UNCTAD TRAINING MANUAL ON INTELLECTUAL PROPERTY RIGHTS AND WTO TRIPS AGREEMENT

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Contents

LIST OF ABREVIATIONS

This list includes all the abbreviations used in this Manual as well as in all the PowerPoint online training course materials on IPRs and WTO TRIPS Agreement.

AIFA: Agenzia Italiana del Farmaco

ACP: African, Caribbean and the Pacific

ARVs: Antiretroviral drugs

BITs: Bilateral investment treaties

CAFTA: Central American Free Trade Agreement

CBD: Convention on Biological Diversity

CETA: EU-Canada Comprehensive Economic and Trade Agreement

CL: Competition Law

CPTPP: Comprehensive and Progressive Agreement for Trans-Pacific Partnership

DSU: Dispute Settlement Understanding

ECJ: European Court of Justice

EC: European Community

EPA: Economic Partnership Agreement

EPC: European Patent Convention

EFTA: European Free Trade Association

FDI: Foreign Direct Investment

FTA: Free Trade Agreement

GI: Geographical Indication

GDP: Gross Domestic Product

GSK: GlaxoSmithKline

IIAs: International investment agreements

IP: Intellectual Property

IPRs: Intellectual Property Rights

LDC: Least Developed Country

MPI: Max Planck Institute

MFN: Most Favored Nation

NT: National treatment

PCT: Patent Cooperation Treaty

R&D: Research and Development

RTA: Regional Trade Agreement

SMEs: Small and Medium Sized Enterprises

SSN: Sistema Sanitario Nazionale

SADC: Southern African Development Community

TRIPS: Trade-Related Aspects of Intellectual Property Rights

TCA: UK/EU and European Atomic Energy Community (EAEC) Trade and Cooperation Agreement

TT: Technology Transfer

TFEU: Treaty on the Functioning of the European Union

TIFA: Trade and Investment Framework Agreement

UPOV: The International Convention for the Protection of New Varieties of Plants

USMCA: United States-Mexico-Canada Agreement

WCT: WIPO Copyright Treaty

WIPO: World Intellectual Property Organization

WPPT: WIPO Performances and Phonograms Treaty

WTO: World Trade Organization

WHO: World Health Organization

MODULE 1

Introduction to Intellectual Property, Innovation and Development

1 INTRODUCTION TO INTELLECTUAL PROPERTY, INNOVATION AND DEVELOPMENT[1]

1.1 THE RATIONALE OF INTELLECTUAL PROPERTY[2]

1.1.1 THE NATURE OF IPRS

Intellectual Property (IP) refers to a legal right granted by the State to persons over the creations of their minds in the literary, artistic, and scientific fields.[3] IP rights (IPRs) are granted in the form of '**exclusive rights**' to an author or inventor over the use of their creation for a limited period of time. Exclusive rights exclude others from using or exploiting the creation without the **consent** of the author or inventor. Consent can be granted in the form of a license which enables the author or inventor to gain some **economic value** from the creation. Certain IPRs also grant **moral rights** which enable the author to claim authorship and prevent any modification to the protected work.

IP protection covers the intangible creations[4] of the mind and not the tangible medium within which they are mostly fixed. For instance, a physical book is not protected under IP per se but the intangible literary work expressed in the book by ink may qualify for IP protection.

IPRs are **territorial rights**. This means that an IPR is valid in the country/jurisdiction where it was granted[5] and can only be enforced in the said jurisdiction.

According to the World Intellectual Property Organization (WIPO), IPRs "include rights relating to

- **literary, artistic and scientific works,**
- **performances of performing artists, phonograms and broadcasts,**
- **inventions in all fields of human endeavour,**
- **scientific discoveries,**
- **industrial designs,**
- **trademarks, service marks and commercial names and designations,**
- **protection against unfair competition, and**

all other rights resulting from intellectual activity in the industrial, scientific, literary or artistic fields."[6]

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[1] Session 1

[2] See Jennifer Davis, *Intellectual Property Law* (Nicola Padfield ed, Oxford University Press 2012).

[3] Anthony Taubman, Hannu Wager and Jayashree Watal (eds), *A Handbook on the WTO TRIPS Agreement* (2nd edn, Cambridge University Press 2021).

[4] "Unlike a piece of land or a car, for example, intellectual property has no material existence". See Davis (n 2) 2.

[5] Taubman et al. (n 3) 2. See also Annette Kur and Thomas Dreier, *European Intellectual Property Law: Text, Cases and Materials* (Edward Edgar Publishing Ltd 2013)13.

[6] Art. 2(viii) of the Convention Establishing the World Intellectual Property Organization (WIPO), concluded in Stockholm on July 14, 1967.

These rights are traditionally classified as either **Copyrights or Industrial Property**.[7] Copyrights refer to the rights of literary, artistic, and scientific works such as books, sculptures, and films. The rights referred to above as performances of performing artists, phonograms and broadcasts are called 'related rights' or 'neighbouring rights' which denote rights related to, or neighbouring on' copyrights. Industrial property, on the other hand, is used to describe rights granted for the protection of distinctive signs such as trademarks and geographical indications, rights granted in recognition of technological inventions such as patents and utility models, as well as 'rights' used to prevent acts of unfair competition.[8] Industrial property generally covers inventions and industrial designs.

1.1.2 WHY IP PROTECTION?

According to WIPO,

> "Countries have laws to protect intellectual property for two main reasons. One is to give statutory expression to the moral and economic rights of creators in their creations and the right of the public in access to those creations. The second is to promote as a deliberate act of Government policy, creativity and the dissemination and application of its results and to encourage fair trading which would contribute to economic and social development."[9]

Governments across the globe take deliberate steps to acknowledge and grant IPRs as a public policy tool to "***promote economic, social and cultural welfare by stimulating creative work and technological innovation, and by enabling their benefits to reach the public.***"[10] For instance, copyrights and related rights are granted to *encourage* creative work by enabling authors and artists to gain income through the licensing of their work. Likewise, patents and other industrial property rights are also designed to stimulate innovation by providing an incentive for investing into research and development (R&D) through the grant of exclusive rights to the patent holder to use or authorize the use of the invention to third parties in exchange for income. It is known that investment in R&D is expensive. Investors will therefore not be motivated to invest in research for the discovery of new inventions if they are not assured of reaping some benefit from this venture. It is therefore safe to argue that the grant of lPRs plays an enormous role in stimulating R&D.[11]

It has also been posited that the protection of IP has the potential to "contribute positively to a country's efforts to attract FDI, increase foreign trade, and provide the

[7] Taubman, Wager and Watal (n 3) 2.
[8] A detailed account of these rights are discussed below in clause 1.2.
[9] WIPO, *Intellectual Property Handbook: Policy, Law and Use* (2nd ed, 2004) 3.
[10] Taubman, Wager and Watal (n 3) 3.
[11] Kamil Idris, *Intellectual Property: A Power Tool for Economic Growth*, vol 25 (2003) 170.

necessary conditions for transfer of technology"[12] which said factors will collectively contribute to the growth of the economy.[13]

Below is a summary of the reasons attributed to the adoption of IPRs by States:

1.1.2.1 ECONOMIC AND SOCIAL GAINS[14]

- IPRs recognize the economic rights of creators in their creations: the right to license or sell creations for some financial gain.
- IPRs provides incentives to create and disseminate information to the public: but for the existence of IP's exclusive rights, there would be little to deter third parties from copying and distributing works created by others as soon as it is made available to the public, which will prevent creators from spending their time and resources in creating same.

This reason explains the rationale underlying the relevance of IP from an economic perspective: Works resulting from a creative mental process are classified as ***public goods.*** *That is, in the absence of specific legal measures to the contrary, once an IP work is created, no one can be prevented from exploiting or using them (****'non-excludable'****) and one person's use of that work does not prevent others from using it (****'non-rivalrous'****).*

This situation breeds freeriding and would deter investment into R&D and lead to a stunt in innovation as well as act as a disincentive for authors to create. This could potentially lead to a market failure which is "underinvestment in socially beneficial creative and innovative work".[15]

IPRs therefore offer a legal 'solution' to the 'public good problem' through the grant of IPRs in the form of exclusive rights to authors and inventors for a limited period of time which prevents others from freeriding on their work for the time prescribed and also give creators the opportunity to license their work for economic gains.

- IPRs exclusive rights encourage others to invent around the IP protected work thereby enhancing innovation and increasing competition in a given market.

[12] Ibid.
[13] Kamil Idris gives the example of Japan, where the rate of technological development since 1945 can partly, albeit significantly, be associated with IP. See ibid. See also Ove Granstrand, The Economics and Management of Intellectual Property: Towards Intellectual Capitalism, (Northampton, MA: Edward Elgar Publishing, 2000) 170.
[14] Taubman, Wager and Watal (n 3) 3., See also Kur and Dreier (n 5).
[15] Taubman, Wager and Watal (n 3).

- IPRs facilitate the transfer and dissemination of technology through direct or indirect transfer of technology, foreign direct investment, and licensing.[16]

The grant of a patent, for instance, results in the dissemination of technological information due to the obligation of the inventor to disclose the new technology in their patent applications before the patent is granted. Upon the expiry of the patent term, the invention can be used by all without the authorization of the patent holder.

- IPRs such as trademarks and geographical indications (GIs) facilitate transparency in the marketplace which enables consumers to make informed purchases, prevent consumer deception, and ensure fair competition among producers.

This is very beneficial for businesses and consumers alike: For businesses, these forms of IPRs provide an opportunity and incentive to invest and protect their reputation through the provision of quality products and services. Consumers also benefit from these quality goods and services.

- The incentives created by the exclusive rights of IP encourages research and development by guaranteeing for a stated time the opportunity to recoup investments made in creating and marketing the creation.
- Deliberate act of government to promote economic and social development by encouraging creativity and the dissemination of information and products to the public.

According to Annette Kur,

> "The economic importance of IPRs already mentioned above, can be ascertained on both the macro and the micro level.
>
> At the macro level they foster innovation and competition which in turn – so it is believed in view of some evidence – leads to employment, improves the gross national product and results in a higher per-capita-income. Already in the late 1970s and early 1980s of the 20th century, first statistical evaluations showed a 2–3 per cent of industrialized nations' gross domestic product (GDP) being generated by IP-related industries. The boost of the media sector and the development of the software industries (computer programs have enjoyed copyright protection since the early 1990s) have led to a tremendous increase of this percentage (some 12 or more than 12 per

[16] Art. 7 TRIPS Agreement recognizes that the protection and enforcement of IPRs should contribute to the promotion of technological innovation and to the transfer and dissemination of technology.

cent of some countries' GDP). Today, intellectual innovative creations and the IPRs which protect them are the number one 'raw material' in the information and knowledge economy. It comes as no surprise that their legal protection is of paramount importance, in particular for all countries with a strong IP production. This is the main reason why IP and IPRs were 'discovered' in the 1990s as items of international trade, a development that culminated in the adoption of the WTO/TRIPS Agreement and which still dominates the international debate today.

On the micro level, whereas in earlier years, the IP owned by a company often lay dormant, in particular if the company in question did not have a tradition of licensing, the role of IPRs as valuable company assets is by now generally recognized. For instance, it is said that the most valuable single item of the Coca Cola company is its trademark, which surpasses in value the combined value of the production and distribution facilities. IPRs can be used as generators of income and be valuable as such. Increasingly, they are regarded as an indicator for the innovative and creative strength and potential of a given company, thus determining the companies' market value.[17]

1.1.2.2 MORAL RIGHTS[18]

The exclusive rights granted by IPRs recognize the ownership of creators over their creations and their 'natural' right as owners to prevent others from exploiting the creations they have laboured to create, without their consent.[19]

The rights are attributable to the creator as emanating from his inalienable personality or as a fruit of his intellectual labour.

1.2 DIFFERENT FORMS OF INTELLECTUAL PROPERTY PROTECTION

1.2.1 PATENTS

A patent is an exclusive right granted for an invention. It is granted by the State to an inventor to exclude others from commercially exploiting the invention (manufacturing, using, selling, importing) for a limited period of time, usually twenty (20) years, in return for disclosing the invention to the public. [20] This exclusive right is given to an inventor in exchange for the disclosure of the invention. A patent owner has the right to authorize

[17] Kur and Dreier (n 5) 8-9.
[18] See Art. 6*bis* of the Berne Convention.
[19] See Rudolph J.R. Peritz, "Competition Policy and its implications for intellectual property rights in the United States" Steven D Anderman (ed), *The Interface between Intellectual Property Rights and Competition Policy* (Cambridge University Press 2007) 125.
[20] An invention is a a product or a process that provides a new way of doing something or offers a new technical solution to a problem. See also Idris (n 11).

third parties to use the patented invention, and this authorization is usually in the form of a license.[21]

To qualify for a patent, the invention must be **new** (novel, not part of existing knowledge at the time of disclosure through a patent application)[22], **involve an inventive step** (non-obvious)[23] and be **industrially applicable** (useful and capable of being applied for practical purposes). The conditions of patentability also include the requirement that the subject matter must be patentable and that the disclosure to the public must meet certain laid down standards.

Disclosure is very important under the patent system and underscores the public policy reason for the grant of patents. The patent application must be disclosed in a manner sufficiently clear for the invention to be carried out by a person skilled in the art. In tandem with this requirement, the application must contain a description which sets out at least one mode of carrying out the invention claimed.[24]

As a general rule, patent protection must be available for all inventions in all fields of technology, whether as a product or a process, so far as the invention is new, involve an inventive step and is industrially applicable.[25] Notwithstanding this general rule, States are allowed to exclude certain inventions from patentability within their jurisdiction in order to protect public order or morality including the protection of "human, animal or plant life or health or to avoid serious prejudice to the environment, provided that such exclusion is not made merely because the exploitation is prohibited by their law",[26] among others.[27]

A patent is acquired through application in the individual jurisdictions where protection is sought and meet certain substantive and formal requirements. The application, grant or cancellation of a patent in one jurisdiction does not have an automatic effect for the same invention in another jurisdiction.[28] Article 4 of the Paris Convention for the

[21] It is important to note that a patent does not give an inventor the right to use the invention personally. The effects of the grant of a patent are that the patented invention may not be exploited in the country by persons other than the owner of the patent unless the owner agrees to such exploitation. Thus, while the owner is not given a statutory right to practice his invention, he is given a statutory right to prevent others from commercially exploiting his invention, which is frequently referred to as a right to exclude others from making, using or selling the invention.

[22] The term 'new' is understood to mean that the invention shows a new characteristic which has not already been disclosed to the public before the relevant date in the body of existing knowledge in its technical field, generally termed as 'prior art' or 'state of the art'. Prior art consists of all knowledge disclosed or existing at the time of the relevant filing or first filing also known as priority date. The invention must not have been disclosed to the public through having been made, carried out or used before. See Richard A. Epstein, " The Basic Structure of Intellectual Property Law" Rochelle Dreyfuss and Justine Pila (eds), *The Oxford Handbook of Intellectual Property Law* (OPOCE 2018) 3.

