pharmaceutical companies. Moreover, in Bird's opinion countries where compulsory licenses are granted

[232] *Ibid.*

[233] See AGCM, 26th March 2007, n. A364.

[234] See among the others, Robert C. Bird, "Developing nations and the compulsory license: maximizing access to essential medicines while minimizing investment side effects," *Journal of Law, Medicine and Ethics* 37, No. 2 (2009): 209-221, https://doi.org/10.1111/j.1748-720X.2009.00366.x ; and Richard P. Rozek, "The effects of compulsory licensing on innovation and access to health care," *Journal of World Intellectual Property* 3, No. 6 (2000): 889-918, https://doi.org/10.1111/j.1747-1796.2000.tb00158.x

[235] Bird, "Developing nations," 209-221.

become less attractive for Foreign Direct Investments (FDI) by multinational pharmaceutical companies and expose themselves to the risk of sanctions, as it happened for example to Thailand when the country was inserted in the US "priority watch list". The solution he proposed is to draft norms which are not overly broad but narrowly tailored so that they can be used only in case of lack of life-saving medicines and to involve the sector of patentees pharmaceutical companies in the drafting process.

On the other hand, as concerns the second current of thought, among the most authoritative contributions Chien's work[236] argues that the use of compulsory licenses in markets that are not significant for large pharmaceutical companies, as the market of low and middle-income countries, has a negligible impact on their innovation activity. Her study had as object six cases of compulsory licenses on pharmaceutical products granted by the FTC in the United States between the 1980s and 1990s. Her conclusion is that in these cases there was no decrease in the innovation activity of the involved pharmaceutical companies, neither right after the granting of the license, nor in the following years. In her opinion it is therefore wrong to affirm that compulsory licenses damage innovation categorically, but it is necessary to take into consideration other factors, such as the significance of the affected markets. In fact, in markets that are less relevant for large pharmaceutical companies, the impact of compulsory licensing is supposed to be negligible, especially in the case of global drugs that "are created for rich markets, but are also useful in developing countries"[237]. For this category of medicines, pharmaceutical companies find their main incentive in the supply of rich countries. However, even in the case of medicines that cannot be defined as global because they treat specific diseases only present in DCs, the so-called "neglected diseases", it is unlikely that compulsory licensing can have a detrimental impact. In fact, it is clear that patent protection did not stimulate much research in this sector and cannot be considered as a driver of innovation. Consequently, a waiver to patent protection in the form of a compulsory license cannot harm an incentive that is already absent.

To give a small contribution to the present discussion and to particularly support Chien's thesis described above, I analysed data contained in the annual reports of three patentee pharmaceutical companies which were involved in some of the compulsory licensing cases introduced in this work. The companies that were taken into consideration are Merck, in respect of the compulsory license granted in Brazil in 2007 for the antiretroviral Efavirenz,

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[236] See Colleen Chien, "Cheap drugs at what price to innovation: does the compulsory licensing of pharmaceuticals hurt innovation?," *Berkeley Technology Law Journal* 18, No. 853 (2003): 853-907, https://doi.org/10.15779/Z38ZX0X

[237] Chien, "Cheap drugs," 892.

Bayer for the compulsory license granted in India in 2011 and having as object the medicine Sorafenib and lastly GlaxoSmithKline for the license granted in South Africa in 2002 by the Competition Commission. I observed data related to the investments in R&D in order to verify if there have been significant variations after the compulsory license episodes, which could indicate possible decreases in the companies' innovation activity.

As for Merck, as showed by the income statement related to the 2008 annual report[238], data on R&D spending record an increase of about 206 million euros in 2008 compared to 2007. In fact, R&D spending shifted from 1,027.7 million to 1,234.4 million. A further increase happened in 2009 as well, with the R&D spending increasing to 1,334.6 million, approximately 110 million more than the previous year[239].

The information concerning Bayer[240] presents a similar picture, with data showing an increase in the R&D spending in 2012, compared to 2011, the year in which the license was granted, and an increase in 2013, compared to 2012.

As for data on the British multinational GSK[241], it records a slight reduction[242] of the R&D spending in 2003, if compared to 2002 the year in which the agreement concluded with the Competition Commission provided for the granting of voluntary licenses to generic producers. Nevertheless, it would be rash to attribute such reduction to the voluntary licenses not least because, the GSK annual report ascribes the variation to the interruption of some development projects at an advanced stage[243] and to the reduction of integration costs resulting from the merger[244] taken place in 2000 between GlaxoWellcome and SmithKline and from which GSK originates.

This brief analysis was intended to show that there were no reductions in R&D investments of pharmaceutical companies following the selected compulsory licensing episodes in the three countries object of the study, or if they occur, they are not attributable to the licensing episodes. Consequently, in such cases compulsory licensing did not reduce the incentive of

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238 Merck (2008) *Annual report 2008,* p. 72, https://www.merckgroup.com/investors/reports-and-financials/earnings-materials/2008-q4/en/2008-AR-EN.pdf

239 Merck (2009) *Annual report 2009,* p. 96, https://www.merckgroup.com/investors/reports-and-financials/earnings-materials/2009-q4/en/2009-Annual-Report-EN.pdf

240 Bayer (2012) *Annual report 2012,* (table 1.1), https://www.bayer.com/sites/default/files/2020-05/ar-2012.pdf; and Bayer (2013) *Annual report 2013,* (table 1.1), https://www.bayer.com/sites/default/files/2020-05/ar-2013.pdf

241 GlaxoSmithKline (2003) *Annual report 2003,* p. 60, https://www.gsk.com/media/8033/annual-report-2003.pdf

242 In this case, the R&D expenditure variation amounted to -£109 million compared to the previous year, with total R&D costs being £2,791 million in 2003 and £2,900 million in 2002.

243 More specifically, the development projects that were interrupted were those regarding vilazodane and oxibendazolo. See GSK 2003 annual report, p. 23 (*supra note 119).*

244 *Ibid.* p. 66

the pharmaceutical industry to researching and developing new pharmaceuticals. Nevertheless, the analysis does not have the intention to claim that investments in R&D by pharmaceutical companies would not be affected if compulsory licensing became a more frequent and regular remedy to the shortage of affordable medicines in Developing Countries, as there are still no empirical analyses able to demonstrate it.

Chapter 3

3. A critical analysis of the norms impacting access to pharmaceuticals: does the international patent system balance the interests of Developed Countries with the needs of Developing Countries?

3.1 Negotiation of the TRIPS Agreement: moving IP into the multilateral trade framework as a strategy to "export" IP standards

The majority of the rules on which the international system of Intellectual Property Rights protection is based are contained in the TRIPS Agreement, which was negotiated within the framework of the General Agreement on Tariffs and Trade (GATT)[245] during the Uruguay Round of multilateral trade negotiations between 1986 and 1994. Actually, the fact that the TRIPS Agreement was negotiated in the context of GATT was not accidental but was determined by the United States' efforts to link the protection of Intellectual Property to trade. In fact, the World Intellectual Property Organization (WIPO) would have been the most appropriate venue to negotiate an agreement on IP. Such organization originated in 1967[246] from the union of the *bureaux international* established by both the Paris Convention from the protection of industrial property and the Berne Convention on the protection of literary and artistic works. It became a specialized agency of the United Nations in 1974 and has significantly among its main functions the conception of measures aimed at protecting and harmonizing IP throughout the world and the promotion of international agreements in the field[247]. The crux of the matter is that the WIPO Convention provided for the one-vote-

[245] The General Agreement for Tariffs and Trade was stipulated in October 1947 with the fundamental goal of liberalizing trade between the States, reducing tariff barriers and eliminating discriminatory practices. The article XXVIII bis of the agreement, among the other things, establishes periodic negotiations between the contracting States, the so-called negotiation rounds, and provides that negotiations have to be conducted on a mutually beneficial basis.

[246] WIPO was officially founded as a result of the signing of the WIPO Convention in Stockholm on July 14th 1967. Entered into force in 1970, its origins actually date back to the conclusion of the Paris Convention for the protection of industrial property and of the Berne Convention on the protection of literary and artistic works which established two international offices, "*bureau international",* that were later united and replaced exactly by WIPO.

[247] See paragraphs (i) and (iv) of the WIPO Convention.

one-State voting system[248] so that DCs had the possibility to matter in every decision, also through the creation of veto coalitions.

It has been claimed that the United States put in place a "horizontal forum-shifting strategy[249]" in bringing negotiations on IP from WIPO to the GATT, where they could use the access to their market with low or no tariff barriers as leveraging tool to obtain the acceptance of restrictive IP norms from other countries, especially from the developing ones. It was the first time that Intellectual Property fell within GATT's negotiation rounds, in all the previous rounds IP had never been an object of negotiation.

Before the TRIPS' negotiations started, the United States which was also representing the demands of the industrial technology and pharmaceutical sectors[250], sensitised the European Community on the importance of introducing a code on the intellectual property protection. Negotiations proceeded through "circles of consensus"[251] with the first discussions involving only a very small group of countries which, other than the US and the European community, included Japan and Canada, the so-called quadrilateral group or "quad". Once an agreement was reached within this circle, other countries were gradually involved in the negotiations, also depending on the negotiated matter. LDCs were never involved in the negotiations that mattered most[252]. This was also the strategy used during the GATT Tokyo round of negotiations preceding the Uruguay round, where first negotiations only involved the United States, the European Economic Community and Japan[253].

Furthermore, the introduction of "Special 301" provisions[254] in the United States put DCs in an even weaker bargaining position due to the risk to be subject to trade sanctions, including

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[248] See article 7 (3) (a) of WIPO Convention.

[249] See Susan K. Sell, "TRIPS was never enough: Vertical Forum Shifting, FTAS, ACTA, and TTP," *Journal of Intellectual Property Law* 18, No. 2 (2011): 449. Despite mainly focusing on vertical forum-shifting, the author mentions horizontal forum-shifting by referring to the practice of moving from one policy-making institution to another for expanding access to IP.

[250] See Van Anh Le, *Compulsory Patent Licensing and Access to Medicines: A Silver Bullet Approach to Public Health?* (Palgrave Macmillan, 2022), 24. Specifically, in paragraph 2.3.2 the authors explains that, after having been pressured by the technology and pharmaceutical industry sectors and having failed in obtaining the adoption of more restrictive IP norms through multilateral international institutions, the US were able to use the national legislation on trade to conduct bilateral international negotiations and obtain the reinforcement of IP norms by its international partner States.

[251] See Peter Drahos, "Developing Countries and International Intellectual Property Standard-Setting," *The Journal of World Intellectual Property* 5, No. 5 (2005), https://doi.org/10.1111/j.1747-1796.2002.tb00181.x The expression "circles of consensus" was first used by professor Drahos when describing the strategic process used in the negotiations of the TRIPS Agreement, consisting in beginning negotiations only inside a very small group of countries and then involving gradually other countries only when an agreement had been reached in the first group.

[252] Drahos, "Developing Countries," 12.

[253] *Ibid.*

[254] See 19 U.S.C. § 2411. The introduction of "special 301" provisions occurred as a result of the Trade and Tariffs Act (TTA), passed in 1984, which conferred increased powers to the US President for reacting to foreign practices deemed unfair towards the US exports. More specifically, from then on, the President could undertake retaliatory measures in the form of access barriers to the US market for any good or service, with the purpose

the loss of the Generalized System of Preferences (GSP) status[255], if they had not introduced IP rules that satisfied the normative standards of Developed Countries.

Part of the countries that had opposed negotiating the TRIPS Agreement within the GATT's framework, as they considered that the WIPO was the most appropriate forum for such purpose, were enumerated by the United States in a sort of black list[256] containing countries that merited trade sanctions, as happened for example to Brazil[257]; other countries renounced to oppose when they obtained from the US trade-offs in the agriculture and textile sectors[258]. Therefore, during the TRIPS Agreement negotiations, the leveraging tool used by the US was not only the access to its market, but also the threat of retaliatory measures through Section 301 during bilateral negotiations[259]. A further example of the US using Section 301 for coercing Developing Countries to adopt more restrictive rule on IP protection was the complaint submitted in February 1988 from the US Pharmaceutical Manufacturers Association (PMA) before the USTR against Chile, whose legislation did not provide patent protection for pharmaceutical products. Under threat of retaliatory measures pursuant to Section 301 and after bilateral negotiations, Chile accepted to introduce patent protection for pharmaceutical products in September 1991[260].

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of responding to a foreign practice considered as unjustified, unreasonable or discriminatory. Foreign practices so identified were then reported annually by the USTR to the US congress. Significantly, failing to provide adequate protection to Intellectual Property was enumerated among foreign practices deemed as unfair.

[255] Introduced by the Trade Act of 1974, the GSP system provided for the elimination of duties on thousands of imported products from the beneficiary countries with the purpose of promoting the economic development of such countries.

[256] The reports submitted annually by the USTR to the US Congress as a consequence of Section 301 consisted in lists often referred to as "watch list" and "priority watch list". On the topic, see Drahos "Developing Countries," 14.

[257] See Le, *Compulsory Patent Licensing and Access to Medicines,* 28.

[258] *Ibid.*

[259] The bilateral negotiations undertaken by the US with the purpose of making Developing Countries accept the TRIPS norms have been described by Sell (*supra note* 5) as "vertical forum shifting".

[260] See Susan K. Sell, "Intellectual Property Protection and Antitrust in the Developing World: Crisis, Coercion, and Choice," *International Organization* 49, no. 2 (1995): 330, https://doi.org/10.1017/S0020818300028411

3.2 The rules of the TRIPS Agreement under discussion

The TRIPS Agreement was eventually concluded during the Marrakesh ministerial conference in April 1994 and entered into force on 1st January 1995, as part of the Annex 1C of the Marrakesh Agreement, which created the WTO. It established a minimum level of IP protection that contracting States must ensure and its provisions are binding for every WTO member country.

The following paragraphs focus on a selected group of TRIPS' provisions which have stood out for sparking criticism among DCs, because of their unsuitability to the economic characteristics, legal and cultural traditions of such countries.

3.2.1 Article 27

Article 27 concerns patentable inventions and specifically establishes that patents must be granted to inventions in any field of technology provided that they meet the patentability requirements - novelty, inventiveness and industrial applicability -, irrespective of whether inventions are produced within the State territory or imported from other countries. Paragraphs (2) and (3) of the provision introduce exceptions to patentability that member countries may decide to implement in their national legislation. One is the exclusion set in paragraph (2) of patentability for morality or public order issues, e.g. in the case an invention poses ethical issues for the human, animal or plant life or represents a threat to health and the environment. The paragraph concludes by specifying that an exclusion from patentability shall not be provided for merely on the ground that before the adoption of TRIPS, national patent legislations prohibited patentability of specific types of inventions.

The other two cases of exclusions from patentability are set in paragraph (3) and concern diagnostic, therapeutic and surgical methods for the treatment of human or animal life, and plants and animals, with the exception of microorganisms – which are the basis of production of several pharmaceutical products -, and essentially biological processes for the production of plants and animals. The exclusion of plants is however limited by the provision due to the

obligation – stated in the same norm - to protect plants either through patents or through a *Sui generis* system[261] or a combination of the two.

The first part of the provision shows that a clear position has been adopted by the drafters of the agreement on the issue of the "working of the patent"[262], as the provision expressly prescribes that the invention can be imported from abroad and implicitly establishes that it is not mandatory to produce an invention on the national territory for the patent to be granted. Moreover, Article 27 (1) obliges the WTO member countries to provide patent protection for inventions in any field of technology, even if many States were prohibiting to grant patents for pharmaceutical products when the TRIPS Agreement entered into force, as for example Argentina[263], Brazil[264] and Turkey[265]. There were even States which lacked a legislative patent system, such as Djibouti[266] and Brunei[267]. By inserting Article 27, the countries having promoted the Agreement were obliging DCs to adopt their own patentability standard, disregarding the fact that they had not an infrastructure ready to produce and sell pharmaceuticals within the country and abroad, and in which pharmaceutical patents remunerated pharmaceutical companies while at the same time acting as an incentive for developing new medicines. To the contrary, the prohibition to grant patents for medicines had led flourishing development of the generic pharmaceutical industry in countries like India, able to produce and sell medicines at significantly lower prices of the corresponding originator brand-name versions, which also resulted in savings in the purchase of pharmaceuticals by public health institutions. It can therefore be stated that after the adoption of the TRIPS Agreement, many countries lost the possibility of choosing an autonomous

[261] The so-called Sui generis system for the protection of new varieties of plants has been established by the International Convention for the Protection of New Varieties of Plants and owes its existence to the fact that plant varieties had been excluded from patent protection. As a consequence, the need for an alternative system began to be felt due to changes brought about by technology especially to the agricultural sector and that specifically concerned the increased industrialization in food production, the use of new technologies in agricultural industry and the shift of plant research from the public to the private sector.

[262] See the discussion of "failure to work" in paragraph 1.3.2 of the present dissertation.

[263] Argentina complied with the TRIPS' obligation to provide for patent protection in every field of technology with the law n. 24481 of September 20th 1995. Before then, a prohibition to patent pharmaceutical compositions had been in force for over one hundred years, as stipulated by the law n. 111 of 1864.

[264] As discussed in detail in the paragraph 1.3.3 of the present work, Brazil introduced patent protection for pharmaceuticals after the entry into force of the TRIPS Agreement, through the law n. 9279/1996.

[265] In Turkey the Patent Act of March, 23rd 1879, remained in force until 1995, prohibited the grant of patents to pharmaceuticals. On the topic, see C. Suluk, "Pharmaceutical patents in Turkey: The State of Turkish Patent Protection and Challenges Remaining to the Implementation of an Effective Legal Framework for Patent Protection in Turkey", *Turkey pharmaceuticals manufacturing*, 2014, https://fikrimulkiyet.com/download/Turkey_Pharmaceuticals_Manufacturing_2014_-_2.pdf

[266] On the specific case of Djibouti, see Émilie Cloatre, "Brevets pharmaceutiques occidentaux et accès aux medicaments dans les pays pauvres: le cas de Djibouti face au droit international de la propriété intellectuelle," *Sciences sociales et santé* 26, No. 4 (2008): 51-74, https://doi.org/10.1684/sss.2008.0403

[267] Brunei introduced a patent system for the protection of industrial inventions only in 2012 through the enactment of the Patent Order No. S 57 of 17th October 2011.

patent policy which was adequate to their characteristics and that possibly favoured a self-sustained pharmaceutical industry. Actually, there were even industrialized countries that had previously opted for the prohibition to patent pharmaceuticals[268].

Both in India and Brazil the prohibition to patent pharmaceuticals in force respectively from 1970 to 2005 and from 1945 to 1996 was decisive for the development of domestic manufacturing capacities in the pharmaceutical sector. Differently South Africa, where pharmaceutical patents have never been subject to limitations, has not experienced such a rapid development of pharmaceutical manufacturing capacity, which would also explain why the country had to rely on parallel importation of generic medicines against HIV/AIDS. Another interesting example taken from today's reality is Bangladesh, a LDC which is benefitting from the transitional period granted under the TRIPS Agreement and therefore can lawfully refrain from implementing a patent protection regime for pharmaceuticals. Particularly, Bangladesh stopped granting pharmaceutical patents in 2008 and this was one of the factors enabling the country to develop strong manufacturing capacities in the sector of generic products[269]. This leads to wonder if binding the expiry of transitional periods to the development of minimum domestic production capacities, rather than to the passage of time, would not be a more suitable solution to the problem of developing countries.

Another issue raised by Article 27 concerns the exploitation of Genetic Resources[270] (GR) and of Traditional Knowledge[271] (TK), as patentable subject-matters. In Developing Countries such resources are often discovered, used and transmitted in indigenous and farmer communities, so that allowing their treatment as possible object of exclusive proprietary rights in the form of patent protection carries the risk of taking away the right of communities to use fundamental resources for their nutrition and health. In fact, Article 27 (3) (b) TRIPS prohibits contracting countries to exclude from patentability microorganisms and can lead to the patenting of GRs that are considered part of the Traditional Knowledge

[268] A case of this kind is represented by Italy, where the prohibition to patent medicines was eliminated as a result of the ruling of the Italian Constitutional Court of 20th March 1978, in the contest of an incidental question of constitutional legitimacy raised by the Board of Appeals against measures of the Italian patent office. The judgment arrived at a time when it was believed that the Italian industry had reached the necessary degree of maturity for the transition to the pharmaceutical patent. See Roberto Pardolesi, "Sentenza 20 marzo 1978, n. 20 (Gazzetta ufficiale 29 marzo 1978, n. 87)," *Il Foro Italiano*, 101 (1978): 809-810, 815-816.

[269] For more insight into the peculiar case of Bangladesh see Sudip Chaudhuri, "Evolution of the Pharmaceutical Industry Bangladesh, 1982 to 2020," *Centre for Development Studies,* working paper 495, (2020).

[270] Genetic Resources have been firstly defined in the Article 2 of the Convention on Biological Diversity (CBD) as "genetic material of actual or potential value" while, in the same provision genetic material is defined as "any material of plant, animal, microbial or other origin containing functional units of heredity." A classic example of GR is genetic material contained in a medicinal plant.

[271] There is still not a legal definition of the expression "Traditional Knowledge". It is however generally understood as the knowledge generated and transmitted within a community, including know-how and practices often forming the cultural identity of that community.

of many Developing Countries' communities. GRs are often essential for the creation of medicinal products and the evolution of the biotechnological sector in the last decades has led to an increase of bioprospecting activities in Developing Countries endangering natural conservation of biological resources, without compensating the local communities who rely on those resources and do not often have instruments to oppose the appropriation of their resources through the IP system. GR and TK are indeed strictly linked to the pharmaceutical sector because they represent a potential source of raw materials for IPRs like patents. More specifically, it is feared that granting patents over genetic material and isolated genes can limit access to these resources and conflicts with the sovereign rights of the States where the resources lie. This can especially happen when patentability requirements are not strictly applied[272]. Moreover, GRs and TK do not fall under the western conception of patentable subject-matters as they are not considered as inventions individually realised but are discovered communally and collectively. Such concerns led first to the signing of the Convention on Biological Diversity[273] (CBD) in 1992 and, after decades of negotiations, of the Treaty on Intellectual Property, Genetic Resources and associated Traditional Knowledge in May 2024. First the CBD and then the treaty on IP, GR and associated TK have established the right and duty of States to protect their biological resources and have introduced some legal safeguards for the communities such as the access and benefit-sharing mechanism and

[272] This for instance happened in 1995 when two Indian nationals of the University of Mississippi Medical Centre were granted a patent by the US patent office on the medical use of Turmeric. As a consequence, the Indian Council of Scientific and Industrial Research (CSIR) managed to obtain the patent revocation by proving that the Turmeric medical use had been known for thousands of years.
Another case concerned the granting in the United States of a patent in 1986 on *Ayahuasca*, a substance contained in a plant named *Banisteriopsis Caapi* which was used and considered sacred by indigenous tribes of Amazonia. As a consequence, the indigenous organizations via the Centre for International Environmental Law (CIEL) submitted a request for the patent reexamination on the ground that *Ayahuasca* was not novel and should have been excluded from patentability for morality reasons as it was considered sacred. In 1999 the USPTO accepted the reexamination request but reversed the decision two years later since the patent had been filed when the rules governing patent reexamination were not still in force. For a more detailed overview on the two above-mentioned cases see Bernard O'Connor, "Protecting Traditional Knowledge: an overview of developing area of intellectual property law," *Journal of World Intellectual Property* 6, no. 5 (2003): 677-698, https://doi.org/10.1111/j.1747-1796.2003.tb00236.x
[273] See "Convention on Biological Diversity," signed on 5th June 1992, 1760 UNTS 79.

the Prior Informed Consent[274] (PIC), the patent disclosure of origin requirement[275], and the establishment of information systems[276].