[23] Upon ascertaining novelty, the invention must also be passed through the test of non-obviousness which establishes whether or not the invention would have been obvious to a person having ordinary skill in the art. Ordinary skill has been explained to mean an average level of skill in the field concerned. See WIPO (n 9) 20. See also Footnote 5 of the TRIPS Agreement, which states that 'inventive step' may be deemed by a member to be synonymous with the term 'non-obvious'.

[24] See art. 29 TRIPS.

[25] See art. 27.1 TRIPS.

[26] See art. 27.2 TRIPS.

[27] See art 27.3 TRIPS.

[28] See art 4bis Paris Convention.

Protection of Industrial Property, as incorporated in the TRIPS Agreement, provides for a right of priority to benefit an inventor applicant from members who file patent applications abroad after an initial original filing. The right of priority entitles a patent applicant, when filing subsequent applications abroad, to claim priority based on a regular first application filed in any member, provided the later applications are filed within twelve (12) months.

The exclusive rights conferred on patent owners may be limited in specific instances and also through the issuance of compulsory licenses. Article 30 of the TRIPS Agreement for instance recognizes that members may allow limited exceptions to the exclusive rights conferred by a patent, provided that such exceptions do not unreasonably conflict with a normal exploitation of the patent and do not unreasonably prejudice the legitimate interests of the patent owner, taking into account the legitimate interests of third parties. The said exceptions must be limited, not unreasonably conflict with a normal exploitation of the patent; and not unreasonably prejudice the legitimate interests of the patent owner, taking account of the legitimate interests of third parties.[29] Compulsory licenses, or rather 'use without authorization of the right holder' deals with licenses granted to third parties for their own use and use by or on behalf of governments without the authorization of the right holder.[30]

1.2.2 COPYRIGHTS AND RELATED RIGHTS[31]

Copyright is a branch of IP which provides protection to "original works of authorship" including writings, paintings, sculpture, musical compositions, novels, poems, plays, architecture, dance, instruction manuals, technical documentation, and software, among other works.[32] The law grants this legal protection to an author who independently creates an original work which has not been copied from another person. Copyright protection is only granted to the original "expressions of ideas" and concepts, and not to the ideas or concepts themselves.[33] Therefore the public is free to use the information contained in a work, including for the purpose of creating new works.

Copyright law deals primarily with particular forms of creativity, involving mass communication. In a broad sense, copyrights also include performing artists, phonogram producers as well as broadcasting organizations, which rights are generally

[29] Usually referred to as a 'three-step test'. TRIPS member States laws have allowed for limited use of the patented invention for private, non-commercial purposes; research or experimental purposes; use of patented pharmaceuticals solely for the purpose of obtaining regulatory approval (the so-called regulatory use or 'Bolar' exception); prior use, i.e. continuing use of the invention initiated secretly prior to the priority date/filing date; among other uses.
[30] See art. 31 TRIPS., See also art.5A Paris Convention.
[31] Paul Goldstein and P Bernt Hugenholtz, *International Copyright: Principles, Law, and Practice* (4th edn, Oxford University Press 2019).
[32] Idris (n 11) 190.
[33] Idris (n 11). See also art 9.2 TRIPS.

protected by so-called related or neighbouring rights. Computer programs and databases are also protected under Copyright.[34]

Copyright law protects the creator against "copying", that is "those who take and use the form in which the original work was expressed by the author".[35] The primary social purpose of protection of copyright is to encourage and reward creative work. In terms of economic benefits, the income generated by copyright may allow authors to dedicate themselves to creating more creative works and act as an incentive to justify the considerable upfront investment involved in creating certain types of works, such as films. Authors may exploit their works through licenses to publishers and producers.

Unlike patent law which requires registration before protection is granted, copyright comes into existence without any formalities. Like the term of other IP rights, the term of copyright protection is also limited, but with an international minimum duration of life plus 50 years.[36] The terms of related rights are relatively shorter than the term of protection for copyright. They range from 25 years to 70 years.

Protection of phonogram producers and broadcasting organizations justifies the investments required to produce sound recordings as well as the financial and organizational resources needed to make a broadcast available to the public.[37]

The rights under copyright are divided into two main categories: Economic rights and Moral rights. **Economic rights** allow authors to gain economic value from the exploitation of their works; and moral rights allow authors to claim authorship and protect their integrity. The economic rights include the **reproduction right,** which grants authors an exclusive right to authorize the reproduction (or copying) of their works 'in any manner or form';[38] **rental right,**[39] which allows authors the right to authorize or to prohibit the commercial rental to the public of originals or copies of their copyright works; **right of public performance, broadcasting and communication to the public,**[40] which grants authors an exclusive right to authorize the public performance of their works; **translation and adaptation right,** which also allows authors to consent to the translation of their works into another language.[41]

An author shall also have the right, independently of his economic rights, to claim the authorship of the work and to object to any distortion, mutilation, or other modification

[34] See art. 10.1 TRIPS. Computer programs are protected whether in source code (in a form designed for a person to understand and apply) or object code (in its machine-readable form) as literary works.; Art.10.2 TRIPS; Databases are to be protected only to the extent of the selection and arrangement of their contents, and not the data as such. See also Feist v. Rural Telephone Services Co. 499 U.S. 340.
[35] WIPO (n 9) 40.
[36] See art. 12 TRIPS, See also Art. 5(2) Berne Convention.
[37] Taubman, Wager and Watal (n 3) 40.
[38] See art 9.2 Berne Convention.
[39] See art. 11 TRIPS
[40] See art. 11 Berne Convention.
[41] See art. 8 Berne Convention.

of, or other derogatory action in relation to, the said work, which would be prejudicial to the author's honour or reputation.[42] This is referred to as the **moral rights**.

Neighbouring right holders also have protection under the law: performers have the right to prevent the unauthorized fixation of their performance on a sound recording, such as on a CD, as well the reproduction of such a fixation[43]; producers of phonograms also have an exclusive reproduction right and an exclusive rental right in some instances;[44] and broadcasting organizations also have the right to prohibit unauthorized fixation, the reproduction of fixations, and the rebroadcasting by wireless means of broadcasts, as well as the communication to the public of their television broadcasts.[45]

Copyright protection also admits of some exceptions and limitations in the nature of free use and non-voluntary licenses.[46] Free use involves the use of a copyrighted material without the consent of the copyright holder and at no cost whereas non-voluntary licenses also allow for use without the consent of the copyright holder but with the obligation to pay equitable remuneration.[47]

1.2.3 TRADEMARKS

A trademark is a sign or a combination of signs that is used to distinguish the goods or services of one enterprise from another.[48] Signs in the form of words (personal names, geographical names, slogans, and any other word or sets of words), letters, drawings, colour combinations or colour as such (the red soles of Christian Louboutin shoes, the magenta colour of 'Deutsche Telekom'), logos, three-dimensional signs such as the shape of a packaging (e.g. the triangular shape of 'Toblerone' chocolate, or the particular shape of the 'Coca-Cola' bottle), sound marks also known as audible signs ('Nokia' ringtone; 'MGM' lion roar), and smell marks.[49] A trade name or 'business name' being the name or designation identifying the enterprise of a natural or legal person has also been held as eligible for protection.[50] Other marks are also eligible for registration as collective marks and certification marks[51] which allows signs to be registered in respect of products belonging to a group of enterprises or an association.

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[42] See art. 6*bis* Berne Convention. It has been argued that moral rights were explicitly excluded from TRIPS because these rights protect the personal link between the author and his or her work and are not trade-related. See Taubman, Wager and Watal (n 3) 49.
[43] See art. 14.1 TRIPS.
[44] See arts. 14.2, 14.4 TRIPS.
[45] See art. 14.3 TRIPS.
[46] See art. 13 TRIPS.
[47] Taubman, Wager and Watal (n 3) 50.
[48] Taubman, Wager and Watal (n 3) 58., See also art. 15.1 TRIPS. Distinctiveness is the key word when it comes to Trademarks. That is the ability of the mark to distinguish the products of one enterprise from those of another. See also the Australia – Tobacco Plain Packaging case (WT/DS467/23).
[49] See WIPO (n 9) 70. See also Irene Calboli and Jane C Ginsburg (eds), *The Cambridge Handbook of International and Comparative Trademark Law* (Cambridge University Press 2020).
[50] Appellate Body Report, US – Section 211 Appropriations Act; See also art. 8 of Paris Convention as incorporated into TRIPS by art. 2.1.
[51] See art. 7bis Paris Convention.

Trademarks protect producers against unfair competition from other producers seeking to free ride on the goodwill earned by the trademark owner and also inform consumers on the market by helping them to make informed decisions on what to buy or otherwise, on the market.[52] These rights are also territorial rights, which means that they are valid only in the country/jurisdiction where they have been registered or otherwise acquired. To be protected in different countries, therefore, a mark needs to be registered in each individual jurisdiction.[53]

In order to make a mark eligible for trademark protection, it must be able to distinguish the products or services of one enterprise from the products or services of other enterprises and must not be misleading or violate public order or morality.[54]

A trademark gives its owner an exclusive right to prevent all third parties, without the owner's consent, from using 'in the course of trade identical or similar signs for goods or services identical or similar to those in respect of which the trademark is registered where such use would result in a likelihood of confusion'.[55] This underscores the point that trademarks are only protected in commercial settings. According to Article 6bis of the Paris Convention, as incorporated into the TRIPS Agreement (see article 16), a member State must refuse or cancel the registration of a sign as a trademark and prohibit its use if that trademark is liable to cause confusion with a mark that is considered well known in that country and used for identical or similar goods, regardless of whether the well-known trademark is registered in that country.

Trademarks can be acquired through use or registration.[56] Trademark rights are eligible for a minimum of 7 years with regard to the initial registration and each renewal of registration. However, the holder of a trademark may renew the registration indefinitely.[57] If trademark rights are acquired through actual use, the trademark may only be cancelled after an uninterrupted period of three years of non-use.[58]

The permissible exceptions to the rights of a trademark owner are to be limited, and take into account the legitimate interests of the owner of the trademark and of those of third parties.[59]

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[52] Ibid.

[53] Taubman, Wager and Watal (n 3). See also Graeme B Dinwoodie and Mark D Janis, *TRADEMARKS AND UNFAIR COMPETITION - LAW AND POLICY* (5th edn, Wolters Kluwer 2018).

[54] See article 6quinquies B Paris Convention which states that that trademarks may be denied registration if "they are devoid of any distinctive character" or if "they are contrary to morality or public order and, in particular, of such a nature as to deceive the public."

[55] See art. 16.1 TRIPS. See also the Panels and Appellate Body in Australia – Tobacco Plain Packaging (DS435, 441, 458, 467) where it was clarified that article 16.1 does not establish a trademark owner's right to use its registered trademark but, rather, provides a right to prevent third parties who do not have the owner's consent to use the mark.

[56] Ibid.

[57] See art. 18 TRIPS.

[58] See art. 19 TRIPS.

[59] See art. 17 TRIPS. See also EC – Trademarks and Geographical Indications (DS174, DS290).

1.2.4 INDUSTRIAL DESIGNS

Industrial designs rights protect the original ornamental or aesthetic features of an industrial article or product that result from design activity.[60] Industrial designs are present in a wide variety of industrial products such as vehicles, medical instruments, watches, jewelry, and electrical appliances. Industrial design protection is not granted to the articles or products as such, but to the design which is applied to or embodied in the articles or products. The design may be expressed either as a two-dimensional or three-dimensional design.[61] The technical or functional features of a design are not protected under industrial design rights.[62]

Protection may be acquired through registration[63] and only extended to original or new designs.[64] The term for an industrial design right varies depending on the particular country. Under the TRIPS Agreement, the duration of protection for industrial designs is at least 10 years.[65] The owner of a protected design has exclusive rights to prevent the manufacture, sale or importation for commercial purposes of articles bearing or embodying a design which is a copy, or essentially a copy, of the protected design.[66]

Unlike trademarks where owners have the right to prevent the use of similar signs where their use may cause confusion among consumers, owners of industrial designs only have exclusive rights to prevent the making, selling or importing of goods that carry or include a design that is a copy, or substantially a copy, of the protected design. Hence, the test for infringement of a protected industrial design essentially concerns the act of copying, rather than deception or confusion of consumers.

Industrial design exclusive rights also admit of exceptions which are limited, do not unreasonably conflict with the normal exploitation of protected industrial designs, and do not unreasonably prejudice the legitimate interests of the owner of the protected design, taking account of the legitimate interests of third parties.[67] The minimum term of protection shall amount to at least ten years.[68]

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[60] WIPO (n 9) 112.

[61] See sec. 1 of the UK Registered Designs Act 1949 which defines a design as "features of shape, configuration, pattern or ornament". See also the UK Copyright, Designs and Patents Act 1988.

[62] Art. 25.1 TRIPS. Many products to which designs are applied such as cars, jewellery, or bags are not themselves novel or original and are produced by a large number of manufacturers. Therefore, if a design for one such article, for example, an earring, is dictated purely by the function which the earring is intended to perform, it would not generally be eligible to be protected as an industrial design.

[63] In certain jurisdictions such as France, design laws may be acquired through creation and fixation of the design, in a document or by embodying the design in an article. These systems therefore do not require any formal registration procedure for the grant of exclusive design rights. See WIPO (n 9) 117.

[64] Ibid.

[65] Art. 26.3 TRIPS.

[66] See art. 26.1 TRIPS.

[67] See art. 26. 2 TRIPS. Compare to arts. 13, 17 and 30 TRIPS.

[68] See art. 26.3 TRIPS. The wording 'amount to' has been explained as allowing members to maintain systems where the term is divided into shorter successive periods of protection that can be renewed upon request of the right holder. Due to the fact that registration of designs is not necessarily a requirement for protection, the TRIPS Agreement is not specific on the starting point of the period of protection. Therefore, the starting point can be the date of creation, or the date of application or the date of grant. See WIPO (n 9).

The layout-designs of integrated circuits, which require huge investments, are also creations of the human mind which are protected as IP.[69] Integrated circuits are utilized in a large range of products including watches, television sets, vehicles, and washing machines. These designs are protected from copying.

1.2.5 GEOGRAPHICAL INDICATIONS

Geographical indications (GI) are signs which identify a good as originating from a particular region or locality where a given quality, reputation or other characteristic of the good is essentially attributable to its geographical origin.[70] Well known examples of GIs are: "Cognac" for a brandy coming from that region of France, "Darjeeling" for tea coming from that region of India, "Champagne", "Roquefort" for ewe's milk cheese is the name of a place located in a region of France, "Chianti", "Ceylon" tea that comes from that region in Sri Lanka, "Pilsen", "Porto", "Sheffield", "Havana" and "Tequila".