3.2.1.2 Protection of Genetic Resources and Traditional Knowledge in the three case studies

3.2.1.2.1 India

In India these legal safeguards were transposed into national law through the 2002 Biological Diversity Act[277], enacted on 5th February 2003 and recently amended by the 2023 Biological Diversity amendment Act[278]. The act obliges[279] who apply for an IPR on inventions based on biological resources[280] or on associated TK accessed from India to obtain prior approval from the National Biodiversity Authority[281] (NBA), representing the implementation of the so-called PIC requirement, introduced by the CBD. Since the 2023 amendment, this obligation has only been applied to persons that are not citizens of India, or that are not resident in the country, or to companies, associations and organizations that are not incorporated or registered in India, or that despite being incorporated or registered in India

[274] Article 15 CBD established that the terms of access to the Genetic Resource by an "user", such as for example a pharmaceutical company, are negotiated with the "provider" of GR, that is the country where the resource is present. The negotiation aims at reaching a fair and equitable sharing of benefits deriving from the resource exploitation and national legislation of provider countries can authorize local and indigenous communities to negotiate the terms of access and the sharing of benefits. In this framework, the expression Prior Informed Consent (PIC) indicates the permission given by the national competent authority of the provider country to the user of the GR, which has to occur before access is provided.

[275] The disclosure of origin requirement has been introduced by the Treaty on IP, GR and associated TK and establishes that who applies for a patent on a GR shall disclose the country of origin of that GR and, if applicable, the local community or indigenous group who provided for the TK associated to the GR in question. See articles 3.1 (a) and 3.2 (a) of the Treaty.

[276] Article 6 of the Treaty on IP, GR and associated TK provides that contracting States can establish, in consultation with indigenous and local communities, information systems such as databases containing data on GRs and associated TK and make them accessible by offices who deal with patents search and examination.

[277] See Biological Diversity Act, 2002 No. 18 of 5th February 2003.

[278] See the Biological Diversity (Amendment) Act, 2023, No. 10 of 3rd August 2023.

[279] Such obligation is established by Sec. 6 (1) of the Biological Diversity Act.

[280] According to the Article 2 CBD the term "Biological resources" includes "genetic resources, organisms or parts thereof, populations, or any other biotic component of ecosystems with actual or potential use or value for humanity.".

[281] The Indian National Biodiversity Authority (NBA), established by the 2002 Biological Diversity Act, is the Indian authority competent to give the Prior Informed Consent (PIC) to users of Genetic Resources (GRs).

have any non-Indian participation in their share capital or management[282]. Persons that are not included in the above-mentioned categories have only to register their IPR application to the NBA before being granted the right in question[283] and before obtaining its authorization for the commercial use of the resource[284]. Therefore, through the 2023 amendment, the Indian legislator has intended to reduce the risk of biopiracy and of unregulated transfer of biological resources and TK abroad. It has also intended to incentivize Indian undertakings to the commercial development based on GRs and TK by simplifying access and use of these resources. Nevertheless, it has been rightly underlined that excessive tolerance towards domestic undertakings carries the risk of damaging local communities[285].

The system that has been designed and regulated by the Biological Diversity Act also gives the power to NBA to impose sharing of royalties or fees derived from the proceeds of commercial exploitation of resources[286], in compliance with Article 5 of the Nagoya Protocol on Access and Benefit-sharing[287], providing for the obligation to share benefits arising from the use of GRs with the country of origin as well as indigenous and local communities. Moreover, Section 7 of the Biological Diversity Act imposes on subjects not included in the categories listed above and covered by Section 3 (2), to give prior intimation to State Biodiversity Boards (SBBs), before accessing to any biological resource and its associated knowledge for commercial utilization. The act has envisaged one SBB for each state of India, with the power to grant approval or refuse it in case the commercial activity in question is deemed to damage or conflict with conservation, sustainable use and equitable sharing of benefits[288]. Local communities are then exempted from the obligation to give prior intimation to the SBB in case they intend to access biological resources for commercial use[289]. Other authorities envisaged by the Biodiversity Act are the Biodiversity Management Committees (BMCs) established at the local level by Section 41, in charge of promoting conservation, sustainable use and documentation of biological diversity and having the

[282] As it is established by Sec. 6 (1) of the Biological Diversity act, these are the persons covered by Sec. 3 (2).
[283] See Sec. 6 (1A) *ibid.*
[284] See Sec. 6 (1B) *ibid.*
[285] See Sabeeha Ali, "Access to Benefit Sharing and Traditional Knowledge under Biological Diversity Act, 2002: Comprehensive Overview," *International Journal of Law Management & Humanities* 6, (2023): 2007-2015.
[286] See Sec. 6 (2) of Biological Diversity Act.
[287] The *Nagoya Protocol on Access to Genetic Resources and the Fair and Equitable Sharing of Benefits Arising from their Utilization* (ABS) is a supplementary agreement of the CBD, entered into force in October 2014, well about twenty years after the CBD, with the purpose of improving effective implementation of the ABS system.
[288] See Sec. 24 (2) Biological Diversity Act.
[289] See Sec. 7 (1) *Ibid.*

power to charge fees for accessing to biological resources for commercial purposes. Significantly, under paragraph (2) of the section, BMCs shall be consulted by the NBA and by SBBs while taking decisions relating to the use of biological resources in the BMC's territorial area of competence. It has been noted that the provision on the establishment of these local authority bodies could be improved by specifically providing for the inclusion of tribal and local people in the committees[290].

In India the patent disclosure of origin requirement[291] was introduced in the national patent legislation about twenty years before the Treaty on IP, GR and associated TK has made it compulsory. In particular, the 2002 Patents Amendment Act provided for mandatory disclosure of the source and geographical origin of an invention consisting of biological material[292]. The *ratio* of original disclosure requirement is to ensure compliance with the PIC as well as benefit-sharing. Furthermore, in case the source and geographical origin of such inventions are not disclosed or are incorrectly identified, the related patent can be revoked under Section 64 (1) (p) of the Patents Act. Lastly, in 2001 India implemented the Traditional Knowledge Digital Library (TKDL), a database to prevent patenting and misappropriation of TK and collecting information on medicine practices and formulations originating in the four main TK "families": Ayurveda, Siddha, Unani and Yoga[293]. In particular, the TKDL was aimed at solving the problem of TK documenting, as many patents having as object Indian medical knowledge had been granted due to the difficulty of patent examiners to recognize and identify relevant prior art in this field[294]. It is likely that the Indian TKDL, which among other things is used to support patent examiners in their search of prior art related to TK, has inspired the provision on the establishment of information systems, which is present in the treaty on IP, GR and associated TK[295].

3.2.1.2.2 Brazil

In Brazil access to GRs and associated TK is regulated by the Act 13123 of 20 May 2015, which has replaced the provisional measure 2186-16 of 23 August 2001, the first legal framework on the matter. Prior consent is defined by Article 2 of the act and regulated by

[290] See Ali, "Access to Benefit Sharing and Traditional Knowledge", 2007-2015.
[291] See *supra note* 31.
[292] See Sec. 10 (4) (d) (ii) (D) of 2002 Patents Amendment Act.
[293] See Martin Fredriksson, "India's Traditional Knowledge Digital Library and the Politics of Patent Classifications", *Law and Critique* 34 (2023): 1-19, https://doi.org/10.1007/s10978-021-09299-7
[294] To make an example, prior art related to TK was sometimes documented in ancient Sanskrit texts which were difficult to access. See Fredriksson, "India's Traditional Knowledge Digital Library," 3.
[295] See *supra note 32.*

Article 9. Differently from India, where PIC is given by the national authority NBA, in Brazil indigenous populations or traditional communities have the right and power to give PIC to the resource's user[296]. Nevertheless, the user does not need to obtain PIC in case of access to associated TK of non-identifiable origin[297]. The Brazilian law indeed makes a distinction between associated TK of identifiable origin and associated TK of non-identifiable origin. Associated TK of identifiable origin are those for which it is possible at least to establish a connection with one indigenous population, traditional community or traditional farmer. While associated TK of non-identifiable origin are those for which it is not possible to establish a connection with one indigenous population, traditional community or traditional farmer[298].

As concerns the sharing of benefits deriving from the use of GRs associated to TK, the act provides for the right of the TK provider (normally, indigenous populations, traditional communities or traditional farmers) to receive benefits through a benefit sharing agreement[299]. Since the law presumes the existence of other holders of the same associated TK, the user shall have to disburse a part of the benefits to the National Fund for Benefits Sharing[300], as well as sharing benefits with the identified provider of the TK. The obligation to stipulate agreements for the sharing of benefits however provides for a number of exemptions relieving some subjects from the conclusion of a benefit-sharing agreement. To make an example, micro-businesses, small enterprises, agricultural microentrepreneurs, traditional farmers and their cooperatives below a certain income threshold[301] are exempted. In case the economic exploitation is related to access to the country's genetic heritage or to associated TK of non-identifiable origin, the benefit sharing agreement shall be stipulated between the federal government, represented by the Ministry of the Environment, and the part who economically exploits the product or material[302]. Activities involving access to genetic heritage or associated TK must be preceded by registration on the electronic register "SisGen" created by the decree 8772 of 11 May 2016 and managed by the Genetic Heritage Management Council (CGen). Such activities include applying for any Intellectual Property Right[303] e.g. applications for IPRs having as object genetic heritage or associated TK cannot

[296] See Article 2 (VI) of Act 13123 of 20th May 2015.
[297] See Article 9 (2) *ibid.*
[298] See Article 2 (III) *ibid.*
[299] See Article 24 *ibid.*
[300] See Article 24 (2) *ibid.*
[301] See Article 17 (5) i*bid.*
[302] See Article 25 *ibid.*
[303] See Article 20 (1) (II) of decree 8772/2016.

be filed without prior registration[304]. They include granting IPR on products or materials obtained from access to the genetic heritage or associated TK as well[305] and the law provides for fines addressed to natural and juridical persons failing to comply[306]. After completing electronic modules on SisGen, a registration receipt is automatically issued. Significantly, juridical persons being based abroad must be associated to a national scientific and technological research institution in order to register their activity[307]. The registration system which has the function of monitoring access to genetic heritage and associated Traditional Knowledge has replaced a system based on authorization, which had been established by the law previously in force and was considered overly bureaucratic.

The satisfaction of the disclosure of origin requirement is then required by Article 17 (v) of decree 8772, under which the documentation proving PIC shall indicate the geographic area where the material is located and the indigenous populations, traditional communities or traditional farmers possibly involved.

3.2.1.2.3 South Africa

The South African regulatory framework for the protection of Genetic Resources and Indigenous Knowledge includes the National Environmental Management Biodiversity Act (NEMBA)[308], adopted in 2004 and amended in 2002, 2009 and 2013, the Regulations on Bio-Prospecting, Access and Benefit Sharing passed in 2008 and amended in 2015, the Protection, Promotion Development and Management of Indigenous Knowledge Act 6 of 13 August 2019 and lastly some norms contained in the South African Patents Act of 1979, as amended in 2005.

The disclosure of origin requirement is included in Section 30 (3A) of the Patents Act, under which every patent applicant has to declare, before its application is accepted, if the invention object of the application is based or derives from an indigenous biological resource, a GR or TK. Furthermore, subsection 3B establishes that the patent applicant shall give proof its title or authority to make use of the resource in question. In the case of misrepresentation, the patent in question can be revoked under Section 61 (g). It follows that the person who has not obtained the PIC or who has not concluded an Access and Benefit Sharing Agreement

[304] See Article 12 (2) of Act 13123.
[305] See Article 47 *ibid.*
[306] See Article 80 decree 8772/2016.
[307] See Article 12 (II) Act 13123.
[308] See National Environmental Management Biodiversity Act, no. 10 of 7 June 2004.

(ABSA) will not be able to claim any patent right, or other IP right, on the resource in question, as highlighted in the Regulations on Bio-Prospecting, Access and Benefit Sharing as well.

PIC is regulated by Chapters 6 and 7 of NEMBA, according to which it is compulsory to obtain the permit to commercialise an indigenous biological resource and for exporting it abroad[309]. The authority in charge of issuing PIC is the Minister for the national environmental management[310], who has also the duty of protecting the interest of persons, State bodies, communities, indigenous communities or specific individuals, providing or granting access to biological indigenous resources, may have with respect to the bioprospecting project which is the object of the consent request[311]. Crucially, if one of the "stakeholders"[312] has an interest involved in the biological resources in question, the consent can be issued by the ministry only if the applicant obtained PIC from the stakeholder and, in case of an indigenous community involved, the two parties[313] concluded an ABSA for the sharing of any future benefits derived from the relevant bioprospecting, which is also approved by the ministry[314]. In essence, even though the indigenous community or another stakeholder may refuse to give its consent for the use of the resource in question, it is the State, via the government, which has the responsibility and the right to grant or deny the consent, as it is also mandated by Article 15 CBD. A question has been raised at this point on whether the ministry may grant PIC even in case the involved indigenous community refuses a benefit-sharing agreement. The answer should be in the negative as reflected in Section 82 (3) (a) of NEMBA, stating that the permit can be issued only if the applicant has obtained the prior consent of the stakeholder. However, the government plays an important role during negotiations of ABSAs, as it proposes the terms of the agreement and ultimately approve it. As a consequence, even if indigenous communities may formally refuse to give their consent to the exploitation of the resource, the government exerts a significant influence in the decision-making process[315].

The ABS system, as already mentioned, allows to subordinate the use by third parties of indigenous biological resources held by communities of origin to the conclusion of an

[309] See Sec. 81, NEMBA.
[310] See Sec. 87 (A) (d) (e) *ibid.*
[311] See Sec. 82 *ibid.*
[312] Persons, State bodies, communities, indigenous communities or specific individuals, providing or granting access to biological indigenous resources, are named "Stakeholders" in the relevant provision.
[313] The two parties here are the indigenous community on the one hand and the applicant for PIC who wants to commercialise the resource, on the other.
[314] See Sec. 82 (3) (a) *ibid.*
[315] See Enyinna Nwauche, *The Protection of Indigenous Knowledge in Africa*, (Springer, 2025).

agreement regulating conditions for sharing the benefits that will derive from the resources' exploitation. The provisions regulating this system are contained in chapter 6 of NEMBA and in chapter 4 of the Regulations on Bio-Prospecting, Access and Benefit Sharing. Moreover, Section 12 of the Protection, Promotion Development and Management of Indigenous Knowledge Act 6 of 2019 entrusts custody of indigenous knowledge to a trustee of the indigenous community, which holds it on behalf of the community. The trustee has been introduced in an attempt to overcome the difficulties of finding the right person with whom to negotiate with a view to ease negotiations in the context of an indigenous community[316].

As for the establishment of information systems, the National Indigenous Knowledge Registration System (NIRKS), launched in 2003 and managed by the National Indigenous Knowledge Systems Office (NIKSO) at the Department of Science and Technology, is a technology platform supporting indigenous communities to record their indigenous knowledge and serving at the same time as a database helping the patent office in assessing prior art and novelty of patent applications which potentially fall within the scope of GRs and TK.

It is possible to draw some considerations on the three case studies having been illustrated in the preceding subparagraphs and to dwell on certain aspects that either could be improved or potentially serve as a model for other legal systems.

First of all, in the Brazilian framework a provision on the patent revocation in case of a description that does not disclose the source of origin of the subject-matter is lacking, so that it is unclear what would happen to a patented subject-matter whose source of origin has not been sufficiently disclosed in the PIC documentation.

Secondly, there seems to be a relevant difference between the three countries in the level of involvement of indigenous communities in the process leading to the granting of PIC. In the Brazilian system the involvement of indigenous community is considerably high given the provision contained in Article 2 (VI) of the law no. 13123 of 20 May 2015, which in fact

[316] The provision establishing the figure of the trustee of the indigenous community could have been inspired by the case of the San people, an indigenous community of the Kalahari desert in South Africa and of their Hoodia plant, which has been used by the community for thousands of years, as source of energy for their nutrition and health. The plant described in the thirties by a Dutch anthropologist and patented at the end of the nineties by the South African Council for Scientific and Industrial Research (CSIR). Relevantly and after initial contention, a benefit sharing agreement was concluded between the CSIR and the San people, providing for payment to the San community of royalties derived from the commercialisation of the product containing the pharmaceutical composition extracted by the Hoodia plant. For managing the benefit sharing agreement the San Hoodia Benefit Sharing trust was established whose composition includes, among the others, three representatives of the South African San Council and a representative of CSIR. More detailed insight on the Hoodia plant case can be found on the WIPO website at https://www.wipo.int/en/web/ip-advantage/w/stories/leveraging-economic-growth-through-benefit-sharing accessed on 26 April 2025.

delegates power to the indigenous community involved to grant PIC for the use of a GR or associated TK of identifiable origin. The South African system also provides for a considerable involvement of the indigenous community, which gives its consent to the use of GR and associated TK with the approval of the government, which is able to exert strong influence in the decision-making process. Lastly, in the Indian system the decision of whether to grant PIC is taken by the national agency NBA, possibly in consultation with the BMC competent for geographical area, which does not compulsorily include members of indigenous communities. It therefore appears there is a lower involvement of indigenous communities if compared to the other two systems.

As for the conclusion of ABSAs derived from the use of indigenous knowledge, the introduction of the figure of the trustee by the South African legislation, entrusted with the custody of indigenous knowledge and the authority to negotiate the agreements on behalf of the community appears to be a positive model for other systems that intend to involve indigenous community more closely in decisions concerning their resources.

Lastly, it may be interesting to note how the Indian and Brazilian systems are oriented towards the protection of their domestic undertakings and institutions reserving them greater access to the countries' resources if compared to foreign entities. As evidenced above, India has recently exempted domestic undertakings from the obligation to obtain prior approval from the NBA, and in Brazil foreign undertakings may only register their bioprospecting activity if they are associated to a Brazilian scientific and technological research institution.

3.2.2 Article 31 (b)

Article 31 (b) TRIPS establishes that the use of a patented invention without the patent holder's authorization, i.e. compulsory license, shall be allowed only if the applicant makes efforts to obtain from the patentee a voluntary license on reasonable terms and conditions "within a reasonable period of time" before using the invention in question. The norm formulation appears as vague as it does not explicitly mention compulsory licensing in, preferring the more general expression "Other Use Without Authorization of the Right Holder", and especially because it does not define the length of the reasonable period of time within which the negotiation between the patent holders and the license applicant must be concluded. This particularly leads patentees to extend negotiations on purpose even if they have no real intention of granting the license to delay market entry of licensed products and

the ensuing increase of competition. India has for example remedied this vagueness by establishing that the reasonable period must not exceed six months[317].

3.2.3 TRIPS' provisions on the transfer of technology to Developing Countries

Transfer of technology to Developing Countries is traditionally understood to mean the flows of technology and knowledge from technologically advanced countries and firms to less technologically advanced countries. This can take the form of international trade in technological inputs, FDIs disseminating technological information in local firms, technological licensing, patent pools and the setting up of joint ventures. The TRIPS Agreement mentions technology transfer in articles 7, 8 (2), 40 (1) and 66 (2), which are illustrated below. According to Article 7, the protection and application of IPRs should contribute to technology transfer to the mutual advantage both of intellectual property holders and of IP's users, in such a way to favour the social and economic welfare and to balance rights and obligations. Article 8 (2) legitimates the contracting States to adopt the necessary though TRIPS-consistent measures to remedy to practices that negatively affect international technology transfer. Article 40 (1) uses the terminology of technology transfer not by referring to the flow of technologies from Developed to Developing Countries but to refer to the transfer of technology occurring between firms and it particularly acknowledges that some IPRs contractual licenses and the clauses therein contained may hinder competition and technology transfer. Last but not the least, Article 66 (2) obliges Developed Countries members to provide incentives to their institutions and firms to promote and encourage technology transfer to Least-Developed Countries with the purpose of enabling them to develop a solid technological base. This last specific provision had remained non-operational until the institution by the Council for TRIPS of an implementation monitoring mechanism through a decision dated 19th February 2003[318]. It was there decided that Developed Countries had to submit reports every three years with annual updates on undertaken or planned actions to comply with the technology transfer obligation set by the Article 66 (2)[319]. It was the Doha Declaration on the TRIPS Agreement and public health[320]

[317] See Section 84 (6) *Explanation,* Indian Patents act, 1970.
[318] See the Decision of the Council for TRIPS of 19 February 2003, *"*Implementation of article 66.2 of the TRIPS agreement*",* IP/C/28, 20 February 2003.
[319] The reports shall, among the other things, include information on any specific legislative, policy and regulatory framework put in place to comply with the obligation of Article 66, the agency or other entity providing for the incentive, the type of technology that has been transferred and the least-developed countries that have received it. *Ibid.*
[320] See § 2.1.2 of chapter II of the present work.

to give impetus to the establishment of the monitoring mechanism, by reaffirming the Developed Countries' commitment to provide incentive to technology transfer, precisely because the norm had not worked until that moment. In spite of the institution of the monitoring mechanism, LDCs have repeatedly criticized Developed Countries for not effectively implementing their TRIPS' technology transfer obligation[321]. According to secondary data concerning the reports submitted to the Council for TRIPS from 1999 to 2010[322], only 21 Developed Countries members and the European Union submitted their reports but none of them presented the annual updates. Moreover, just a minority of the reported policies and programmes specifically targeted LDCs. In addition to this, primary data related to reports submitted in 2024[323] by Developed Countries reveal that in most cases there is still a trend towards reporting programs not specifically addressed to LDCs but putting them together with Developing Countries and sometimes even Developed ones. Furthermore, in 2024 17 reports were submitted, which represents a much lower figure than the number of Developed Countries being part of the WTO. After all, failure to comply with Article 66 (2) is not actually sanctioned, which is why there were some proposals[324] to ensure the enforcement of such TRIPS' norm through the WTO DSB, whose authority arises in case of breach of the WTO agreement. Other than the lack of a clear binding obligation, there is also an issue concerning how to assess adequacy and effectiveness of technology transfer programs reported by Developed Countries as to the development of domestic technological capacity building in LDCs. As specifically concerns the development of the necessary industrial and technological infrastructure, patent protection has not always and not everywhere played a significant role in the industrial transformation; conversely, there are actually cases in which less rigid patentability standard rules accelerated industrial development[325].