Signs which qualify as GIs have not been specified[71] and may either be a word or a combination of words such as "Champagne" or "Swiss Chocolate" or graphical representations of places, symbols and emblems. For example, the image of a famous mountain in Switzerland, the Matterhorn, is said to be a GI under Swiss law, which identifies that a product comes from Switzerland.[72] The geographical origin identified by a GI could be the name of a jurisdiction or territory (such as "Ceylon" above); or the name of a region ("Napa Valley" for wine coming from a region in the US State of California), or "Idaho" for potatoes produced in the US State of Idaho); or names that are not geographical names but are considered as GIs because they evoke a geographical location, for example, "Feta" (for a Greek cheese in brine).

Both GIs and trademarks have an identification function. Trademarks distinguish the goods of one enterprise from those of another, whereas GIs identify the location from where the good originates. GIs may also cover all types of goods.[73] An essential requirement under TRIPS for GI protection is that the good identified by the GI has a given quality, reputation or other characteristic that is essentially due to its geographical origin.[74] This means that there must be a direct linkage between the place identified by the GI and quality, reputation or other characteristic of the good.[75]

Some international treaties, such as the Paris Convention, do not use the term geographical indication, but rather 'indications of source' and 'appellations of origin'.[76]

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[69] See sec. 6 of Part 11 TRIPS.
[70] See art. 22.1 TRIPS.
[71] Ibid.
[72] See Taubman, Wager and Watal (n 3) 88.; See also WIPO (n 9) 76.
[73] Art. 22.1 TRIPS does not limit the type of goods subject to protection.
[74] See art. 22 TRIPS.
[75] Taubman, Wager and Watal (n 3) 89.
[76] See also the WIPO-Lisbon Agreement for the Protection of Appellations of Origin and their International Registration. Art. 2(1) defines an appellation of origin as "the geographical denomination of a country, region, or locality, which serves to designate a product originating therein, the quality or characteristics of which are due exclusively or essentially to the geographical environment, including natural and human factors."

Indications of source, such as 'Made in Switzerland' or 'Produce of Switzerland', informs the consumer that the good comes from a particular country without necessarily any link to the features of the good as originating from that country, whereas appellations of origin serves to designate a product which has the quality or characteristics due exclusively or essentially to the geographical region, including natural and human factors. 'Roquefort', 'Tequila' and 'Cognac' are registered under the Lisbon Agreement as appellations of origin. Certain types of trademarks, known as certification (or guarantee) and collective marks, may also be used to protect GIs.[77]

GIs must be protected against the use of any means in the designation or presentation of a good that indicates or suggests that that good originates in a particular geographical area other than the true place of origin in a manner which misleads the public as to the geographical origin of the good; and any use which constitutes an act of unfair competition.[78] There is additional protection for wines and spirits, namely that countries must "provide the legal means for interested parties to prevent use of a geographical indication identifying wines for wines not originating in the place indicated by the geographical indication in question or identifying spirits for spirits not originating in the place indicated by the geographical indication in question, even where the true origin of the goods is indicated or the geographical indication is used in translation or accompanied by expressions such as 'kind', 'type', 'style', 'imitation' or the like."[79]

States use a variety of different legal means to protect GIs[80] including general trademark laws, laws of general application on deceptive or unfair business practices, or sui generis GI protection. These forms of protection may or may not require formal registration procedures. GI protection under TRIPS also allows certain exceptions including lack of protection for GIs identical to generic terms, GIs similar to trademarks already applied for and acquired through good faith, and prior use of a particular GI sought to the protected.[81]

1.2.6 PROTECTION AGAINST UNFAIR COMPETITION

Protection against unfair competition is also recognized as forming part of industrial property protection.[82] Countries are to make arrangements to protect their nationals

[77] An example is 'Roquefort' which is protected as a GI in Europe, and also protected through collective and certification marks in many jurisdictions.
[78] See art. 22.1 TRIPS and art. 10bis Paris Convention. Article 10bis of the Paris Convention gives a non-exhaustive list of acts of competition contrary to honest practices in industrial or commercial matters that constitute an act of unfair competition and they include all acts of such a nature as to create confusion by any means whatsoever with the establishment, the goods, or the industrial or commercial activities, of a competitor; false allegations in the course of trade of such a nature as to discredit the establishment, the goods, or the industrial or commercial activities, of a competitor; and indications or allegations the use of which in the course of trade is liable to mislead the public as to the nature, the manufacturing process, the characteristics, the suitability for their purposes, or the quality, of the goods.
[79] See art. 23.1 TRIPS
[80] According to art. 62.1 TRIPS, members can require compliance with reasonable procedures and formalities as a condition for the acquisition and maintenance of rights to GIs. See also Taubman, Wager and Watal (n 3) 94.
[81] See Art. 24 TRIPS.
[82] See art. 10bis Paris Convention; see also WIPO (n 9) 131.

against any act of competition contrary to honest practices in industrial or commercial matters, including

> "(i) all acts of such a nature as to create confusion by any means whatever with the establishment, the goods, or the industrial or commercial activities, of a competitor;
>
> (ii) false allegations in the course of trade of such a nature as to discredit the establishment, the goods, or the industrial or commercial activities, of a competitor;
>
> (iii) indications or allegations the use of which in the course of trade is liable to mislead the public as to the nature, the manufacturing process, the characteristics, the suitability for their purpose, or the quantity, of the goods."[83]

The protection against unfair competition protects both competitors and consumers and is a matter of public interest.[84]

1.2.7 TRADE SECRETS

The protection of undisclosed information, which covers both trade secrets and test data submitted to government agencies, is protected under article 39 of the TRIPS Agreement. Under the said article, member states are enjoined to protect undisclosed information, which has been defined to mean

> "(a) is secret in the sense that it is not, as a body or in the precise configuration and assembly of its components[85], generally known among or readily accessible to persons within the circles that normally deal with the kind of information in question;
>
> (b) has commercial value because it is secret;[86] and
>
> (c) has been subject to reasonable steps[87] under the circumstances, by the person lawfully in control of the information, to keep it secret."

The person lawfully in control of the trade secret must be able to prevent it from being disclosed to, acquired by, or used by third parties without the owner's consent in a

[83] Art. 10bis (3) Paris Convention. See also the Panels in Australia – Tobacco Plain Packaging (DS435, 441, 458, 467) where they clarified the definition of 'an act of unfair competition' in paragraph 2 art. 10 bis Paris Convention as referring to "something that is done by a market actor to compete against other actors in the market in a manner that is contrary to what would usually or customarily be regarded as truthful, fair and free from deceit within a certain market."

[84] The Panel reports, Australia – Tobacco Plain Packaging case (DS435, 441, 458, 467).

[85] The information as a whole can be secret or the information may be composed of individual pieces of information which may not be a secret even though the compilation of it is. An example is the formula for Coca-Cola.

[86] The value of the information will be lost if it is made available to the public.

[87] What constitutes reasonable steps must be determined on a case-by-case basis.

'manner contrary to honest commercial practices'.[88] The protection of undisclosed information remains as long as the conditions stated above remains. Just like copyrights, there is no protection against a competitor that develops the information independently. Commercial secrets include sales methods, distribution methods, contract forms, business schedules, details of price agreements, consumer profiles, advertising strategies and lists of suppliers or clients.

Undisclosed test data and other data required to be submitted as a requirement for the attainment of marketing approval for pharmaceutical or for agricultural chemical products are also protected under the TRIPS Agreement.[89] Protection to be provided for such data is required if the data have not been disclosed; their submission is required as a condition of approving the marketing of pharmaceutical or agricultural chemical products; the products utilize new chemical entities; and the origination of the test or other data has required a considerable effort.[90] Such data must be protected against unfair commercial use and against disclosure.

1.3 THE INTERFACE BETWEEN INTELLECTUAL PROPERTY AND INNOVATION

A balanced and effective IP system is recognized as an integral element of the policy framework that supports innovation.[91] Article 7 of the TRIPS Agreement underscores the significance of the IP system for innovation and provides that the 'protection and enforcement of intellectual property rights should contribute to the promotion of technological innovation and to the transfer and dissemination of technology'. In essence therefore, innovation is an objective of IP.

Innovation is said to be a key factor in the creation of new industries and the revamping of existing ones, in both developed and developing countries.[92]

According to WIPO,

> "One of the important elements in the sound management of a science and technology policy based, inter alia, on encouraging invention and innovation is, undoubtedly, the patent system. An efficient patent system contributes to the stimulation of innovation in three main ways.
>
> First, the existence of the patent system, with the possibility of obtaining the exclusive right to work an invention for a limited period of time, constitutes an important incentive to inventive and innovative activity.

[88] A manner contrary to honest commercial practices means at least the following practices: breach of contract; breach of confidence; inducement to breach of contract or confidence; acquisition of undisclosed information by third parties who knew, or were grossly negligent in failing to know, that the above-mentioned practices were involved in the acquisition. See art 39.2 TRIPS.
[89] See art. 39.3 TRIPS.
[90] Ibid.
[91] Taubman, Wager and Watal (n 3) 238.
[92] Ibid.

> Second, the limited period of time during which the holder of a patent is entitled to prevent others from using his invention creates an environment which facilitates the efficient development and utilization of patented inventions. It protects the inventor against uncontrolled competition from those who have not taken the initial financial risk. It thus creates conditions in which risk capital can be safely advanced for the transformation of an invention into an innovation. The inventor will be at ease to further develop the invention into a final, commercially polished, product or process that could be marketed and produce a benefit.
>
> Third, the patent system provides the framework for the collection, classification and dissemination of the richest store of technological information existing in the world today. In other words, it contributes to the dissemination of new knowledge since the right of the inventor to prevent others from using his invention for a limited period is not granted freely. In return for the grant of a patent, the inventor must disclose the details of his invention to society. Thus, the information contained in a patent is available for research and experimental purposes (although not, of course, for commercial use) by all during the term of the patent grant. On the expiration of the patent term the information falls into the public domain and is freely available for full commercial use by all.
>
> The patent system thereby contributes to the evolution of the technological base of industry."[93]

This underscores the point that the grant of IPRs, and in this case patents, provide an incentive to innovate. Kur and Dreier also posit that the core objective pursued by the grant of patents is to spur innovative activities in order to promote technical progress.[94]

1.4 INTELLECTUAL PROPERTY, INNOVATION AND ECONOMIC DEVELOPMENT

As pointed out earlier, beyond economic gains and moral rights, another benefit of IP is the promotion of creativity and innovation as well as fair trading for economic and social development through a deliberate act of government policy.[95] According to WIPO, intellectual property has been used for many years by industrialized countries and some developing countries, as an important tool for technological and economic development.[96]

[93] WIPO Intellectual Property Handbook (n 9) 166-167.
[94] Kur and Dreier (n 5) 84.
[95] WIPO Intellectual Property Handbook (n 9) 3.
[96] WIPO Intellectual Property Handbook (n 9) 165.

Economic progress or development is measured by productivity which can be stimulated by innovation through the grant of IP rights. For instance:[97]

Patents: The **promise of exclusive rights** to create an invention protected by patents gives an important **incentive to innovate** and engenders transfer of technology. **The limited time** period allowing a patent holder to exclude third parties facilitates the **efficient utilization of the patented invention.** Through the patent system, **technological information is disseminated to the public** through the disclosure of the information during the application process; and utilization of information attained through patent disclosure avoids wasteful duplication of efforts and saves costs, which acts as a catalyst for further invention and leads to the advancement of science and technology.

In the end, **technological and economic development is stimulated**, and **competition is also enhanced** by creating a financial motivation to invent.

Industrial designs: Industrial designs protection stimulates creativity, which is beneficial for a country and its people, especially in the case of developing countries with extremely rich traditional art and folklore which is often protected under this form of IP.

Trademarks: Trademarks add substantial economic benefits to the business of an enterprise, allowing it to establish a market position and goodwill in the marketplace. This engenders commercial activity, which then contributes to economic development through increased production.

Copyright: Copyright is a limitless resource and capable of creating jobs, businesses, new industries, etc., and this can expedite economic development.

In order to reap the full gamut of the benefits of innovation towards economic development, innovation must exist in all levels of IP creation and administration. The Government must be innovative in structuring policies which will stimulate the creation of more IP including:

- Administration of IP must be effective and affordable.
- Creation of agencies to assist SMEs in obtaining IP protection as well as engaging in IP advocacy.
- Favourable tax regime for inventors.
- Rewards and recognition for inventors.
- Effective policies to attract foreign direct investment.
- Creation of an innovation and entrepreneurial culture.

[97] Ibid.

- The private sector must also adopt innovative IP strategies to exploit their IPRs within the legal framework allowed by a given jurisdiction.[98]

It is equally crucial for Governments put in place measures to prevent the abuse of IPRs to close the market to newcomers or competitors; or hinder access to IP embodying technologies. Governments need to strike the right balance between IP policies that stimulate innovation on the one hand and measures and mechanisms that prevent IPR holders from abusing these rights and preventing competition on the other hand. This is especially important for developing countries.

1.5 INTELLECTUAL PROPERTY, INNOVATION AND TECHNOLOGY TRANSFER

Technology transfer is the commercial transfer and acquisition of technology and leads to economic development.[99] According to article 7 of the TRIPS Agreement, the enforcement of IPRs should

> "***contribute to the promotion of technological innovation and to the transfer and dissemination of technology to the mutual benefit 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***".

According to the WTO, developed countries are obligated to provide '***incentives to enterprises and institutions in their territories for the purpose of promoting and encouraging technology transfer to Least Developed Countries members, to enable those countries to create a sound and viable technological base***.'[100]

Technology transfer agreements enable third parties to use a patented invention as well as buy the know-how that enables the invention to be worked or put into practice. Technology transfer (TT) is part of the bargain by IP right holders and the State in exchange for exclusive rights: Exclusive rights in exchange for disclosure during the patent application process. Disclosure can be fully realized by third parties after the patent term expires or through TT agreements by way of granting consent to exploit the patent.

This agreement is usually between the owner of the exclusive right, who may be the inventor, known as the transferor and the third party, known as the transferee, who is granted authorization to exploit the patent in the way stated in the agreement.

[98] WIPO (n 9) 165 - 171.
[99] WIPO (n 9) 17.
[100] Art. 66.2 TRIPS.

Technology can be transferred by right owners through:

- **Licenses** confer on a third party the right to use the protected technology or invention for one or more acts covered under the exclusive rights for the duration of the patent life (a contract between the licensor (right holder) and the licensee (third party)). There are also:

  a. Trademark licenses which may be granted as adjuncts to or separately from a patent license and this grants permission to use the mark among others.

  b**. Copyright licenses** which are primarily publishing contracts.