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[321] See David M. Fox, "Technology Transfer and the TRIPS Agreement Are Developed Countries Meeting their End of the Bargain?," *Hastings Science and Technology Law Journal* 10, No.1 (2019): 18.

[322] See Suerie Moon, "Meaningful Technology Transfer to LDCs: A Proposal for a Monitoring Mechanism for TRIPS Article 66.2," *International Centre for Trade and Sustainable Development,* Policy Brief Number 9, (April 2011), https://www.files.ethz.ch/isn/138434/technology-transfer-to-the-ldcs.pdf

[323] Such reports are made available in the dedicated on-line portal on the WTO web-site, https://e-trips.wto.org/

[324] See Andrew C. Michaels, "International Technology Transfer and TRIPS Article 66.2: Can Global Administrative Law Help Least-Developed Countries Get What They Bargained for?", *Georgetown Journal of International Law* 41, no. 1 (2009): 223-262.

[325] Among the most known cases, there are the experiences of Japan and of South Korea. On the particular characteristics of the Japanese patent system and its impact on technological development see Keith E. Maskus, and Christine McDaniel, "Impacts of the Japanese patent system on productivity growth", *Japan and the World Economy* 11, (1999): 557-574, https://doi.org/10.1016/S0922-1425(99)00012-2 As concerns South Korea, in its industrial development and transformation phase, occurring from the '60s to mid '70s, the country benefitted from weak IPRs protection and from the imitation of technologies of foreign countries so that only afterwards it was able to develop its own technological capacity. During this industrial transformation period in which the

3.2.4 Article 70 (8) (9) – The "mailbox system" and Exclusive Marketing Rights (EMRs)

As already mentioned in paragraph 1.4.2 of the first chapter, the provision contained in paragraph (8) of Article 70 TRIPS instituted the so-called "mailbox system" giving to patent applicants the opportunity to deposit patent applications in those countries which prohibited patent protection for certain categories of inventions such as pharmaceuticals and agrochemical products and were benefitting from transitional periods[326] under Articles 65 and 66 (1). The purpose of the norm was to ensure that patent applicants could maintain the filing and priority date related to their applications and in this way preserve the novelty and priority of the invention object of the application. The patent would then be examined, granted or refused only once the transitional period elapsed and the country member had to comply with the TRIPS-obligation to provide patent protection in every field of technology under Article 27.

Paragraph (9) of Article 70 establishes that Exclusive Marketing Rights (EMRs) shall be attributed to those applying for a patent through the mailbox system described above for five years starting from the date of obtaining the marketing authorisation in the country. This was therefore a form of privileged commercial protection measure that was given to patent applicants well before the patent examination. As a results, patent applicants for pharmaceutical and agrochemical inventions were able to effectively receive EMRs during transitional periods before the related patent was granted or rejected, provided that the for the invention in question a patent was granted in another WTO member country (in most cases a Developed Country) and the marketing authorization was obtained in such other country[327]. The norm could create situations in which a patentee received EMRs for an invention that could later receive a refusal by patent offices. It was probably the awareness

country had low indigenous technological capacity, patent protection was not considered as an adequate form of protection for domestic inventions while the less rigid protection conferred by utility models was promoted, as also Japan had done. For more detailed insight into the stages of industrial development and its connection to the patent system see Jeeyoun Shin and Juyeon Lee, *2011 Modularization of Korea's Development Experience Korea's Intellectual Property Rights System and its Application to the Phases of Industrial Development: Focusing on the Patent System* (Korea Institute of Intellectual Property - KIIP, Ministry of Strategy and Finance, Republic of Korea, 2012). Government publications registration number 11-1051000-000196-01

[326] See an explanation of transitional periods in § 1.4.2 of Chapter I of the present work.

[327] See Article 70 (9) TRIPS.

of such a problematic issue that led the Council for TRIPS to suspend the rule exclusively for LDCs in June 2002[328].

3.2.5 Balance between rights and obligations: a linguistic analysis of the TRIPS Agreement

According to Article 7 of the TRIPS Agreement, 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*". It is actually matter of debate whether the agreement is able to create the conditions for the mutual advantage of producers and users of technological knowledge and for balanced rights and obligations. Moreover, it is important for the present research to understand if the IPRs international system, as embodied in the TRIPS Agreement, has succeeded in balancing the public interest, particularly public health, with the right incentives to patent holders. In this respect, it is worth noting that there is a significant difference in the way in which TRIPS provisions are formulated, i.e. provisions strengthening IP protection create clear binding obligations through the use of the term *shall,* while provisions aimed at preventing abuses of IPRs seem to have the character of an indication and indeed use terms such as *may* or *should,* so that they lack the character of cogency. To make an example, Article 8 (2) states that appropriate measures 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. Notwithstanding it opens up the possibility to undertake legal measures to counter IPRs abuses, the provision does not create a real obligation to do that.

Another example is represented by Article 30, entitled "exceptions to rights conferred", it establishes that the States may introduce in their legislation limited exceptions to rights conferred by patents 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*.". This is the

[328] See the related press release available at: https://www.wto.org/english/news_e/pres02_e/pr301_e.htm accessed on 31th March 2025.

provision under which the exception for experimentational purposes and the so-called Bolar exception generally fall. The first exception allows to use a patented invention without the consent of the patent holder for carrying out research and experimental activities without incurring patent infringement and in the sake of dissemination and advancement of technical knowledge. Secondly, the Bolar exception allows generic producers to use a patented invention before the related patent expires for the purpose of conducting activities aimed to obtain marketing authorization from regulatory agencies so that generic products can enter the market right after the related patent expires. If, on the contrary, the generic producer had to wait for the patent to expire before being able to conduct activities for obtaining marketing authorization, i.e. conducting studies proving that the generic version is bioequivalent to the originator version, the entry into the market of such generic medicine would be delayed. The TRIPS Agreement does not provide for an obligation to implement such circumscribed limitations to patent rights but it simply foresees its possibility with the result that countries that could benefit from such limitations are actually lacking them, such as for example Sri Lanka[329].

The same applies to Article 31, which dictates a number of conditions to be observed when the national legislation of a member country provides for the granting of compulsory license, named in the agreement with the complex terminology of "other use of the subject-matter of a patent without the authorization of the right holder". The emphasis of the norm is therefore not on the obligation to transpose into national legislation the compulsory license, which among other things has proved useful to pursue public health objectives in a number of cases, but the focus is on restricting its use through the conditions enlisted in the several subparagraphs of the article[330].

In the light of this, it is claimed here that the balance between obligations and rights sought by the Article 7 and considered by the same as an objective of the agreement has not been achieved as the mandatory character denoting the rules aimed at protecting IP does not equally characterize the rules aimed at preventing abuses of IPRs and at protecting the public interest.

[329] See Kiyoshi Adachi, "An Examination of Selected Public Health Exceptions in Asian Patent Laws", *South Centre,* Research Paper 152, part of the South Centre's Doha Declaration on the TRIPS Agreement and Public Health Series, (2022), https://www.southcentre.int/research-paper-152-21-april-2022/#more-19777
The scholar reviews patent legislations of south, southeast and east Asian countries comparing national incorporation of public health exceptions.

[330] For a detailed explanation of Article 31 TRIPS and of its subparagraphs, see paragraph 2.1 of chapter II of the present work.

3.3 TRIPS-plus standards in Free Trade Agreements (FTAs)

The TRIPS Agreement has established a compulsory minimum standard of IP protection that WTO's member countries have to ensure so that nothing prevents them from providing for levels of protection which are stricter than those imposed by the agreement[331]. More specifically, promoting countries, especially the United States and those part of the EU, were able to force the adoption of levels of protection of rights holders that are stronger than those dictated by the TRIPS Agreement and that are therefore often called "TRIPS-plus" standards. The strategy used by some Developed Countries to impose such stricter rules has been to include IP clauses in bilateral or regional trade agreements aimed at regulating trade between the parties by leveraging access to their markets. To give some examples, Free Trade Agreements (FTAs) containing TRIPS-plus clauses were concluded bilaterally by the US with Chile, Colombia, Morocco, Jordan, Panama and Peru and regionally within the framework of the Central America Free Trade Agreement (CAFTA) with Costa Rica, Dominican Republic, El Salvador, Guatemala, Honduras and Nicaragua. A close analysis of the FTAs' chapters dedicated to Intellectual Property reveals the presence, among the others, of the following TRIPS-plus clauses: data exclusivity, imposition of the IPRs national exhaustion regime, patent linkage, limitation of legal grounds legitimising compulsory licensing, obligation to implement a loose criterion for the invention anticipation and the description. Each of them is illustrated below.

3.3.1 Data exclusivity

The TRIPS-plus clauses on data exclusivity concern data submitted to national regulatory agencies in order to prove efficacy, quality and safety of a pharmaceutical product and obtain marketing approval. Their purpose is to protect for a certain period of time data derived from clinical trials conducted by originator pharmaceutical companies as a form of reward for their economic investment, which is also said to represent an incentive of their R&D activities. It is therefore an additional incentive to that which is already represented by exclusive rights conferred by patents. More specifically, data exclusivity clauses generally provide that the data in question cannot be used by a person other than the person that

[331] In this respect, Article 1 of the TRIPS Agreement states that "*(…) Members may, but shall not be obliged to, implement in their law more extensive protection than is required by this Agreement, provided that such protection does not contravene the provisions of this Agreement. (…)".*

submitted them and without its permission for a certain number of years e.g. a five-year period from the date of obtaining marketing approval. This is crucially relevant as it affects the possibility of manufacturers of generic medicines to rely on the data submitted by the originator company to prove equivalence of their generic version and obtain marketing approval. Generic producers are indeed generally not required to conduct their own clinical trial studies but can rely on data derived from the studies carried out by originator companies on the reference product to prove that the generic version has the same effects as the reference originator's version. However, some jurisdictions, especially the US and the EU, prohibit to use the data for a certain time without the consent of the person that submitted them first, the originator. As a result, the entry into markets of generics can be significantly delayed, because conducting clinical trials may in essence be economically unsustainable for generic manufacturers so that, if there is a data exclusivity regime in place, they have to wait until the period of protection elapses before they can start procedures for marketing approval by regulatory agencies.