- **Assignments** lead to the sale and purchase of all the exclusive rights to a patented technology or invention (a contract between the assignor (right holder/ seller) and assignee (third party/ buyer)).
- **Know-how contracts** may also be used to transfer technology within a separate contract or part of a license contract. Here, the supplier of the know-how undertakes to communicate the know-how to another party, who is the recipient of the know-how.
- **Sale and import of capital goods** such as machinery and tools needed for the manufacture of products are sometimes considered as technology transfer transactions, which may be in a separate contract or form part of a license or know-how contract.
- **Franchising and distributorship agreements** form part of commercial transfer of technology through a franchise agreement. Here, the technical information and expertise of one party (franchisor or licensor) is combined with the investment of another (franchisee or licensee) for the purpose of selling goods and rendering services directly to the customer.
- **Consultancy services** (technology transfer through the help of a consultant who will give advice on the business and the appropriate technology to be used or render services on design and engineering services embodied in either know-how or consultancy agreements).
- **Turn-key projects** (whereby the right holder undertakes to supply the recipient the needed design and technical information for the industrial plant).
- **Joint venture agreements** whether contractual or equity, where a license or supply of know-how is one party's contribution to the joint venture.

MODULE 2

Overview of the WTO TRIPS Agreement and TRIPS Flexibilities

2 OVERVIEW OF THE WTO TRIPS AGREEMENT AND TRIPS FLEXIBILITIES[101]

2.1 THE TRIPS AGREEMENT

The TRIPS Agreement forms part of the Multilateral Trade Agreements integral to the Marrakesh Agreement Establishing the World Trade Organization (WTO Agreement) and is binding on all WTO Members and entered into force on 1 January 1995. In fact, TRIPS is only Annex 1C of the Agreement Establishing the World Trade Organization.[102]

TRIPS formally incorporated IP into the international trading system which resulted in IP being subject to the international trading principles of national treatment and most favoured nation treatment (MFN), as well as the Dispute Settlement Understanding (DSU) of the WTO Agreement.

TRIPS also constitutes a milestone in the process of harmonization of IP standards and includes, in one single instrument, all the major IP disciplines and sets minimum standards for their protection. TRIPS, sometimes referred to as a minimum standards agreement, may be supplemented by, among other things, the substantive provisions of the Paris and Berne Conventions, that are explicitly imported into TRIPS by reference, as well as national IP laws .[103] Over the next several years, countries entered into "TRIPS Plus" regional and bilateral agreements which sought stricter IP protection than those found in TRIPS. [104]

The Preamble and Articles 7 and 8 express a range of general goals, objectives and principles of the Agreement. The general goals of the TRIPS Agreement are set out in its Preamble, and include reducing distortions and impediments to international trade, promoting effective and adequate protection of IPRs, and ensuring that measures and procedures to enforce IPRs do not themselves become barriers to legitimate trade.[105] The objectives of the Agreement is that the "protection and enforcement of IPRs 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

[101] Session 5.
[102] April 15, 1994, Final Act Embodying the Results of the Uruguay Round of Multilateral Trade Negotiations; Legal Instruments-Results of the Uruguay Round 6, 6–18, 33 ILM 1140, 1144–53 (1994); See also Daniel J Gervais "The Changing Landscape of International Intellectual Property" Christopher Heath and Anselm Kamperman Sanders (eds), *INTELLECTUAL PROPERTY AND FREE TRADE AGREEMENTS*, vol 4 (Hart Publishing 2007) 51.
[103] Pedro Roffe, Christoph Spennemann and Johanna von Braun "Intellectual property rights in free trade agreements: moving beyond TRIPS minimum standards" Carlos M. Correa (ed), *Research Handbook on the Protection of Intellectual Property under WTO Rules*, vol 1, Edward Elgar Publishing, 2010, p. 267.
[104] Laurence R. Helfer " Intellectual Property and Human Rights: Mapping an Evolving and Contested Relationship" Dreyfuss and Pila (n 22) 5.
[105] See also Taubman, Wager and Watal (n 3) 14.

and economic welfare, and to a balance of rights and obligations."[106] Article 8, entitled 'Principles', recognizes the rights of Members to adopt measures for public health and other public interest reasons and to prevent the abuse of IPRs, provided that such measures are consistent with the provisions of the TRIPS Agreement.

The Agreement protects IP under four main headings: 1) The subject matter eligible for protection; 2) The scope of rights to be conferred; 3) Permissible exceptions to those rights; and 4) The minimum duration of protection, if applicable.

2.2 TRIPS MINIMUM STANDARDS APPROACH

According to article 1 of the TRIPS Agreement, member states '***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. Member states are also "**free to determine the appropriate method of implementing** the provisions of this Agreement within their own legal system and practice." This provision underscores the point that TRIPS is a minimum standards agreement.[107] Being minimum, these standards may be exceeded by a Member autonomously in its national laws, provided that such further protection does not contravene the provisions of the Agreement.[108]

This minimum standard approach, which allows members the freedom of implementation, also means that to establish how the law applies in any concrete practical situation, the applicable national law of a country will have to be consulted.[109]

Part 11 of the Agreement sets out the **minimum standards of IPRs** to be provided by members in the fields of copyright and related rights; trademarks, GIs, industrial designs, patents including plant varieties, layout-designs of integrated circuits and undisclosed information including trade secrets and test data. Members are also obligated to repress unfair competition through the incorporation of ***Art. 10bis of the Paris Convention for the Protection of Industrial Property***.

Compliance with the Paris Convention and the ***Berne Convention for the Protection of Literary and Artistic Works*** are required by all WTO members through the incorporation of all the main substantive provisions (except moral rights) in the TRIPS Agreement, while maintaining the obligations parties have towards each other under the said Agreements (the safeguard clause). TRIPS also adds several other obligations on matters not previously or adequately addressed by other

[106] Art. 7 TRIPS.
[107] Denis Borges Barbosa "Minimum standards vs. harmonization in the TRIPS context" Carlos M. Correa (ed), *Research Handbook on the Protection of Intellectual Property under WTO Rules*, vol 1, Edward Elgar Publishing, 2010, p. 67.
[108] For instance, in light of the principle of non-discrimination, longer protection cannot be made available only to nationals of one country. This will contravene the non-discriminatory principles under TRIPS.
[109] Taubman, Wager and Watal (n 3) 15.

conventions. Hence why TRIPS is sometimes referred to as a '**Berne-plus**' and '**Paris-plus'** agreement.[110]

2.3 TRIPS MINIMUM PROTECTION FOR IPRS

The TRIPS Agreement minimum standards relate to copyright and related rights, trademarks, geographical indications, industrial designs, patents, layout designs of integrated circuits and undisclosed information. These minimum standards are largely in relation to:

- The subject matter eligible for protection,
- The scope of rights to be conferred,
- Permissible exceptions to those rights, and
- The minimum duration of protection, if applicable.[111]

For more detailed information on the minimum protection for IPRs under TRIPS, see the PowerPoint presentation for Session 5 (Slides 6 – 12).

2.4 EXHAUSTION OF RIGHTS AND PARALLEL IMPORTATION

According to the principle of exhaustion of IPRs, once an IPR protected product is legitimately put on the market, the IPR owner cannot exclude any person who acquires the product from the IPR owner or from another person with the consent of the IPR owner from exploiting the product.[112] This principle limits the power of the IPR owner, and allows persons to exploit (use, offer to sell or sell a product embodying an IPR) without the consent of the IPR owner or without suffering any infringement action. It is sometimes referred to as the ***'first sale' doctrine***. Under US copyright law, once a copyright owner sells a copyrighted work in the US, that owner cannot prevent the resale of that work.[113] Once the item has been put on the market by or with the consent of the right owner, the exclusive distribution right is 'exhausted' and further circulation of that item can no longer be controlled by the right holder. Exhaustion specifically limits a right owner's exclusive right to control the distribution of a protected item, which lapses after the first act of distribution.[114]

Parallel imports, also known as grey markets products, is said to be 'a direct consequence of the extension of the exhaustion doctrine to international sales'. Here, the protected products are put on the market lawfully (either by the IPR owner or

[110] Taubman, Wager and Watal (n 3) 12.
[111] Roffe, Spennemann and Braun (n 103).
[112] See also Luis Mariano Genovesi "The TRIPS Agreement and Intellectual Property Rights Exhaustion", Correa (n 103) 216.
[113] WIPO (n 9) 44.
[114] See Genovesi (n 112).

with its consent) in the place of export (the foreign country) and a third party then makes an importation 'in parallel to the authorized distribution network'.[115]

While it may generally accepted that IPRs are exhausted within the jurisdiction where the first sale took place, the issue which brings parallel importation to the forefront is whether such rights are exhausted when the first sale takes place outside the jurisdiction in question, and the protected goods then find their way into foreign markets?[116] The answer to this depends on the applicable exhaustion principle chosen by a particular jurisdiction, be it a regime of national, regional or international exhaustion and whether or not parallel importation is permitted.[117]

The distinction among these three regimes of exhaustion takes into account the territory in which the product covered by the IPR has been placed.[118] **National exhaustion** occurs when the product is placed in the territory of the country that confers the IPR. Here, the IP right owner's distribution rights are exhausted once the owner or a third party authorized by the owner puts the protected product on the market in that country. Therefore, the rights of the IP owner are not exhausted with regards to protected products put on the market in another country. **Regional exhaustion** means that the IPR is exhausted when the product is put in the territory of a regional trade agreement, for instance the European Union and in this case the IP holder's rights are exhausted once the first authorized sale takes place anywhere within the specified region. **International exhaustion** happens when the product is put on the market in any country. Here, the IP right owner's distribution right in that country is exhausted upon first sale of the protected product, regardless of the country where the first act of distribution took place.

Note that during the Uruguay Round negotiations, members to the TRIPS Agreement negotiated a clause that gave them discretion on which exhaustion regime to adopt. Article 6 provides that, subject to the MFN and national treatment obligations, nothing in the Agreement shall be used to address the issue of the exhaustion of intellectual property rights.[119]

The concept of exhaustion of rights and parallel importation are very relevant for a number of reasons:[120]

- National exhaustion may favour market segmentation, with respect to differential or discriminatory pricing *(allowing for the rights holder to set different*

[115] Ibid. See also Warwick A. Rothnie, Parallel Imports 1 (Sweet & Maxwell 1993).
[116] Ibid.
[117] Ibid.
[118] Genovesi (n 112).
[119] See also the 2001 Doha Ministerial Declaration on TRIPS. See also Taubman et. al (n 3) 20. See also Luis Mariano Genovesi "The TRIPS Agreement and Intellectual Property rights exhaustion" Correa (n 103) 216. See also Warwick A. Rothnie, Parallel Imports 1 (Sweet & Maxwell 1993).
[120] See Miranda Forsyth and Warwick A. Rothnie, "Parallel Imports" Anderman (n 19) 429.; See also Idris (n 11).

prices in the different countries), product differentiation, etc. while international exhaustion allows parallel importation of the same product at lower prices in other countries.

- Members seeking to stress competition will adopt a doctrine of international exhaustion, which will allow for parallel imports and thus enhance competition.

- Members which are in favour of strengthened exclusive rights will operate on the basis of national (or regional exhaustion).

2.5 COMPULSORY LICENSE/GOVERNMENT USE[121]

Licenses that are granted by the owner of the patent are considered "voluntary", as distinguished from "compulsory" or "non-voluntary" licenses, which are granted without the consent or authorization of the rights holder. The beneficiary of a compulsory license has the right to perform acts covered by the exclusive right under an authorization given by a government authority against the will of the owner of the patent for invention.[122] A government can also decide to use the patent itself. This particular form of compulsory license is called '**government use**' or "**public non-commercial use**".[123]

Countries generally grant compulsory licenses to prevent the abuses which might result from the exercise of the exclusive rights conferred by the patent,[124] where a compulsory license is deemed necessary for reasons including public welfare, including health, defense, and development of the economy. In the latter instance, abuse may not be prevalent.

Article 31 of the TRIPS Agreement allows Members to authorize third persons to exploit a patented invention, without the consent of the patent owner, subject to the fulfilment of certain conditions. There are no limitations on the grounds upon which a government can authorize use of a patent by third parties. The conditions to be met are as follows:

> "(a) authorization of such use shall be considered on its individual merits;
>
> (b) such use may only be permitted if, prior to such use, the proposed user has made efforts to obtain authorization from the right holder on reasonable commercial terms and conditions and that such efforts have not been successful within a reasonable period of time. This requirement may be waived by a Member in the case of a national emergency or other circumstances of extreme urgency or in cases of public non-commercial use.

[121] Anderman (n 19) introductory note.
[122] WIPO (n 9) 409.
[123] See art. 31 TRIPS.
[124] See art. 5(2) Paris convention where failure to work a patent is given as an example of patent abuse.

In situations of national emergency or other circumstances of extreme urgency, the right holder shall, nevertheless, be notified as soon as reasonably practicable. In the case of public non-commercial use, where the government or contractor, without making a patent search, knows or has demonstrable grounds to know that a valid patent is or will be used by or for the government, the right holder shall be informed promptly;

(c) the scope and duration of such use shall be limited to the purpose for which it was authorized, and in the case of semi-conductor technology shall only be for public non-commercial use or to remedy a practice determined after judicial or administrative process to be anti-competitive;

(d) such use shall be non-exclusive;

(e) such use shall be non-assignable, except with that part of the enterprise or goodwill which enjoys such use;

(f) any such use shall be authorized predominantly for the supply of the domestic market of the Member authorizing such use;

(g) authorization for such use shall be liable, subject to adequate protection of the legitimate interests of the persons so authorized, to be terminated if and when the circumstances which led to it cease to exist and are unlikely to recur. The competent authority shall have the authority to review, upon motivated request, the continued existence of these circumstances;

(h) the right holder shall be paid adequate remuneration in the circumstances of each case, taking into account the economic value of the authorization;

(i) the legal validity of any decision relating to the authorization of such use shall be subject to judicial review or other independent review by a distinct higher authority in that Member;

(j) any decision relating to the remuneration provided in respect of such use shall be subject to judicial review or other independent review by a distinct higher authority in that Member;

(k) Members are not obliged to apply the conditions set forth in subparagraphs (b) and (f) where such use is permitted to remedy a practice determined after judicial or administrative process to be anti-competitive. The need to correct anti-competitive practices may be taken into account in determining the amount of remuneration in such cases. Competent

authorities shall have the authority to refuse termination of authorization if and when the conditions which led to such authorization are likely to recur;

(l) where such use is authorized to permit the exploitation of a patent ("the second patent") which cannot be exploited without infringing another patent ("the first patent"), the following additional conditions shall apply:

(i) the invention claimed in the second patent shall involve an important technical advance of considerable economic significance in relation to the invention claimed in the first patent;

(ii) the owner of the first patent shall be entitled to a cross-license on reasonable terms to use the invention claimed in the second patent; and

(iii) the use authorized in respect of the first patent shall be non-assignable except with the assignment of the second patent."

Further grounds can be found in Article 8(1), which also allows Members to adopt measures necessary to protect public health and nutrition, and to promote the public interest in sectors of vital importance to their socio-economic and technological development. Furthermore Art 8(2) also permits members to take necessary measures to prevent the abuse of IPR by right holders and practices that unreasonably restrain trade or adversely affect the international transfer of technology.