Data exclusivity clauses probably represent the clearest example of a provision which is tailored on Developed Countries' characteristics[332], while most developing WTO member countries has not implemented such regime[333]. Setting a prohibition to rely on data submitted by originators may especially put small and medium generic companies in difficulty[334]. Furthermore, this is a TRIPS-plus standard because the TRIPS Agreement does not require that data resulting from clinical trials conducted by originator companies cannot be used for the achievement of marketing authorization by generic producers but the agreement is rather quite vague on the subject just providing that data "shall be protected against unfair commercial use[335]" without defining how the expression *unfair commercial use* shall be intended. Actually, during the TRIPS' negotiations there were proposals to include in Article 39.3 a prohibition to rely on tests and data of the originator for the approval of competing products for a minimum of five years, but this was eventually conceptually rejected[336]. In addition to delay generics' entry into the market, data exclusivity regimes have the potential to undermine compulsory licensing of pharmaceutical patents, i.e. in the case a compulsory

[332] In the United States the introduction of data exclusivity dates back to 1984 with the entry into force of the Drug Price Competition and Patent Term Restoration Act. In the EU it was initially introduced by Directive 1987/21/EC, which is no longer in force, and is currently established by Directive 2004/27/EC.

[333] See Ellen 't Hoen, "Protection of Clinical Test Data and Public Health: A Proposal to End the Stronghold of Data Exclusivity," in *Access to medicines and vaccines. Implementing Flexibilities Under Intellectual Property Law,* ed. Carlos M. Correa and Reto M. Hilty (Springer, 2022), 188.

[334] See Carlos M. Correa, *Protection of data submitted for the registration of pharmaceuticals: implementing the standards of the TRIPS Agreement* (South Centre, 2002), 6.

[335] See Article 39 (3) of the TRIPS Agreement.

[336] See Correa, *Protection of data submitted for the registration of pharmaceuticals,* 54.

license is granted in a country with a data exclusivity regime in place, once the patent barrier has been overcome through the license, the generic manufacturer still could not rely on the originator's data to obtain marketing authorization by the national regulatory agency. This is why some developing countries as Chile and Colombia introduced provisions waiving data exclusivity in case of compulsory licensing or when necessary to protect the public interest[337].

As for the three case studies, India does not currently provide for data exclusivity to test data in spite of pressure from Developed Countries to implement a data exclusivity regime. In particular, the EU has been negotiating with India a trade agreement for several years now which is expected to be finalised soon and that has raised concerns for the IP TRIPS-plus clauses that it is expected to introduce[338]. Brazil does not have a data exclusivity regime covering test data of pharmaceuticals for human use either, but the country only provides for data exclusivity in respect of veterinary pharmaceutical products and agrochemicals[339]. Lastly, to date even South Africa has not introduced a data exclusivity regime.

3.3.2 Determination of the rights exhaustion regime

According to the doctrine of IPRs exhaustion with particular regard to exhaustion of patent rights, which was originally conceived for balancing the rights of IPRs holders with those of sellers, patentees cannot prevent the others from reselling a patented invention after having put it on the market for the first time. The exclusive right to sell the patented invention is thus exhausted right after the first lawful marketing of the product by the patentee. From that moment on, whoever buys the patented product can freely resell it, provided that the purchaser does not alter it without the patentee's consent.

By observing national IP legislations, it is possible to distinguish between three main exhaustion regimes having significantly different characteristics: national exhaustion, international exhaustion and regional exhaustion. In the realm of patents, the adoption of the

[337] As for Colombia, see Article 4 (c) of decree n. 2085 of 19 September 2002 establishing that data exclusivity will not be applied when necessary to protect the public. In a more specific manner, Article 91 (c) of Chilean law n.19996 has provided for an exception to data exclusivity when the product concerned is the object of a compulsory license.

[338] The EU has circulated a draft of the proposed agreement whose most problematic clauses are those providing for eight years of data exclusivity, term extension of pharmaceutical patents, the imposition of a regime of IP rights exhaustion. The draft can be accessed on the official website of the European Commission to the following link: https://policy.trade.ec.europa.eu/eu-trade-relationships-country-and-region/countries-and-regions/india/eu-india-agreement/documents_en accessed on 21 April 2025.

[339] Such protection is conferred by the law n. 10603 of 17 December 2002.

national exhaustion regime implies that patentees cannot control the resale of the patented invention after they put the patented product into the market on the national territory for the first time, while they can control and prevent the resale of the product outside the national territory as their rights are only exhausted at the national level but not on the international territory where they can still exercise their rights. Accordingly, within this system, patentees not only maintain control over exportation of the product to foreign countries but they can also prevent parallel importation into their country. Conversely, when a State has in place an international exhaustion regime, once the patented invention has been put on the market for the first time in any part of the world by the patentee, that product will be considered as a freely tradable good because the exclusive resale right of the patent holder is exhausted at the international level after the first lawful marketing. Therefore, anyone will be able to buy the patented invention to freely resell it in parallel to the official distribution channel of the patent holder[340] without the need for its consent. This phenomenon is known as parallel importation and it implies that who buys the patented product in a country where the selling price is lower tends to export it in countries where the price is higher[341], competing on price with official distributors. According to some academics[342], the international exhaustion regime is the most logic in a harmonized international trade system aimed at reducing trade barriers between the States.

Lastly, as for regional exhaustion regimes, the best example is currently in force in the EU, where patentees cannot control resale of the patented invention within the union, after it has been put on the market for the first time by the patent holder within the EU's borders. The doctrine of IPRs regional exhaustion in the EU is founded on the principles of free movement and free competition, which are embodied in some of the norms[343] which are part of the Treaty on the Functioning of the European Union (TFEU), and on the landmark ruling given by the Court of Justice of the European Union (CJEU) in *Centrafarm v Winthrop*[344].

Article 6 of the TRIPS Agreement establishes that every member country is free to determine the exhaustion regime to be adopted, which is often considered as a *flexibility* rule allowed by the agreement. In this respect, it has been noted[345] that countries which are net importers

[340] See Santanu Mukherjee*, Patent Exhaustion and International Trade Regulation* (Leiden, The Netherlands, Brill | Nijhoff, 2023), 278.
[341] See Vanzetti, Di Cataldo, Spolidoro, *Manuale di Diritto Industriale,* 516.
[342] See among the others, Irene Calboli, "Intellectual Property Exhaustion and Parallel Imports of Pharmaceuticals: A Comparative and Critical Review*", Access to Medicines and Vaccines*, ed. Carlos M. Correa and Reto M. Hilty (Springer, 2022), 37.
[343] The principle of free movement of goods is embodied in articles 28 – 37 TFEU, while articles 101 – 109 TFEU are dedicated to free competition.
[344] Court of Justice of the European Union, 31 October 1974, Case 16-74, *Centrafarm v Winthrop.*
[345] See Mukherjee, *"*Adoption of International Exhaustion of Patents", 278.

of patented inventions often prefer to adopt an international exhaustion regime in which parallel importations are allowed, while countries that tend to be net exporters of patented inventions, especially those where IP holders exert significant influence, frequently adopt a national exhaustion regime where parallel importations are restricted.

The clause in Article 15.9 (4) of the bilateral agreement between the US and Morocco states that: "*Each party shall provide that the exclusive right of the patent owner to prevent importation of a patented product, or a product that results from patented process, without the consent of the patent owner shall not be limited by the sale or distribution of that product outside its territory*." It therefore limits the autonomy granted by the TRIPS Agreement as to the choice of the preferred exhaustion regime and obliges the parties to adopt a national exhaustion regime. Significantly, the issue of exhaustion is relevantly interconnected to access to pharmaceutical products and specifically to the possibility of parallel importations of medicines at a lower price by the countries lacking manufacturing capacity in the pharmaceutical field.

Indian legislation provides for the international exhaustion of patent rights as established by Section 107A (b) of the Patents Act stating that "*importation of patented products by any person from a person who is duly authorised under the law to produce and sell or distribute the product, shall not be considered as an infringement of patent rights*.". The introduction of this provision would *inter alia* have been motivated by the willingness to balance the protection of intellectual property with public health, national security and public interest and it became part of the Patents Act after the 2005 amendment after the Doha Declaration[346] sparked the debate on access to medicines in developing countries[347].

Brazil adopts a national exhaustion regime as reflected in Article 184 (II) of law n. 9279/1996, which considers as a crime the action of importing a patented product which was not put into foreign market directly by the patent holder or with its consent. It is recalled that, unlike Brazilian provision, an international exhaustion regime of patents rights is in force when the patented product is put for the first into the market in any part of the world by the patent holder and from then on it can no longer control the resale of the product. Derogations to the national exhaustion regime are however in force in the case of compulsory license granted due to abuse of economic power or for lack of patent exploitation on the Brazilian territory. Therefore, it is permitted to import the object of the license for a limited

[346] See paragraph 2.1.2 of Chapter II of the present work.
[347] See Mukherjee, *Patent Exhaustion,* 83.

period of time after it has been put for the first time on the market by the patentee or with its consent[348].

In South Africa Section 45 (1) of the 1978 Patents Act[349], as amended by Section 40 of the act n. 38 of 1997[350], establishes that the holder of a patent in the South-African Republic has *inter alia* the right to prevent the others from importing the invention it patented. Accordingly, it is possible to affirm that South Africa has in place a national exhaustion regime of patent rights. There is however a significant exception, represented by the law named Medicines and related Substances Control Act, discussed in more detail in paragraph 1.5.3 of the present work, which has legalised parallel importation of medicines and was used for the purpose of importing generic antiretrovirals pharmaceutical from abroad.

3.3.3 Patent linkage

The expression patent linkage is usually referred to the practice of linking the marketing approval of a pharmaceutical product given by regulatory agencies to the status of the patent which covers the product in question. More specifically, patent linkage provisions usually prevent generic producers to initiate the procedure for obtaining marketing authorisation if the patent related to the reference product is still in force[351]. Implications of patent linkage provisions are especially relevant for the generic drug sector because if generic producers have to wait until the patent expiration to initiate the procedure to obtain marketing authorization, this will inevitably result in a delay of their market entry.

None of the three legal systems analysed in the present work have introduced patent linkage provisions in their legislation.

3.3.4 Restriction of legal grounds for compulsory licensing

Clause 20 of Article 4 of the bilateral trade agreement between the US and Jordan reads as follows: "*Neither Party shall permit the use of the subject matter of a patent without the authorization of the right holder except in the following circumstances: (a) to remedy a practice determined after judicial or administrative process to be anti-competitive (b) in*

[348] See Article 68 (3) and (4) of law 9279 of 14 May 1996.
[349] See Patents Act 57 of 17 May 1978.
[350] See Intellectual Property Laws Amendment Act 38 of 1 October 1997.
[351] See Mercurio, "Challenging Coerced Conformity", 337-338.

cases of public non-commercial use or in the case of a national emergency or other circumstances of extreme urgency, provided that such use is limited to use by government entities or legal entities acting under the authority of a government or (c) on the ground of failure to meet working requirements, provided that importation shall constitute working. (...)". Establishing the grounds legitimating compulsory licenses so strictly means to deny to the contracting State the possibility to autonomously determine such grounds. An autonomy that even the TRIPS Agreement has not affected as Article 31 is limited to listing a number of conditions to be respected by national contracting States when providing for a compulsory license, but without dictating the grounds themselves. Moreover, the provision in the bilateral agreement also rules out the possibility for the contracting State of establishing other grounds on which compulsory licensing could be based, such as for example the circumstance in which the public demand related to the patented invention is not satisfied, provided by the Indian law[352], or the case when the marketing of the patented invention does not meet market needs, provided by the Brazilian law[353], or the situation where the patented invention is not available on the domestic market at an affordable price[354].