MODULE 3

TRIPS Agreement and Public Health

3 TRIPS AGREEMENT AND PUBLIC HEALTH[125]

3.1 IPRS AND PUBLIC HEALTH

Public health[126] remains a global concern despite significant breakthroughs in scientific and technological innovation. According to the World Health Organization (WHO), in 2002, 1.7 billion people, or one out of three on the planet, lacked access to essential medicines.[127] Research also shows that about 3 million people died from HIV/AIDS in 2001, 2.3 million of these deaths occurring in Sub- Saharan Africa, and also nearly 1.7 million people worldwide died from tuberculosis in the same year and there were as many as 10.2 million new cases in 2005.[128]

Generally, the granting of exclusive patent rights through the patent system means that patented medicines are more expensive than 'generic' or 'off-patent' medicines. Higher prices associated with patented medicines create particular difficulties for developing countries seeking to manufacture or import them to deal with serious public health concerns, such as the HIV/AIDS crisis.[129] The TRIPS Agreement makes it mandatory to grant patents for all fields of technology, which makes it impossible to exclude innovation relating to medicine.

On the other hand, the development of new drugs is expensive. It involves high R&D costs, long and expensive clinical trials, protracted regulatory approval processes, including the process of acquiring patents covering the invention. Exclusive rights for a limited period of time were therefore used as an incentive to promote the research and development of new drugs by granting the inventor the right to exclude others from exploiting the patented invention.

The TRIPS Agreement represents an attempt at the multilateral level to achieve the difficult task of striking the right balance between providing incentives for research and development of new drugs (grant of exclusive rights) and making these drugs globally accessible to patients who need them. This balancing act accounts for the right of member States under TRIPS to limit the use of IPRs in favor of public health.[130]

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[125] Session 6.

[126] According to Rebecca S. Eisenberg, the term "public health" connotes that "health is a public good that might be provided through collective action and initiatives of social planners." See Rebecca S. Eisenberg "Intellectual Property and Public Health" Dreyfuss and Pila (n 22) 1, 932.

[127] WHO Bulletin (2004), p. 61, 'The World Medicines Situation', WHO/ EDM/PAR/2004.5. See also S.K. Verma "The Doha Declaration and access to medicines by countries without manufacturing capacity" Correa (n 34) 624.

[128] Commission on Intellectual Property Rights, Integrating Intellectual Property Rights and Development Policy, Report of the Commission on Intellectual Property Rights, London, September 2002, available at http://www.iprcommission.org/papers/pdfs/final_report/CIPRfullfinal.pdf.

[129] Stine Jessen Haakonsson and Lisa Ann Richey, 'TRIPs and Public Health: The Doha Declaration and Africa' (2007) 25 Development Policy Review 71.

[130] See art 8. TRIPS.

The 2001 Doha Ministerial Declaration on the TRIPS Agreement recognizes the importance of creating a positive, mutually reinforcing link between the IP system and access to medicines, and this informed the later amendment of the TRIPS Agreement.

3.2 PATENTABILITY, PATENT TERMS AND PUBLIC HEALTH

The TRIPS Agreement creates an obligation for all WTO Members to grant patents with a minimum of 20 years as well as the obligation to grant patents in all fields of technology.[131] Before TRIPS, many developing countries did not grant pharmaceutical product patents and/or they limited patent terms, which allowed generic medicines industry to flourish in some of those countries.[132] Generic companies made relatively new products available at lower prices. These products would have been expensive or unavailable had they been patent protected.[133] However, the requirement for a minimum term of 20 years delays the entry of generic companies. There is also the problem of evergreening of patents[134] (where a pharmaceutical company blocks or delays market access for generic versions of its drug even after the expiry of the patent).

The TRIPS Agreement, however, allows Members to determine the criteria of patentability even though no field of technology, such as medicines or food, should be excluded. Members can set patenting standards so as to ensure patents are awarded only for true innovation.[135] This can help prevent the practices of follow-on patenting and 'evergreening', and make it difficult for patents to be granted. Members can also **set high criteria for patentability, allow for pre-grant opposition, protect generic production of 'mail-box' patented drugs** (continuation of generic drugs for which patent applications were received during the transition period granted to developing countries under TRIPS)[136] in order to make it stricter to acquire patent protection for pharmaceuticals.

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[131] See art. 27. TRIPS.

[132] The 1970 Indian Act did not allow patents for pharmaceuticals.

[133] Marion Motari and others, 'The Role of Intellectual Property Rights on Access to Medicines in the WHO African Region: 25 Years after the TRIPS Agreement' (2021) 21 BMC Public Health 1.; Research also shows that in 1996, when a medical breakthroughs ushered in highly active antiretroviral therapy (HAART), which combined several (usually three) different classes of antiretrovirals (ARVs) into one treatment regimen that attacked the virus at various places in its life cycle, this new treatment strategy promised to change HIV infection from a death sentence into a manageable chronic disease. However, the drugs were purchasable only from originator companies, which produced them in small quantities carrying paralysing price tags of US$ 10,000 to US$ 15,000 per person per year, and controlled the patents to maintain their monopoly. See Ellen FM 't Hoen, *Private Patents and Public Health. Changing Intellectual Property Rules for Access to Medicines* (Health Action International 2016), https://haiweb.org/publication/private-patents-public-health-changing-intellectual-property-rules-access-medicines/.

[134] The 2003 WHO Commission on IP, Innovation and Public Health (CIPIH) defined evergreening as "a term popularly used to describe patenting strategies when, in the absence of any apparent additional therapeutic benefits, patent holders use various strategies to extend the length of their exclusivity beyond the 20-year patent term".

[135] 't Hoen (n 133) 92.

[136] See the Indian Patent Amendment Act, 2005.

This must be done cautiously considering the possible effect of such measures on investment in R&D for the innovation of new drugs.

3.3 DEVELOPMENT IN THE FRAMEWORK OF DOHA[137]

The Doha Declaration on the TRIPS Agreement and Public Health was adopted, at the WTO Ministerial Meeting at Doha in 2001, in order to meet the health crisis that faced the world, especially developing countries with regards to access to affordable medicines [138]

The 7-paragraph Declaration emphasizes the importance of public health considerations in implementing the TRIPS Agreement. It affirms the point that the TRIPS Agreement can and should be interpreted and implemented in a manner that takes full cognizance of WTO Members' right to protect public health and, in particular, to promote access to medicines for all. The Declaration was adopted on 14 November 2001 and states as follows:

> "1. We recognize the gravity of the public health problems afflicting many developing and least-developed countries, especially those resulting from HIV/AIDS, tuberculosis, malaria and other epidemics.
>
> 2. We stress the need for the WTO Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS Agreement) to be part of the wider national and international action to address these problems.
>
> 3. We recognize that intellectual property protection is important for the development of new medicines. We also recognize the concerns about its effects on prices.
>
> 4. We agree that the TRIPS Agreement does not and should not prevent members from taking measures to protect public health. Accordingly, while reiterating our commitment to the TRIPS Agreement, we affirm that the Agreement can and should be interpreted and implemented in a manner supportive of WTO members' right to protect public health and, in particular, to promote access to medicines for all.
>
> In this connection, we reaffirm the right of WTO members to use, to the full, the provisions in the TRIPS Agreement, which provide flexibility for this purpose.

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[137] For a thorough understanding of the events leading to Doha, see Ellen FM 't Hoen, *The Global Politics of Pharmaceutical Monopoly Power. Drug Patents, Access, Innovation and the Application of the WTO Doha Declaration on TRIPS and Public Health* (AMB Publishers 2009). See also 't Hoen (n 133).

[138] Commission on Intellectual Property Rights, Integrating Intellectual Property Rights and Development Policy, Report of the Commission on Intellectual Property Rights, London, September 2002, available at http://www.iprcommission.org/papers/pdfs/final_report/CIPRfullfinal.pdf.

5. Accordingly and in the light of paragraph 4 above, while maintaining our commitments in the TRIPS Agreement, we recognize that these flexibilities include:

a. In applying the customary rules of interpretation of public international law, each provision of the TRIPS Agreement shall be read in the light of the object and purpose of the Agreement as expressed, in particular, in its objectives and principles.

b. Each member has the right to grant compulsory licences and the freedom to determine the grounds upon which such licences are granted.

c. Each member has the right to determine what constitutes a national emergency or other circumstances of extreme urgency, it being understood that public health crises, including those relating to HIV/AIDS, tuberculosis, malaria and other epidemics, can represent a national emergency or other circumstances of extreme urgency.

d. The effect of the provisions in the TRIPS Agreement that are relevant to the exhaustion of intellectual property rights is to leave each member free to establish its own regime for such exhaustion without challenge, subject to the MFN and national treatment provisions of Articles 3 and 4.

6. We recognize that WTO members with insufficient or no manufacturing capacities in the pharmaceutical sector could face difficulties in making effective use of compulsory licensing under the TRIPS Agreement. We instruct the Council for TRIPS to find an expeditious solution to this problem and to report to the General Council before the end of 2002.

7. We reaffirm the commitment of developed-country members to provide incentives to their enterprises and institutions to promote and encourage technology transfer to least-developed country members pursuant to Article 66.2. We also agree that the least-developed country members will not be obliged, with respect to pharmaceutical products, to implement or apply Sections 5 and 7 of Part II of the TRIPS Agreement or to enforce rights provided for under these Sections until 1 January 2016, without prejudice to the right of least-developed country members to seek other extensions of the transition periods as provided for in Article 66.1 of the TRIPS Agreement. We instruct the Council for TRIPS to take the necessary action to give effect to this pursuant to Article 66.1 of the TRIPS Agreement."

The Declaration was followed by the Implementing Decision on its Paragraph 6 of 30 August 2003 and an accompanying Chairperson's statement at the General Council meeting on 30 August 2003. The Declaration and Decision are related to national health emergencies, namely, HIV/AIDS, TB, Malaria and other epidemics.

In order to make the Decision part of the TRIPS Agreement, the WTO Members on 6 December 2005 approved an amendment of the TRIPS Agreement in the form of

Article 31*bis* making permanent the decision on intellectual property and public health. Article 31*bis* deals primarily with the problem with Article 31 TRIPS (on compulsory licenses) which allows a country to issue a compulsory license that only covers drugs manufactured and predominantly used within the country's borders. This posed a difficult problem for poor countries, which lack the necessary manufacturing capacity in the pharmaceutical sector, but who needed access to medicines.[139]

The practical application and implication of the DOHA Declaration are as follows:[140]

- The TRIPS Agreement does not and should not prevent members from taking measures to protect public health including but not limited to those resulting from HIV/AIDS, tuberculosis and malaria.

- TRIPS should be interpreted and implemented in a manner that recognizes the right of Members to protect public health and promote access to medicines.

    - TRIPS must be interpreted in light of its objectives and principles which include the protection and enforcement of IPRs in a manner conducive to social welfare and the adoption of measures necessary to protect public health.

- The grant of compulsory licenses is allowed without any conditions including the need to first ascertain the prevalence of an emergency.

    - Doha Declaration allows Members to decide what constitutes a national emergency.

- Members can determine the rules on exhaustion, and by extension, parallel importation.

- TRIPS Council Decision and the WTO General Council extended the paragraph 7 of Doha Declaration on the exemption for patents and rights in undisclosed information for pharmaceutical products to 2016 and further extended to 2033 or until a Member graduates from the least developed country (LDC) category, whichever is earlier. LDC Members will therefore be allowed to maintain maximum flexibility in their approach to patenting

[139] See also S.K. Verma "The Doha Declaration and access to medicines by countries without manufacturing capacity" Correa (n 103) 627.
[140] 't Hoen (n 133) 47.

pharmaceutical products until at least 2033. They can decide to refuse patent protection for pharmaceuticals during this period.

- Pursuant to para.6 of Doha Declaration, a system of special compulsory licensing regime was established for the export of pharmaceuticals to countries in need.[141]

    - The General Council Decision **(2003 Decision)** allows for waiver of article 31(f) TRIPS condition for exporting members to grant compulsory licenses for predominantly supplying the domestic market.
        - Importing members must also pay adequate remuneration to the right holder upon grant of a compulsory license, under art 31(h) TRIPS.

    - General Council Protocol Amending the TRIPS Agreement (**2005 Protocol**)[142]
        - This protocol was a more permanent solution to the health problem.
        - This allowed for the insertion of **Art 31*bis* and Annex to TRIPS** pursuant to the 2003 Decision. Members who have not yet accepted the 2005 Protocol continue to operate under the 2003 Decision.
        - Applies to members who have accepted the 2005 Protocol. The rest are bound by the 2003 Decision, which is in *pari materia* to the 2005 Protocol.

- LDCs can authorize the importation or production of patented medicines under the paragraph 7 pharmaceutical waiver or exemption, without threats of patent infringement suits.

    - Many LDCs, including Angola, invoked the paragraph 7 exemption to procure affordable essential medicines for the treatment of HIV.

        - At least 31 LDCs authorized the importation of antiretroviral drugs (ARVs) invoking this exemption.[143]

    - There have been many instances of Compulsory Licenses issued for medicines, including:

[141] Wenwei Guan, 'IPRs, Public Health, and International Trade: An International Law Perspective on the TRIPS Amendment' (2016) 29 Leiden Journal of International Law 411.
[142] The 2005 Protocol became effective on 23rd January 2017.
[143] 't Hoen (n 133) 53.

- Government use licenses issued by Mozambique and Zambia for local production of ARVs.
- Government use license issued by Ghana to allow importation of ARVs after declaring HIV/AIDS a national emergency.[144]

- The notification by a country of its intention to issue compulsory licenses often resulted in the reduction of prices by the patent holder.[145]

  - Thailand suspended its compulsory license for the cancer drug 'imatinib' after the patent holder established a donation program in Thailand (Novartis).
  - Voluntary licenses were granted in Kenya for the production of ARVs after a local manufacturer won a bid to provide the drug.
  - **Medicine Patent Pool** was created by UNITAID[146] for the negotiation of licenses for HIV medicines for the supply to low-and-middle-income countries.

3.4 ARTICLE 31*BIS* TRIPS

Article 31*bis* represents the first amendment to the 1994 TRIPS Agreement. This amendment provides a special compulsory licensing system, also referred to as the "Paragraph 6 System", entitles WTO Members to grant a special type of compulsory license primarily permitting the production of medicines exclusively for export to meet the needs of other WTO Members.[147] Practically, the amendment contains waivers derogating from the obligations set out in article 31 TRIPS concerning pharmaceuticals. Article 31bis made the following permissible:

- A member country can export medicines under a compulsory license to countries with no or inadequate production facilities or manufacturing capability, thereby waiving the obligation of the exporting member under Article 31(f) to issue compulsory licenses predominantly for the domestic market.

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[144] "Notification of Emergency and Issuance of Government Use License," Accra, Ghana: 26 October 2005, available at http://www.cptech.org/ip/health/cl/Ghana.png (last accessed 29 December 2022); See also http://www.cptech.org/ip/health/cl/recent-examples.html for other examples.

[145] 't Hoen (n 133) 108.; See also Alexandra Bhattacharya, 'The Use of Paragraph 6 of the Doha Declaration on the TRIPS Agreement and Public Health (2001): A Review of Implementation Experiences in the Developing Countries' (2012) 13 Journal of World Investment and Trade 186.

[146] https://unitaid.org/#en.

[147] Roger Kampf, 'Special Compulsory Licences for Export of Medicines: Key Features of WTO Members' Implementing Legislation', WTO Staff Working Paper ERSD-2015-07, 31 July 2015, available at: https://www.wto-ilibrary.org/content/papers/25189808/185/read.

- The requirement to pay adequate remuneration for compulsory licenses under Article 31(h) was also modified to avoid double remuneration of the right holder. To this end, if a compulsory license has to be granted in both the exporting and the importing countries, remuneration need only be paid in the exporting country.

- Under article 31*bis*.3, a Member may also export products manufactured or imported under a compulsory license more easily amongst members of a regional trade agreement (RTA) at least half the membership of which consists of LDCs.

The implementation and use of these waivers is optional. Members who wish to utilize the system must adopt specific implementing measures which incorporate the "Paragraph 6 System" in their respective legal orders, satisfying the various requirements as either an importer or exporter. Kampf shows in his findings that as of July 2015: [148]

- 51 WTO Members (and Serbia) have adopted specific implementing measures with a variable degree of detail.
- Members that have specifically adopted legislation in their national legal framework to use the System either as exporters, importers or both include:
    - 35 industrialized Members (including the EU and its member States)
    - Two transition countries
    - 12 developing country Members
    - Two least developed countries (Burundi and Zanzibar (as part of the United Republic of Tanzania).

Article 31*bis* has now incorporated the solution of Paragraph 6.

3.5 TRIPS-PLUS AGREEMENTS AND PUBLIC HEALTH

The TRIPS minimum standards, which are permissive and not mandatory, provides **flexibility** in implementation as well as specific provisions providing public interest safeguards. Many of these safeguards can be traced back to developing countries' concerns expressed during the negotiations of the TRIPS Agreement about the effects of stricter intellectual property (IP) rules on their ability to access new technologies, including medicines.

The fact that the TRIPS Agreement provides minimum standards, as explained above, implies that variation in national implementation is indeed possible. This also means that the variation could lead to a higher or stricter IP standards. Article 1.1 TRIPS is clear on this when it states that countries are free but not obliged to implement more extensive IP protection than is required by TRIPS.

[148] Ibid.

In the same line, TRIPS permits Members to freely determine the substantive grounds for the issuance of compulsory licenses and authorizes them to determine their own system of IPR exhaustion that might facilitate parallel imports of low-priced drugs. In dealing with test data submitted to regulatory authorities for marketing approval purposes, TRIPS also leaves each Member to determine the appropriate form of protection. The Doha Declaration further reinforced and expanded the flexibilities related to public health and specifically, access to medicines. Under the Doha Declaration, Members have the right 'to use, to the full, the provisions in the TRIPS Agreement, which provide flexibility for this purpose'.

Further, the WTO General Council Decision of 30 August 2003 on the Implementation of Paragraph 6 of the Doha Declaration on the TRIPS Agreement and Public Health also extended the TRIPS flexibilities with regard to compulsory licensing through its special compulsory licensing regime.

These flexibilities and the freedom they give to Members to adopt stricter rules than provided for under the TRIPS Agreement, have led to the proliferation of rules generally termed as TRIPS-plus rules. TRIPS-plus rules add on to the minimum standards of the TRIPS Agreement, providing for much stricter IP standards.[149]

Examples of TRIPS-plus provisions include **patent linkage** (prohibits the grant of marketing approval by drug regulatory authorities during the patent term without the consent of the patent holder), **data exclusivity** (prohibits for a certain period of time the use of pharmaceutical test data for regulatory purposes such as obtaining a marketing authorization), **extension of patent term and scope**, **restrictions on the issuance of compulsory licensing** and **restrictions to parallel importation**.

3.5.1 IP-Related Restrictions of Competition in the Pharmaceutical Sector

Competition is "the process of rivalry between business enterprises for customers".[150] Competition among businesses can lead to better prices (**price competition**) and innovation **(dynamic competition**).[151] Price competition and dynamic competition are necessary for the production and affordability of

[149] Han Bing, 'TRIPS-plus Rules in International Trade Agreements and Access to Medicines Chinese Perspectives and Practices' (2021). Available at: https://www.bu.edu/gdp/files/2021/04/GEGI_WP__Bing_FIN.pdf.
[150] Khemani, R.S. Competition policy and promotion of investment, economic growth and poverty alleviation in least developed countries (English). Foreign Investment Advisory Service (FIAS) occasional paper; no. FIAS 19 Washington, D.C.: World Bank Group.
http://documents.worldbank.org/curated/en/397801468174885108/Competition-policy-and-promotion-of-investment-economic-growth-and-poverty-alleviation-in-least-developed-countries.
[151] David J Gerber, *Global Competition: Laws, Markets and Globalization* (Oxford University Press 2010).

medicines. Research has shown that the presence of generics on the market accounted for the dramatic reduction in the prices of ARVs for HIV treatment.[152]

Exclusive IPRs are granted to **exclude** competitors**,** albeit for a limited period of time, and ***may*** create a monopoly with respect to that invention. This means that the grant of exclusive rights ***may*** restrict competition if the inventor refuses to grant licenses or through the imposition of anti-competitive obligations such as:[153]

- **tie-in clauses**
- **conditions preventing challenging the validity of the patent**
- **minimum royalty clauses**
- **grant back clauses**.

The TRIPS Agreement recognizes that some licensing practices or conditions relating to IPRs may restrain competition and have adverse effects on trade and therefore allows members to specify in their national laws licensing practices or conditions that constitute an abuse of IPRs and have an adverse effect on competition in a relevant market. [154]

3.6 MINISTERIAL DECISION ON THE TRIPS AGREEMENT ADOPTED ON 17 JUNE 2022[155]

The Ministerial decision adopted on 17 June 2022 on the TRIPS Agreement aims to facilitate access to Covid-19 vaccines in eligible countries.

Without prejudice to the different flexibilities recognized in the TRIPS Agreement in relation to access to medicines, such as the Doha Declaration and Article 31bis, the Ministerial decision puts forward a number of additional flexibilities that are summarized below:

Eligible Members: "For the purpose of this Decision, all developing country Members are eligible Members. However, developing country Members with existing capacity to manufacture COVID-19 vaccines are encouraged to make a binding commitment not to avail themselves of this Decision".[156]

Scope of the decision: The decision aims to limit the rights of the patent holder on covid-19 vaccines in order to ensure the supply of vaccines to eligible Members. The

[152] 't Hoen (n 133).
[153] See Anu Bradford and Adam S Chilton, 'Competition Law Around the World from 1889 to 2010: The Competition Law Index' (2018) 14 Journal Of Competition Law & Economics 393.
[154] See art.40 TRIPS. Module 4 provides a detailed discussion on the interface between competition law and IP.
[155] Available at: https://docs.wto.org/dol2fe/Pages/SS/directdoc.aspx?filename=q:/WT/MIN22/W15R2.pdf&Open=True.
[156] See footnote 1 of the Ministerial decision.

decision states: *"Notwithstanding the provision of patent rights under its domestic legislation, an eligible Member may limit the rights provided for under Article 28.1 of the TRIPS Agreement (hereinafter "the Agreement") by authorizing the use of the subject matter of a patent required for the production and supply of COVID-19 vaccines without the consent of the right holder to the extent necessary to address the COVID-19 pandemic, in accordance with the provisions of Article 31 of the Agreement, as clarified and waived in paragraphs 2 to 6 below".*

Instruments at the domestic level: The legal instrument that may be used in order to trigger the use of Article 31 is left to the discretion of the eligible Members. As pointed out, *"an eligible Member may authorize the use of the subject matter of a patent under Article 31 without the right holder's consent through any instrument available in the law of the Member such as executive orders, emergency decrees, government use authorizations, and judicial or administrative orders, whether or not a Member has a compulsory license regime in place".*

Additional flexibilities recognized in the decision:

- Eligible Members are not required to make efforts in order to obtain authorization from the right holder. This requirement of TRIPS Article 31 is waived in the context of this decision (see 3(a) of the decision).
- Vaccines manufactured under this decision could be exported to eligible Members. The decision notes in this regard: "*An eligible Member may waive the requirement of Article 31(f) that authorized use under Article 31 be predominantly to supply its domestic market and may allow any proportion of the products manufactured under the authorization in accordance with this Decision to be exported to eligible Members*».
- Eligible Members are required to take the necessary measures in order to prevent the re-exportation of the vaccines that are produced under the authorization in accordance with this Decision and have been imported into their territories under this Decision. The objective of such limitation is to prevent a market of parallel exports.
- The determination of adequate remuneration under Article 31(h) may take account of the humanitarian and not-for-profit purpose of specific vaccine distribution programs.
- Article 39.3 on the protection of undisclosed information should not prevent an eligible Member from enabling the rapid approval for use of a covid-19 vaccine produced under this decision.
- Eligible Members are required to communicate the implementation of the decision to the TRIPS Council.

MODULE 4

The Interface between IP and Competition Law

4 THE INTERFACE[157] BETWEEN IP AND COMPETITION LAW[158]

IPRs confer exclusive rights on their holders regarding the exploitation of their work. Whereas the aim of granting IPRs is usually to provide incentives for innovation, the exclusive rights conferred by IPRs may, however, be used by the IPR holder to hinder competition, thus preventing the availability of new and innovative products. Such restrictions include refusal to license or the use of restrictive licensing conditions. This raises questions about the relationship between IPRs and competition law.[159]

4.1 INTRODUCTION TO THE OBJECTIVES OF IP LAW

The IP system is a tool of public policy.[160] It seeks to stimulate **creativity and technological innovation** for the promotion of economic, social and cultural welfare. Without the incentives IPRs grant, it has been opined that research and development investment would decline and with it the innovative capacity of an economy. [161]Copyrights and related rights, for instance, are granted to stimulate and reward creative work, and to create a market for creative work; while patents and other industrial property rights are granted to stimulate and reward innovations resulting from R&D. Without the protection of exclusivity, firms may choose to keep their innovative ideas secret as opposed to disclosing them in their patent claims.[162]

There is also the **economic theory justification for IP protection**:

- Products from creativity are **"public goods"**:
  - they are **"non-excludable"** (*once created, none can be excluded from its use)* and "**non-rivalrous"** (*one person's use of the good does not deprive another of its use)*

In the circumstances, in the absence of any form of protection, the incentive to create and to innovate may be limited. Hence, IP protection through the grant of exclusive rights offers a 'solution' to this problem. Exclusive rights granted to creators and inventors allow the right holder to ***exclude*** or **prevent** other persons from ***copying*** the protected work or invention. These rights are essentially 'negative' rights; they prevent copying of the protected innovation, or what is termed as ***freeriding***.[163]

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[157] The relationship between competition law and intellectual property law has been referred to as the 'interface problem' and seen to be a matter of controversy. See Andreas Heinemann "International Antitrust and Intellectual Property" Heath and Sanders (n 102) 262. See also Sumanjeet Singh, 'Innovation, Intellectual Property Rights and Competition Policy' (2015) 5 Innovation and Development 147.

[158] Session 7.

[159] Kur and Dreier (n 5) 378.

[160] Refer to Session 1 on the 'Rational of IP'.

[161] Anderman (n 19).

[162] Ibid.

[163] Katarzyna Czapracka, *Intellectual Property and the Limits of Antitrust: A Comparative Study of US and EU Approaches* (Rudolph JR Peritz Steven D. Anderman ed, Edward Elgar 2009). See also Anderman (n 19) 5.

IP law also facilitates the transfer and dissemination of technology **through the patent system.** This helps create a 'fair' bargain for the creators/inventors to disclose their work and invention to the public in exchange for exclusive rights for a stated period of time. This bargain leads to advancements in technology and transfer of technology through FDIs, trade and licensing.

Other objectives of IP also include consumer welfare, protection of fair competition through trademarks, GIs, design patents system.[164]

4.2 INTRODUCTION TO THE OBJECTIVES OF COMPETITION LAW[165]

Competition law (also called antitrust law in the United States of America) is generally seen as a public policy aimed at fostering a public good: that is competition.[166] This explains why public bodies or governmental organizations have been entrusted with the task of overseeing the proper functioning of markets and the power to prosecute violations of competition law in many jurisdictions.[167]

Competition means "the process of rivalry between business enterprises for customers".[168] The enactment of competition law does not necessarily result in competition. However, as firms compete, there is a need to protect and promote the competition process to prevent it from being distorted by anticompetitive practices. This is the principal objective of an effective competition law: to maintain and promote competition in markets.[169] It is meant to safeguard and nurture the competition process itself and not necessarily existing competitors. "Defending the utmost freedom to compete" captures the core essence of competition law."[170]

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[164] Refer to Session 1 above.

[165] The United Nations General Assembly entrusted UNCTAD to be the focal point within the United Nations on competition issues, as contained in General Assembly resolutions 35/63 of 22 April 1980. In 1980, the United Nations Conference on Restrictive Business Practices adopted the Set of Multilaterally Agreed Equitable Principles and Rules for the Control of Restrictive Business Practices (The UN Set), which is the only multilateral agreement on competition policy. The UN Set provides a set of equitable rules for the control of anti-competitive practices. UNCTAD has assisted many developing countries in designing and drafting their competition legislation and has been continuing to do so for the last four decades. UNCTAD has developed a Model Law on Competition (see the revised commentaries on the Model Law on Competition at https://unctad.org/meeting/sixth-united-nations-conference-review-all-aspect-set-multilaterally-agreed-equitable). See UNCTAD competition website for more information on UNCTAD's work and publications on competition law and policy, https://unctad.org/Topic/Competition-and-Consumer-Protection. See Chapter I of the UNCTAD Model Law on Competition on the objectives of competition law at https://unctad.org/system/files/official-document/tdrbpconf7L1_en.pdf.

[166] Jonathan B Baker and Timothy F Bresnahan and et al, *Handbook of Antitrust Economics* (Paolo Buccirossi ed, The MIT Press 2008).

[167] Esther Koomson, Developing without a Competition Legislation: An Analysis of Competition Law in Ghana and Its Impact on Competition and Development (September 16, 2020). MIPLC Master Thesis Series (2019/20, Available at SSRN: https://ssrn.com/abstract=3903953 or http://dx.doi.org/10.2139/ssrn.3903953.

[168] Khemani (n 150).

[169] Ibid.

[170] Nicola Giocoli, *Predatory Pricing in Antitrust Law and Economics. A Historical Perspective.* (Michael D Kaplowitz Nicholas Mercuro ed, Routledge).