3.3.5 Patent anticipation

Several bilateral FTAs concluded by the US and Developing Countries require the contracting States not to consider the novelty of an invention destroyed if there has been a public disclosure of the invention, authorized or derived by the patent applicant, which occurred within twelve months prior to the filing of the patent application. The period between the disclosure of the invention and the filing of the patent application is generally called "grace period" and if present in a given legal system, it normally lasts six or twelve months. The bilateral trade agreement between the US and Chile states that "*Neither party shall use a public disclosure to bar patentability based upon lack of novelty or inventive step if the public disclosure (a) was made or authorized by, or derived from, the patent applicant and (b) occurs within 12 months prior to the date of filing of the application in the party."* This is a TRIPS-plus standard as the TRIPS Agreement does not provide for rules concerning

[352] See Sec. 84 (1) (a), Indian Patents Act 1970.
[353] See Art. 68 (1) (ii) Brazilian law n. 9279 of 14 May 1996.
[354] See Sec. 84 (1) (b), Indian Patents Act 1970.

the actions destroying novelty or inventiveness of the invention or its anticipation. Other than in the United States[355], similar provisions are in force in Canada[356] and Brazil[357], to mention only a few examples. They particularly regulate the patent anticipation and the novelty requirement less rigorously than the standard adopted in other jurisdictions, such as the European Union, where the European Patent Convention (EPC) establishes that a non-prejudicial disclosure[358] can only be applied when the disclosure of the invention derived from an evident abuse or when it occurred in the context of an international official exhibition and certain conditions of notification are respected. In recent years, there have been discussions on whether to introduce the grace period in the European system, with proponents of the grace period claiming that it represents a "safety net" for accidental disclosures and for anticipating scientific publication. On the other hand, it has been argued that there is a risk that the grace period provisions cause legal uncertainty for third parties which may unintentionally commit infringements without knowing whether a disclosed invention is deemed part of the state of the art or not[359]. Moreover, from the viewpoint of DCs, it may not be advisable providing for the grace period as this makes the research and exam by patent offices more complex and longer, thereby aggravating the burden of offices that typically have less resources and are less efficient than patent offices in other countries. The Brazilian provision on patent anticipation seems to be loose as it only provides that the disclosure of an invention which occurred within twelve months preceding the patent filing date will not compromise the novelty of the invention if such disclosure has been promoted by the inventor, by INPI or by third parties, on the basis of information obtained directly or indirectly by the inventor or as a result of actions carried out by it. The provision does not dictate any other condition so that it may also lead to consider as new an invention that was commercialized in the twelve months preceding the filing of the patent. The same can be stated with respect to the provision contained in the bilateral agreement between the US and Chile, reported above. Conversely, the Indian provision on patent anticipation is far more detailed as it provides for a number of conditions that must be compulsorily observed so that the novelty of the invention is not considered destroyed. More specifically, in India patent anticipation is regulated by Chapter VI of the Patents Act providing that the patent applicant

[355] See 35 U.S. Code § 102.
[356] See Patent Act R.S.C., 1985, c. P-4, sec. 28.2 (1)
[357] See Law n. 9279 of 14 May 1996, Chapter II, Sec. 1, Art. 12.
[358] See Art. 55, European Patent Convention, Oct. 5, 1973.
[359] See the report of the European Patent Office (EPO), "The European patent system and the grace period. An impact analysis," (June 2022): 9. Available at https://link.epo.org/web/the_european_patent_system_and_the_grace_period_study_en.pdf accessed in May 2025.

must prove that the disclosure of the invention occurred without its consent and that the patent application has been filed as soon as reasonably practicable thereafter[360]. Relevantly, the provision is not applicable to cases where the invention was commercialized in India before the priority date[361], that is the date on which the patent application has been filed. Then, there are other subsequent provisions that make it possible to excuse the patent anticipation in cases that are strictly dictated: patent application submitted by a person contravention of the rights of the true and first inventor or a person deriving title from him[362], communication of the invention to the government with examination purposes[363], anticipation by public display[364], anticipation by public working[365] and anticipation by use and publication after provisional Specification[366].

Lastly, the South African provision[367] provides for two cases in which the patent anticipation does not prejudice the novelty of the invention, namely, when the patentee proves that the disclosure occurred without its knowledge or its consent and that the information on the invention comes from or has been obtained from it itself. Furthermore, if the patentee learned of the disclosure before the priority date, it must have acted timely to apply for and obtain the patent. The second non-prejudicial disclosure is represented by the use of the invention on the national territory with the purpose of "reasonable technical trial or experiment" from the applicant or patentee. In conclusion, every legal system should have the autonomy to decide the rules on patent anticipation that better suits it.

3.3.6 Description of invention

Some of the observed bilateral agreements establish that "*With the aim of ensuring that the claimed invention is sufficiently described, each Party shall provide that a claimed invention is sufficiently supported by its disclosure if the disclosure reasonably conveys to a person skilled in the art that the applicant was in possession of the claimed invention as of the filing date*.". First of all, the description of the invention is one of the essential components of patent applications and it is connected to that logic of disclosure and transparency on the structure of the invention which lies behind the same concept of patent. The disclosure of

[360] See Sec. 29, Indian Patents Act.
[361] *Ibid.*
[362] See Sec. 29 (3) i*bid.*
[363] See Sec. 30 i*bid.*
[364] See Sec. 31 *ibid.*
[365] See Sec. 32 *ibid.*
[366] See Sec. 33 *ibid.*
[367] See Sec. 26 South African Patents Act 1978.

the invention which takes place in the description also represents the "tribute" of the patent applicant for the purpose of obtaining the exclusive use of the invention. It follows that the invention must be disclosed in the description of the invention in the most transparent way, so that once the invention falls in the public domain after the patent expiration, everybody will be able to replicate it. The importance of the description therefore results in normative provisions requiring that the invention is descripted in the clearest and most complete way. To make an example, Article 83 EPC requires that "*The European patent application shall disclose the invention in a manner sufficiently clear and complete for it to be carried out by a person skilled in the art*".

The rule inserted in the bilateral trade agreements reported above seems to set a much less rigorous standard if compared to the standard which is traditionally adopted, and it possibly opens the granting of patents to inventions that are not sufficiently and clearly disclosed in the patent application.

3.4 Can Open Innovation (OI) contribute to improve access to pharmaceuticals in DCs?

The expression "open innovation" is an umbrella term which contains rather different phenomena and experiences which are characterized by forms of openness and sharing of Intellectual Property Rights by way of license or transfer of rights. The first person to use this terminology has been the US professor Henry Chesbrough in describing an approach to innovation which is different from the traditional one and where enterprises do not only use internal ideas[368] but also external ones[369] in their effort to advance their technology and create value. Similarly, according to Chesbrough's Open Innovation theory, enterprises could and should use not only internal paths to market but also external paths, e.g. when a product is developed by a company "A" but enters the market via a start-up "B" in which the developer company "A" has acquired shares or through external licensing[370] to the start-up "B". The OI theoretical approach emphasizes the *business model* used to develop products and bring them to market, in the belief that it is exactly the business model that will determine the value of the product. In a nutshell, in the OI model theorised by Chesbrough the

[368] By internal ideas it is meant ideas originating within companies, typically within their R&D teams.
[369] See Henry Chesbrough, *Open Innovation. The New Imperative for Creating and Profiting from Technology,* (Boston: Harvard Business School Press, 2003).
[370] *Ibid.*

enterprises' need to also use external ideas means that companies should be both active buyers and active sellers of Intellectual Property. In a world in which knowledge is abundant as it is today, the IP management should not be limited to exploit the IP achieved within the company but has to profit from it also through licensing. Moreover, companies should also acquire the IP of other organizations by playing the licensee's role rather than realising an invention from scratch. The adoption of the OI model would be precisely imposed by the abundance of knowledge in every field today, by its rapid spread, as well as by other factors, such as the growing mobility of highly experienced and skilled people[371] taking their knowledge to new employers and the growing presence of private venture capital with the ensuing creation of start-up firms or spin-offs transforming the results or research carried out outside the start-up. These have been listed by Chesbrough among the factors which make the traditional "inwardly focused[372]" closed innovation model less efficient in the present age. Here R&D is carried out exclusively within the enterprise's boundaries, so that inventions and innovative products are realised, developed and brought into market only by the developed enterprise with the purpose of being the first to market the invention. At the same time the developer firm is the only subject to hold and control the IPRs related to inventions developed therein without never engaging in external licensing or acquiring licenses on other firms' IP.

Other than the OI meaning described above, the expression has also recently been used both by Chesbrough[373] and by other scholars[374] to indicate the waiver of IPRs in a solidarity perspective in order to facilitate the realisation of inventions that are useful to face public health crisis, as the Covid-19 pandemic. Examples of initiatives of this kind are: having made public open source Personal Protective Equipment (PPE) designs during the pandemic and facilitating their production in times of shortages, renouncing to patent rights related to ventilators as the US company Medtronic did, the Open Covid Pledge initiative which promoted the conclusion of IP licenses and the pledge not to enforce such rights against who

[371] See Chesbrough, *Open Innovation,* xxii.

[372] *Ibid.*

[373] See Henry Chesbrough, "To recover faster from Covid-19, open up: Managerial implications from an open innovation perspective," *Industrial Marketing Management* 88, (2020): 410-413, https://doi.org/10.1016/j.indmarman.2020.04.010 Here Chesbrough reflects on the application of the OI model to the fight against the pandemic, in the belief that the model can play a role in finding the solution while at the same time representing a useful commercial approach. He also invites companies to manage their IP in a more flexible way and to open access to potential partners such as suppliers and universities, considering that many patents are not implemented by who owns them, which is difficult to justify during the pandemic.

[374] See Zheng Liu, Yongjiang Shi and Bo Yang, B, "Open Innovation in Times of Crisis: An Overview of the Healthcare Sector in Response to the COVID-19 Pandemic", *Journal of Open Innovation: Technology, Market, and Complexity* 8, No. 1 (2022), https://doi.org/10.3390/joitmc8010021

used Covid-related inventions in the search for solutions to the pandemic[375]. In the array of OI initiatives, crowdsourcing initiatives[376] are also generally listed, even if they do not normally affect or involve IPRs. Lastly, the Covid-19 Technology Access Pool has been created within the World Health Organization (WHO) as a global platform for developers of therapeutic and diagnostic instruments for the treatment of Covid-19, aimed at sharing Intellectual Property, knowledge and data with quality-assured manufacturers[377] through the promotion of non-exclusive production licenses. It is indeed one of the implementing partners of MPP, which is presented below.

In spite of the importance of these initiatives, it has been underlined that the OI model often remains "for profit" and that it is limited by patent rights and by the willingness of patentees to license their rights[378].

3.4.1 Patent pools and the Medicines for Patent Pool (MPP)

A further acceptation of Open Innovation is represented by patent pools with humanitarian purpose where patentees limit their patent rights under certain conditions. Medicines for Patent Pools represents the most authoritative example. Traditional non-humanitarian patent pools were created in the late 1800s as contracts aimed at aggregating and putting together the rights conferred by patents of several patent holders. Aggregations of patents through a pool had the purpose of avoiding that the high level of patent litigation paralyzed industrial activities and of resolving the issue of overlapping patents[379]. The first patent pool was precisely created in the United States in 1856 for aggregating patents related to sewing

[375] See www.opencovidpledge.org The initiative has promoted several standardised license-models and its website contains a list of major companies which stipulated such licenses such as Intel, IBM and Microsoft. It can be noticed that no major pharmaceutical company is listed therein and that patent rights having being licensed mainly concern technologies for monitoring and detecting Covid-19. See Ginevra Assia Antonelli, Maria Isabella Leone e Riccardo Ricci, "Exploring the Open COVID Pledge in the fight against COVID-19: a semantic analysis of the Manifesto, the pledgors and the featured patents*," R&D Management* 52, No. 2 (2022): 255–272, https://doi.org/10.1111/radm.12493

[376] Crowdsourcing has been defined as "(…) online, distribute problem-solving and innovative sourcing model, in which members of online communities contribute to carrying out specific tasks (…)". On the topic, see Silvia Vermicelli, Livio Cricelli e Michele Grimaldi, "How can crowdsourcing help tackle the COVID-19 pandemic? An explorative overview of innovative collaborative practices*," R&D Management* 51 (2021): 183-194, https://doi.org/10.1111/radm.12443. According to the authors, who analyzed 16 crowsourcing iniatives, it is a model with great potential in the global health sector as it allows rapid and low-cost collection of large amounts of data and information originating from every part of the world.