The ultimate aim of competition law has often been contested from two main points of view: a total welfare perspective (which includes both consumers' and firms' surpluses with equal weight) or, from only a consumer welfare perspective.[171] Each jurisdiction has a unique history and culture, hence, would have different aims for adopting a competition law. Ultimately, the market conditions ought to be maintained in a manner conducive for competition in that country.[172]

Developed countries take the position that the benefits derived from competition is only for efficiency and consumer welfare through the provision of greater choice of goods and services at lower prices.[173] However, developing countries consider a total welfare perspective with broader subjects of distribution and power in their antitrust laws including goals of promoting the "public interest" which cover economic efficiency and consumer welfare goals as well as other socio-economic and political objectives such as economic development, employment, and protection of SMEs.[174]

Generally, an effective competition law-policy offers the following tools in response to anticompetitive behavior: Measures to deter the establishment of cartels; restrain abuse of power by dominant firms, assess mergers and competition advocacy.[175]

4.2.1 Anti-competitive behaviour prohibited by competition law[176]

4.2.1.1 **Cartels** are the most prohibited anticompetitive behavior or activity. A cartel refers to an agreement between two or more firms supplying similar products or services to fix prices and/or to share the market in order to overcharge customers.[177] The firms earn huge profits and consumers are harmed by paying more for goods and services while consuming less.[178] Cartels are harmful in and of themselves without any concurrent economic benefits because of their tendency to create monopoly power which distorts the proper functioning of the market and weaken its efficiency.[179]

Fighting cartels means fostering competition due to the fact that the very goal of a cartel is to avoid competition.[180] Research shows that the median increase

[171] Baker et al (n 166).
[172] Michal S Gal, *Competition Policy for Small Market Economies* (Harvard University Press 2003).
[173] Eleanor M Fox, 'Economic Development, Poverty, and Antitrust: The Other Path' [2007] NYU School of Law Public Law & Legal Theory Research Paper Series Working Paper No. 07-12 Law.
[174] Ibid.
[175] Khemani (n 150). See also C. Scott Hemphill "Intellectual Property and Competition Law" Dreyfuss and Pila (n 22) 1, 873.
[176] See Chapter III of the UNCTAD Model Law on Competition (2010) restrictive agreements and arrangements at https://unctad.org/system/files/official-document/tdrbpconf7L3_en.pdf.
[177] Koomson (n 167) 17.
[178] Veljanovski, Cento, The Economics of Cartels. Finnish Competition Law Yearbook, 2006, Available at SSRN: https://ssrn.com/abstract=975612.
[179] Ibid.
[180] Giocoli (n 170) 4.

in price attributable to cartel agreements are around 25%.[181] Cartel activities include price fixing[182], market sharing, output limitations and bid rigging.

Research shows that developing countries are highly affected by cartel behavior.[183] High prices, especially in essential goods (such as food, medicine, fuel and transport) and services, make the poor consume less, and SMEs are denied access to markets or subject to exploitative conduct by cartels.

4.2.1.2 Competition law also deals with abuse of dominance. The law does not punish dominant power per se, but the abuse of the same.[184] Dominant firms abuse their power when they engage in 'exclusionary conduct' to maintain or expand that power. A practice is said to be exclusionary when "it is reasonably capable of creating, enlarging, or prolonging monopoly power by limiting the opportunities of rivals [and] either does not benefit consumers at all, or is unnecessary for the particular consumer benefits produced, or produces harms seriously disproportionate to the resulting benefits."[185]

4.2.1.3 Exclusionary conduct includes price predatory pricing, discriminatory pricing, resale price maintenance, unfair or excessive pricing, and anticompetitive discounts, tying and refusal to deal.[186] Dominance is still a huge concern in developing countries because of the prevalence of concentrated markets arising from the abuse of power by the private undertakings and States.[187] Bakhoum posits that due to this entanglement between politics and the functioning of markets, developing countries ought to focus on "fighting dominance effectively and dismantling economic concentrations".[188]

4.2.1.4 Merger control regulations are also catered for under competition law. Merger control rules prevent mergers which may lead to the creation or reinforcement of a dominant position, and thus harm consumers by depriving them of the benefits associated with effective competition such as

[181] Baker et al (n 166).
[182] An agreement or other cooperation between firms that restricts output, overcharges customers and generates excess profits for its members.
[183] There is a lot of research and scholarly commentary on cartels: Gal (n 172).; Fox (n 173); Eleanor M. Fox and Mor Bakhoum, Making Markets Work for Africa, 2019, Oxford University Press; UNCTAD, 'The Impact of Cartels on the Poor', 2013, https://unctad.org/system/files/official-document/ciclpd24rev1_en.pdf.
[184] However, competition law has a long history of looking suspiciously at large concentrations of economic power. Big has been seen as bad for much of antitrust history. Giocoli (n 170).
[185] Ibid.
[186] Anu Bradford and Adam S Chilton, 'Competition Law Around the World from 1889 to 2010: The Competition Law Index' (2018) 14 Journal Of Competition Law & Economics 393.
[187] Mor Bakhoum, 'Interfacing the "Local" with the "Global": A Developing Country Perspective on "Global Competition" ' [2013] Max Planck Insitute for Intellectual Property and Competition Law Research Paper Series, Paper No. 13-02 1.
[188] Ibid.

low prices, high-quality products, wide selection of goods and services, and innovation.[189] Merger control is a concern of competition law authorities because of its potential to lead to coordination among competitors.[190] Often the key question is whether the possible anticompetitive effects outweigh efficiencies that the merger creates.[191] Mergers may be restricted on the grounds that they lessen competition or create or strengthen dominance. Some countries evaluate mergers according to some public interest criteria, such as protection of SMEs, maintaining employment,[192] or national security[193]. Such criteria may be used to block mergers in favor of supporting local businesses or certain national projects that may not necessarily be efficient from a competition perspective.

4.3 THE THEORY OF COMPLEMENTARITY BETWEEN IP LAW AND COMPETITION LAW[194]

Competition policy and IP law have evolved historically as two separate systems of law. Each has its own goals and methods of achieving these goals. However, there is a major overlap in the goals of the two systems of law. Both IP law and Competition law share a common goal of encouraging innovation albeit through different approaches: Competition law by preventing behaviour which is restrictive of competition and IP law by granting exclusive rights as an incentive to innovate.[195] This common goal explains the theory of complementarity, that is, both IP law and competition law share a complimentary goal of promoting innovation.

Prior to the 'acceptance' of this theory, there was the prevailing view that argued some tension between IP laws and competition law under what was generally referred to as the 'doctrine of inherency'.[196] This doctrine perceived IP and competition law as conflicting fields of law due to the particular nature of IPRs which excludes third parties from using a protected work. Patents, for instance, were understood as monopolies that are irreconcilable with the principles of competition law.

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[189] Moritz Lorenz, *An Introduction to EU Competition Law* (Cambridge University Press 2013) 242.
[190] Ibid.
[191] Koomson (n 167) 19.
[192] China and South Africa are good examples for public interest provisions in their competition laws.
[193] Some global mergers have been rejected in the US on national security grounds.
[194] On this topic, see also UNCTAD, Examining the interface between the objectives of competition policy and intellectual property, 2016, https://unctad.org/system/files/official-document/ciclpd36_en.pdf.
[195] For comments on the regulation of mergers, Rudolph J.R. Peritz, "Competition Policy and its implications for intellectual property rights in the United States" Steven D Anderman (ed), *The Interface between Intellectual Property Rights and Competition Policy* (Cambridge University Press 2007) 125.; See also the EU Technology Transfer Guidelines 2014.
[196] See Heaton-Peninsular Button-Fastener Co. v. Eureka Specialty Co., 77 F. 288 (6th Cir. 1896); Standard Sanitary Mfg. Co. v United States, 226 U.S. 20 (1912)., See also Josef Drexl, 'Copyright , Competition and Development' (Report by the Max Planck Institute for Intellectual Property and Competition Law 2013) available at https://www.ip.mpg.de/fileadmin/ipmpg/content/forschung_aktuell/02_copyright_competition/report_copyright-competition-development_december-2013.pdf.

This inherency doctrine is generally not accepted today. There is a general consensus that there is no inherent conflict between the two fields of law, but rather, the two systems are seen to pursue complementary goals.[197] The exclusive rights granted to IP holders to prevent freeriding promote dynamic competition by providing incentives for innovation. Competition laws also promote innovation by prohibiting certain anticompetitive practices or behaviour that aim to unfairly exclude competitors from the market and therefore may be harmful to competition. The "theory of complementarity" is in the United States Antitrust Guidelines for the Licensing of Intellectual Property[198] as well as the EU Technology Transfer Guidelines.[199]

Paragraph 7 of the EU Technology Transfer Guidelines explains the complementarity of IP law and competition law very clearly**:**

> "The fact that intellectual property laws grant exclusive rights of exploitation does not imply that intellectual property rights are immune from competition law intervention. Article 101 of the Treaty is in particular applicable to agreements whereby the holder licenses another undertaking to exploit its intellectual property rights. Nor does it imply that there is an inherent conflict between intellectual property rights and the Union competition rules. Indeed, both bodies of law share the same basic objective of promoting consumer welfare and an efficient allocation of resources. Innovation constitutes an essential and dynamic component of an open and competitive market economy. Intellectual property rights promote dynamic competition by encouraging undertakings to invest in developing new or improved products and processes. So does competition by putting pressure on undertakings to innovate. Therefore, both intellectual property rights and competition are necessary to promote innovation and ensure a competitive exploitation thereof."

4.3.1 BASICS ON THE 'COMPLEMENTARY' RELATIONSHIP BETWEEN IP AND COMPETITION LAW[200]

- **Are IP rights monopoly rights?**
  - It depends on the definition of the market.

[197] Ibid.
[198] Antitrust Guidelines for the Licensing of Intellectual Property, U.S. Department of Justice and the Federal Trade Commission, 1995, https://www.justice.gov/atr/archived-1995-antitrust-guidelines-licensing-intellectual-property.
[199] Guidelines on the application of Article 101 of the Treaty on the Functioning of the European Union to technology transfer agreements 2014/C 89/03, https://ec.europa.eu/competition/antitrust/legislation/transfer.html.
[200] Josef Drexl, *Research Handbook on Intellectual Property and Competition Law* (Josef Drexl ed, Edward Elgar Publishing Ltd 2008). See also Balthasar Strunz, *The Interface of Competition Law, Industrial Policy and Development Concerns: The Case of South Africa* (Josef Drexl and Reto M Hilty eds, Springer 2018).

- IPRs create exclusive rights instead of monopoly rights. In most cases, substitutes are available for products and technologies protected by IPRs.

- **Do IPRs exclude competition completely?**
  - No.
  - The rights can be transferred through licensing which enables the licensee to compete in the given market (price competition).
  - Possibility of inventing around by creating a variation of the product which leads to new technologies (dynamic competition).
  - The mere existence of exclusive rights do not harm or restrict competition per se. Exclusive rights exclude others from copying or free-riding.
  - **Do *all IPRs* exclude competition?**
    - Yes, to some extent. IPRs exclude 'competition by copying' or price competition.
      - As long as IPRs exist, another firm cannot enter the market by imitating or copying the same invention or IP. That is the kind of competition that is excluded by the exclusive rights.
  - **Do IPRs exclude *all competition*?**
    - No. IPRs do not exclude dynamic competition because it creates incentives to innovate or invent around.

- **When should competition law (CL) interfere with IPRs?**[201]
  - Exclusion arising solely due to the existence of IPRs does not justify CL intervention. (No inherency but complementarity with clear lines drawn).
  - In situations where there is an abuse of IPRs, CL may be invoked. Ex: A license agreement concerning IP rights to extend the scope of exclusivity rights beyond the permitted term, seeking royalties beyond the term of the patent, refusal to license, pay-for-delay settlements, blocking patents, etc.
  - The legislature must draw the line between CL and IP legislation.
    - Competition law can be used to prevent or deter practices such as collusive pricing or the use of abusive clauses in licensing agreements that unreasonably restrict access to new technologies or the uses to which such technologies can be put.

[201] Drexl (n 196). See also the Magill case 'Radio Telefis Eireann (RTE) and Independent Television Publications Ltd (ITP) v Commission, Joined cases C-241/91 P and C-242/91 P'; Microsoft case 'Case T-201/04, Microsoft v Commission, [2007] ECR II-3601'; Illinois Tool Works Inc. v. Independent Ink, Inc. Inc., 547 U.S. 28; Case C-238/87 Volvo v. Veng CJEU (2006); Case C-53/87 CICRA v Renault.

- Some countries' competition laws incorporate specific provisions relating to the abuse of IPRs, and a number have established competition policy guidelines specifically dealing with IP. This is the case of Mauritius which has a section on intellectual property in its detailed guidelines on the application of its competition law.[202]

4.4 THE TRIPS APPROACH TO THE INTERFACE BETWEEN IP AND COMPETITION LAW

TRIPS recognizes the legitimate role of competition law and policy in the administration of IPRs. According to WIPO:

> *"The TRIPS Agreement, is generally understood not to be intrinsically in conflict with competition law and policy: to the contrary, both systems of regulation serve the same overall objectives – generally, promoting a dynamic and innovative economy, while also facilitating appropriate diffusion of new technologies, and thereby promoting the welfare of citizens*".[203]

TRIPS spells out at various points in the Agreement the complimentary nature of IP and competition law. In the preamble as well as in Articles 8, 31 and 40 it contains references to competition and competition rules in cases involving IPRs. For example, Article 8 (2) TRIPS states that 'Appropriate measures, provided they are consistent with the provisions of this Agreement, may be needed to prevent the abuse of intellectual property rights by right holders ...' and also stipulates that member States may enact legislation to prevent practices by the right holder that adversely affect the international transfer of technology. Article 40, also specifies the types of IP licensing practices and conditions which restrain competition and impede the transfer and dissemination of technology such as exclusive grant-back conditions, coercive package licensing and clauses preventing challenges to the validity of the IPR. Art 31 also acknowledges that compulsory license may be granted in response to an anti-competitive practice, and waives the requirement to first seek permission from the rights holder or produce predominantly for the domestic market. These provisions make the TRIPS agreement the first international IP convention that explicitly recognizes the necessity of submitting IPRs to regulation through competition law.[204]

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[202] See Section 5 of the Guidelines of the Competition Commission of Mauritius at https://competitioncommission.mu/wp-content/uploads/2019/09/CC7-Guidelines-General-Provisions.pdf.

[203] Taubman, Wager and Watal (n 3) 142.

[204] See Andreas Heinemann "International Antitrust and Intellectual Property" Heath and Sanders (n 102) 262.; see also Beatriz Conde Gallego "Intellectual property rights and competition policy" Correa (n 38) 231., See also UNCTAD- ICTSD (2004), supra note 2, at 541; OECD (1999), 'Competition Elements in International Trade Agreements: A Post- Uruguay Round Overview of WTO Agreements', COM/TD/DAFFE/CLP(98)26/ FINAL, 28 January 1999.

4.5 COMPETITION LAW REMEDIES IN CASES INVOLVING AN IPR[205]

Competition law can be invoked in cases where there is doubt about an abuse of IPRs.