[377] See https://www.who.int/initiatives/covid-19-technology-access-pool

[378] See Karen Walsh, Andrea Wallace, Mathilde Pavis, Natalie Olszowy, James Griffin and Naomi Hawkins, "Intellectual Property Rights and Access in Crisis", *International Review of Intellectual Property and Competition Law,* Vol. 52, (2021): 379-416, https://doi.org/10.1007/s40319-021-01041-1

[379] Here reference is made to the situation in which it is not possible to develop a new invention without infringing a patent covering a previous invention whose rights belong to a different subject.

machines[380]. A more up-to-date normative definition of patent pool can be given by referring to the guide-lines issued in 2014 by the Commission of the European Union and having as object the application of Article 101 of the Treaty on the Functioning of the European Union (TFUE) to technology transfer agreements[381]. Here patent pools are defined as "(…) arrangements whereby two or more parties assemble a package of technology which is licensed not only to contributors to the pool but also to third parties."[382] Patent pools often, but not always, concern technological products that are relevant for industrial standards[383]. They can have procompetitive effects when establishing a single royalty for the use of all the patents included in the pool, which is generally lower than the sum of each royalty that every patentee would charge if standing on its own[384]. Moreover, they typically reduce transaction costs in avoiding separate negotiations with each patentee, acting as "one-stop licensing". They also involve considerable risks for competition especially when the pool includes substitute technologies and patentees engage in price-fixing practices. Furthermore, in this kind of patent pool royalties set by patentees are usually higher because licensees cannot benefit from competition among the pooled products.

Differently, the above-mentioned Medicines for Patent Pool (MPP) can be defined as an atypical patent pool, who is not profit-oriented but is motivated by the humanitarian objective to make pharmaceutical products more affordable in Developing Countries through a particular mechanism. It was launched in July 2010 by Unitaid[385] in order to meet the demand of poor countries' populations for pharmaceuticals. It initially aggregated patents related to the production of pharmaceuticals against HIV, tuberculosis and hepatatis C, as these are some of the diseases which typically affect Developing Countries, and then extended its mandate to other essential patented medicines listed in the WHO's Model List of Essential Medicines (EML) and to medicines with strong potential for being included in the list in the future and to treatments and vaccines against Covid-19.

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[380] See Nancy Gallini, "Private Agreements for Coordinating Patent Rights: The Case of Patent Pools," *Economia e Politica Industriale* 38, No. 3, (2011), https://doi.org/10.3280/POLI2011-003001

[381] Communication from the Commission of 28/03/2014 (2014/C 89/03), *Guidelines on the Application of Article 101 of the Treaty on the Functioning of the European Union to technology transfer agreements,* https://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:52014XC0328(01)&qid=1742546438007

[382] See subparagraph 244 of paragraph 4.4: 45 *ibid.*

[383] See subparagraph 245 of paragraph 4.4: 45 *ibid.*

[384] *Ibid.*

[385] Unitaid is a global health organization created in 2006 in the context of the World Health Organization with the aim to reduce global inequality and promote the availability of affordable medicines. It has been financed among the others by Brazil, France, Chile, Norway, the European Union and the Bill & Melinda Gates foundation.

The functioning mechanism of MPP is based on non-exclusive voluntary licenses granted from pharmaceutical companies or other entities[386] holding pharmaceutical patents to the pool. Afterwards, the pool grants sub-licenses for the use of the pharmaceutical patents to generic producers, binding sub-licensees to a specific geographical area covered by the licence agreement which does not generally include Developed Countries, or if it does, providing for higher royalties compared to those imposed for the use of the patents in Developing Countries. Most of generic sub-licensee producers are based in India which counts 28 sub-licensees according to the last available MPP's report[387]. China follows with 10 sub-licensees[388]. Pharmaceutical companies and other patent holder institutions are incentivized to use the licensing mechanism provided by MPP as they can negotiate just once with the pool rather than having to negotiate with all the potential licensees and they can reach multiple markets with one license. The MPP can also be an opportunity for innovative patent holder companies and institutions to distribute their products in countries' markets that they could not reach without MPP's sublicensees.

[386] They can also be public or private research institutes or universities.
[387] Medicines Patent Pool, (2024), *Update on progress of MPP sublicensees,* available at https://medicinespatentpool.org/ , section "Progress", accessed on March 20th 2025.
[388] *Ibid.*

Conclusions

The present dissertation has attempted to examine the international patents system since its foundation and has observed the predominant role of some countries belonging to the western world. The project to create an internation system of patent norms found its main impetus in the Second Industrial Revolution, occurring in Europe in the second half of 1800, and included among its defining moment the International Patent Congress in Vienna of 1873, which gathered a very limited number of countries with the German leadership. During the subsequent Paris Conference of 1878, it was decided that the international patent norms had to be applied to colonies as well and this principle was incorporated into the first international official treaty on patents and industrial property, the Paris Convention for the protection of industrial property of 1883. Significantly, in several States that are today enlisted in the category of DCs, the first patent legislations were introduced when they were under colonial rule so that their introduction is deemed to be a consequence of the relation of colonial subordination and not the result of an autonomous policy choice. The adoption of Paris Convention in 1883 broke with some norms of the past by dictating new principles, e.g. if before the Convention was adopted national patent legislations could subordinate patent protection to the production of the patented invention on the national territory, – so that the lack of production on the national territory could lead to the revocation of the patent – the Convention prohibited to provide for the patent revocation when the patented invention was merely imported and significantly limited the use of the revocation.

As for the role of colonialism in patent law standard setting, India represented one of the clearest examples of the influence that its coloniser, the British empire, was able to exert on the first national patent provisions, which indeed followed blindly the British patent law without the possibility to adapt the law to their domestic context. After independence was achieved in 1949 a groundbreaking project for the revision of the Indian patent law started with the purpose to adopt a new legislation which better suited the country's characteristics. Similarly, in South Africa the British coloniser also shaped early patent legislation and it is possible to notice – especially by observing the relevant case law – that, even after independence was achieved, the British patent law continued to some extent to inspire the South African one. If compared to the Indian and South African legal systems, in Brazil national patent law was introduced after the nation obtained independence and this could have initially influenced its patent norms in a more autonomous direction, e.g. it is interesting

to notice that Brazil's legal system based for some time the juridical definition of "effective use of the patent" on the proved, continuous and regular exploitation of the invention on an industrial scale and provided for the patent revocation for lack of effective use.

The entry into force of the TRIPS Agreement, a little more than a century later, represents another watershed as it harmonized patent national legislations to an unprecedented extent strengthening the protection of IP holders. It strongly impacted national legislations of some of the countries object of the study, by for example extending and unifying the patent term, obliging to introduce patents for pharmaceutical and food products, limiting and downsizing provisions on compulsory licensing, diminishing the significance of production on the national territory. Each of the legal systems that has been analysed has nevertheless found a way to limit to a certain extent patent rights for the sake of public health. Brazil successfully used the threat to grant compulsory licenses to obtain significant price reductions on HIV antiretrovirals and effectively granted a compulsory license in one case. Moreover, a legal provision subordinating the granting of pharmaceutical patents deemed to be of special interest for healthcare to the consent of the Brazilian regulatory agency, has been in force for twenty years. In India the prohibition to patent pharmaceuticals, in force for about thirty-five years, has generated the most flourishing generic pharmaceutical industry in the world; however, what seems a shifting trend towards the production of innovative pharmaceuticals is currently being observed. Secondly, section 3(d) of the Indian Patents Act represents the example of a legal provision aimed to counter the patent evergreening phenomenon with few or no precedents in the world. As for South Africa, the "Medicines and related Substances Control Act" allowing parallel importation of pharmaceuticals doubled the number of HIV patients that could be treated; moreover, an interesting trend towards the granting of pharmaceutical patent licenses deriving from the judicial enforcement of competition law can be noticed.

As particularly concerns the compulsory licensing instrument, the research shows that it occasionally proved to be very incisive in lowering the prices of medicines both in Developed and Developing countries and that notwithstanding it is often deemed as a *last resort*[389] measure, it actually remains a viable option at the disposal of States[390].

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[389] See European Commission, "Communication from the Commission to the European Parliament, the Council, the European Economic and Social Committee and the Committee of the Regions. Making the most of the EU's innovative potential. An intellectual property action plan to support the EU's recovery and resilience". COM(2020) 760 final. Brussels, November 25th 2020, p. 12. https://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:52020DC0760. See also European Commission, "Call for evidence for an impact assessment", Ares(2022)2413270 – 31/03/2022, p. 4.

[390] This is furtherly demonstrated by the amendments to national legislations introduced during the Covid-19 pandemic to facilitate the use of compulsory licenses e.g. in Canada and Germany, as mentioned in paragraph 2.4, and by the use of the instrument in countries such as Israel, which in 2020 granted a compulsory license

The current IPRs international system is based on the TRIPS Agreement whose negotiations controversially occurred in the GATT framework rather than in the WIPO where DCs could play a role thanks to the one-vote-one-State system. The United States, backed up by other Developed Countries, successfully linked IP protection to trade and to the multilateral trade system, in the context of which they took advantage of their strong position in bilateral negotiations. In this way the US managed to obtain concessions on IP leveraging openness to its market and the threat of sanctions under its Section 301.

Through the conclusion and entry into force of the TRIPS Agreement Developed Countries imposed their own patent policy to DCs, taking away from them the chance to choose an autonomous policy which was possibly more adequate to their development needs and characteristics. Furthermore, by analysing the linguistic formulation of the Agreement it is possible to notice that the provisions reinforcing patent protection create clear binding obligations, while those aimed at preventing IPR abuses and protecting the public interest seem to have more the nature of an indication through the use of "may" and "should". In addition to this, the insertion of the so-called TRIPS-plus clauses in FTAs further strengthen the protection already provided by the Agreement and prescribes to the contracting States the adoption of standards which are typically extraneous to the DCs' characteristics, potentially disadvantageous for their business structures such as for example data exclusivity, and preventing them from parallel importing of generic medicines.

Lastly and in conclusion, when it comes to OI it is important to distinguish between the OI profit-oriented business model on the one hand, and OI initiatives in which the parties involved commit not to assert their IPRs in the sake of the dissemination of knowledge and the achievement of collective objectives. MPP is an extraordinary and peculiar patent pool which effectively pursues the humanitarian purpose of making medicines available at an affordable price in DCs, making it possible to reach the markets of countries that could not otherwise be served.

for Lopinavir/Ritonavir, which is also effective against Covid and that has been patented in the country by AbbVie with the name of "Kaletra".

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