- **Compulsory License**

  In response to refusals to deal, refusals to license, refusals to provide proprietorial software interface codes and tie-ins, a State may issue a compulsory license to make available the needed products. See the Magill case[206] where three broadcasting companies were ordered to license their TV listing to each other and third parties after having refused to supply these to a company, which wished to make a comprehensive television guide, on the basis of copyright protection.

- **Order to supply goods or information**

  There have been cases related to IPRs related restrictions of competition, where competition authorities ordered the supply of goods or information.[207]

- **Restriction of future conduct**

  In the **Tetra Pak II285 case**, the European Court of Justice (ECJ) upheld the Commission's decision to restrict future conduct even where the illegal conduct has already been brought to an end.[208]

- **Restriction of excessive pricing**

  See the General Motors case[209] where the Court refers to excessive prices when prices are set which have no reasonable relation to the 'economic value' of the product. See also the **United Brands case[210]** where the Court amended the criterion slightly to, 'charging a price which is excessive because it had no reasonable relation to the economic value of the product supplied'. Some

[205] Correa, C. (2007). Intellectual Property and Competition Law: Exploration of Some Issues of Relevance to Developing Countries, ICTSD IPRs and Sustainable Development Programme Issue Paper No. 21, International Centre for Trade and Sustainable Development, Geneva, Switzerland, https://www.academia.edu/30233861/Intellectual_Property_and_Competition_Law; See OECD, Competition Policy and Intellectual Property Rights, 1997, https://www.oecd.org/competition/abuse/1920398.pdf; See also Keith E. Maskus and Mohamed Lahouel, Competition Policy and Intellectual Property Rights in Developing Countries, April 2000, The World Economy, Volume 23, Issue 4, https://onlinelibrary.wiley.com/doi/epdf/10.1111/1467-9701.00292.

[206] Taubman, Wager and Watal (n 3).

[207] See the Commercial solvents case for the order to supply raw materials. See also the Case T-201/04, Microsoft v Commission, [2007] ECR II-3601 on supply of information.

[208] Commission Decision of 24 July 1991 relating to a proceeding pursuant to Article 86 of the EEC Treaty (IV/31043 - Tetra Pak II) (92/163/EEC), https://eur-lex.europa.eu/legal-content/EN/ALL/?uri=CELEX:31992D0163; https://blog.ipleaders.in/tetra-pak-case-a-new-dawn/.

[209] United States v. General Motors Corp., 384 U.S. 127 (1966).

[210] Judgment of 14 February 1978, United Brands and United Brands Continental v. Commission, 27/76, EU:C:1978:22, paragraph 252.

competition authorities have investigated excessive pricing practices by big pharmaceutical companies.[211]

4.6 COMPETITION CASES INVOLVING IPRS IN SELECTED SECTORS

4.6.1 PARALLEL IMPORTATION, IPRs AND COMPETITION LAW:[212] THE GLAXOSMITHKLINE CASE[213]

Facts: In 2000, a Greek subsidiary of the UK based GlaxoSmithKline (GSK) pharmaceutical company halted supply of certain drugs directly to Greek wholesalers. The subsidiary instead started supplying directly to hospitals and pharmacies in Greece. When it resumed supply to wholesalers in Greece, it was in very limited quantities which were sufficient only for the market in Greece.

The Greek wholesalers brought an action under Article 82[214] of the Treaty Establishing the European Community (EC Treaty) (current Article 102 of the Treaty on the Functioning of the European Union (TFEU)) and the Greek competition law on the basis that the action of the subsidiary was an abuse of dominant position because it essentially limited the quantities the wholesalers could export to other Member states (Germany and UK) where the prices were relatively higher. Note that the parallel exports of the distributors caused a shortage in Greece.

Questions arising out of the case were referred to the ECJ for a preliminary ruling.

Issue: Whether a dominant supplier could lawfully refuse to meet the orders of wholesalers for the sole purpose of limiting parallel exports to other Member States.
Rules/ Rights: Article 82 of the EC Treaty; Exclusive rights under IP as an incentive for R&D and the promotion of innovation.

Application: Article 82 of the EC Treaty prohibits companies in a dominant position from engaging in activities such as the restriction of parallel trade. Therefore, a dominant company normally abuses its position by refusing to meet ordinary orders from an existing customer for the sole purpose of limiting parallel

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211 https://www.competition.org.za/ccred-blog-competition-review/2017/12/20/excessive-pricing-in-the-global-pharmaceutical-industry.

212 See also the Case C-418/01, IMS Health GmbH v. NDC Health GmbH (IMS Health case). IMS Health, the company that had developed an industry standard for collecting data on the marketing of pharmaceuticals and claimed a copyright in the structure, refused to license the copyright to competitors and thereby had monopoly power in the market for collecting and delivering marketing data to the pharmaceutical companies. See also the AstraZeneca decision of the CJEU (C-457/10 P) on special protection certificates.

213 Case T-168/01 GlaxoSmithKline Services v Commission ECLI:EU:T:2006:265; Joined cases C-501/06 P, C-513/06 P, C-515/06 P and C-519/06 P GlaxoSmithKline Services and Others v Commission and Others ECLI:EU:C:2009:610, paras 54-67.

214 Article 82 of the Treaty Establishing the European Community (EC Treaty), which is replaced by the Treaty on the Functioning of the European Union (TFEU) used to deal with abuse of dominance. Currently, Article 102 of TFEU, which is the European Union's competition legislation, addresses abuse of dominance.

trade. According to the Court, the overall beneficial effects of parallel trade on price fluctuations should not be underestimated.

The ECJ however held that in some instances, it was permissible for dominant companies to take "reasonable and proportionate" measures to protect their commercial interests. Such measures include refusing to meet orders which were "out of the ordinary" and essentially destined for parallel markets. National courts were to determine what "out of the ordinary" means.

GSK argued that the losses due to parallel trade affected research and development budgets and the incentive to innovate.

Holding of the Court: A dominant supplier could lawfully refuse to meet the orders of wholesalers for the sole purpose of limiting parallel exports to other Member States, if such refusal or restriction to parallel trade is done in a reasonable and proportionate way.

4.6.2 REFUSAL TO LICENSE, IPRS AND COMPETITION: THE MAGILL CASE

Facts: Magill publications, an Irish publishing company, sought to develop a new television guide that integrated the copyrighted program listings of all three major Irish TV networks (the BBC, ITP and RTE). At the time, RTE enjoyed a statutory monopoly in Ireland for the provision of culturally oriented television and radio services. The BBC and ITP shared a duopoly within the United Kingdom for the provision of television services.

There was no comprehensive TV guide available in either the UK or in the Republic of Ireland because of licensing policies by the three broadcasters restricting the dissemination of program listings. Magill published a complete TV listings using the listings identical to the copyrighted listings of the broadcasters. The networks refused to license the listings and sought an injunction.

Questions arising out of the case were referred to the ECJ for a preliminary ruling.

Issue: Whether the conduct of the TV Networks constituted an abuse of dominant position under the EU competition law.

Rules/ Rights: Article 86 of the Treaty establishing the European Economic Community (EEC Treaty), the then EU competition legislation, UK and Ireland competition laws; exclusive rights under IP (copyrights) as an incentive for R&D and the promotion of innovation.

Application: According to the TV Networks, the existence of a copyright gave them a dominant position in the market and the freedom to decide to whom these TV stations would license their television programs and the raw information contained therein.

Holding: In its decision in 1995, the ECJ upheld the European Commission's imposition of a compulsory license on copyright owners to remedy the violation of Article 86 of the EEC Treaty. The violation consisted of the exercise by television broadcasters of their exclusive rights under national copyright laws to prevent potential publishers of weekly television guides from copying their copyrighted weekly television listings. This prevented potential competitors from entering the market for weekly television guides in a geographic area comprised of Ireland and Northern Ireland, a portion of the United Kingdom.[215] A copyright cannot be exercised in a manner and under circumstances manifestly contrary to the competition rules laid down in the EEC Treaty. In this case, there was a potential demand from consumers for a new product (a journal encompassing all television programs on a weekly basis). The refusal to license without any objective reason for the denial (because the same program schedules were offered to newspapers without any charge) established a reasonable ground for identifying the existence of an abuse of dominant position.

The ECJ confirmed that reliance of TV broadcasters in Britain and Ireland on copyright to prevent Magill from publishing a weekly TV guide established an abuse of a dominant position contrary to Article 86 of the EC Treaty. The Court held that TV broadcasters must license their respective weekly television listings.[216]

4.6.3 REFUSAL TO SUPPLY INFORMATION ON INTEROPERABILITY, IPRS AND COMPETITION: THE MICROSOFT CASE[217]

Facts: Microsoft refused to make available interoperability information needed to enable an American manufacturer (Sun Microsystems) of servers and server operating systems to communicate with the Windows operating system .

Sun Microsystems filed a complaint to the European Commission (EC) on Microsoft's refusal to supply information for interoperability purposes. The Commission ordered Microsoft to make the information available and Microsoft complied. The Commission then required further information on the interoperability between the Microsoft Windows operating system and Microsoft's Media Player.

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[215] https://www.panix.com/~jesse/magill.html.
[216] https://uk.practicallaw.thomsonreuters.com/7-100-3075?contextData=(sc.Default)&transitionType=Default&firstPage=true.
[217] Microsoft Corp. v Commission of the European Communities Case T-201/04. See also (Unwired Planet v Huawei [2018] EWCA Civ 2344) on the payment under FRAND (fair, reasonable and non-discriminatory) royalties.

The Commission found that Microsoft had abused its dominant position by refusing to provide interoperability information necessary for competitors to be able to compete in the work group server operating systems market, and also by tying its Media Player with its Windows operating system. The Commission ordered that Microsoft supply the needed interoperability information to its competitors when requested.

Microsoft appealed the decision and sought an annulment and reduction of the fine.

Issue: Whether the European Commission was justified in its decision.

Rules/ Rights: Art 82 EC Treaty.

Application: Microsoft had provided its competitors with insufficient degree of interoperability with the existing Windows architecture. It was therefore necessary to remove that obstacle to enable the competitors to properly compete in the operating systems market. Microsoft argued that the request by the Commission would lead competitors to copy its operating system and that the information was protected by IPR.

The Court disagreed stating that, although firms are, in principle, free to choose their trading partners, a refusal to supply at the instance of a company in a dominant position may constitute an abuse in certain circumstances. The Court stated that the refusal to supply information would only strengthen the market position of Microsoft. Microsoft failed to prove that the disclosure of the requested information would affect its incentive to innovate.

Holding: Commission's decision was upheld by the Court.

4.6.4 DIGITAL MARKETS, 'BIG TECH' AND COMPETITION LAW[218]

Facebook, Google, Amazon and Apple, collectively referred to as the 'Big Four' are constantly under the radar of the various competition authorities because of the abuse or likely abuse of their dominant position in relevant digital markets. For instance:

[218] See Neil Hodge 'Competition: Big Four Tech Companies Increasingly on Radar of European and US Regulators', International Bar Association, https://www.ibanet.org/article/B5375E06-0798-4C92-A2AB-DBFC42802DF5. See also Heiko Richter, 'New Rules for Technology Transfer Agreements Companies Have One Year to Adapt Their Agreements to the New Rules' (2014) 101 1.; See also Heiko Richter, Marlene Straub and Erik Tuchtfeld, 'To Break Up or Regulate Big Tech? Avenues to Constrain Private Power in the DSA/DMA Package' [2021] SSRN Electronic Journal, https://www.mpg.de/18346442/new-rules-for-tech-giants. See also Gokce Dessemond, Ebru, 'Restoring competition in "winner-took-all" digital platform markets', UNCTAD Research Paper No. 40, available at https://unctad.org/webflyer/restoring-competition-winner-took-all-digital-platform-markets.

- The European Commission has conducted various investigations and consequently levied fines on Google:
    - Google Shopping case: In June 2017, the Commission imposed a fine of €2.42bn on Google for abusing its dominant position in the market for general search services on the Internet by more favourably positioning and displaying Google Shopping in its general search result pages compared to competing shopping services.
    - Google Android case: In July 2018, the Commission fined Google with €4.34bn for engaging in three types of illegal practices as part of a single strategy to maintain its dominant position in general internet searches: tying, exclusivity payments and conduct obstructing the development of alternative versions of the Android operating system that were not approved by Google.
    - Google AdSense case: In March 2019, the Commission fined Google with €1.49bn for abusing its market dominance by imposing several restrictive clauses in contracts with third-party websites that prevented Google's competitors from placing their search advertisements on these websites.

    There have also been various probes and fines by the EC concerning Amazon[219], Facebook[220] and Apple.[221]

4.6.5 ACCESS TO MEDICINES

The GSK case in South Africa

Facts: A complaint was lodged before the South African Competition Commission against GlaxoSmithKline South Africa (Pty) Ltd (GSK) and Boehringer Ingelheim (Pty) (BI), initially for high pricing, but then the Commission extended the investigation to include an alleged violation of section 8(b) and (c) of the Competition Act, which deals with the essential facilities doctrine and exclusionary conduct respectively. The case was eventually settled. In particular, GSK and BI were accused of anticompetitive conduct involving the following:

● GSK abused its dominant position in the market for antiretroviral drugs (ARVs) by charging excessive prices; making the product inaccessible to the general public;

[219] 'Amazon (AMZN) Given Record $888 Million EU Fine for Data Privacy Breach - Bloomberg', https://www.bloomberg.com/news/articles/2021-07-30/amazon-given-record-888-million-eu-fine-for-data-privacy-breach?leadSource=uverify wall .

[220] 'Facebook Fined $122 Million by EU over Its WhatsApp Takeover', https://www.cnbc.com/2017/05/18/facebook-fine-eu-whatsapp-takeover.html.

[221] 'Apple Hit with EU Antitrust Charge over Mobile Payment Technology', https://www.reuters.com/technology/apple-hit-with-eu-antitrust-charge-over-its-payment-technology-2022-05-02/.

● refusing to grant a competitor access to an essential facility.

The existence of patents prevented sale of generic substitutes in South Africa, which resulted in a dramatic difference in the price of ARVs sold in South Africa and generic alternatives sold outside of South Africa.

Patent protection did not require a firm to charge excessive prices.

Outcome: The Competition Commission concluded its investigation with a finding that GSK and BI abused their dominant position by charging excessive prices, refusing to grant access to essential facilities to a competitor, and engaging in exclusionary conduct. The matter did not come before the Competition Tribunal, as GSK and BI accepted a settlement, which resulted in a drastic reduction in the prices of ARVs in South Africa. As part of the settlement, GSK and BI agreed to:

● grant licenses to generic manufacturers;

● permit licensees to export the relevant ARVs to sub-Saharan African countries;

● where the licensee did not have manufacturing capability in South Africa, permit the importation of the ARV medicines for distribution in South Africa only, provided all the regulatory approvals were obtained;

● permit licensees to combine the relevant ARVs with other ARV medicines; and

● not require royalties in excess of 5 per cent of the net sales of the relevant ARVs.

Two aspects are worth highlighting in this case. First, the competition law offences of which GSK and BI are accused would have been difficult to tackle using only the IP flexibilities, such as compulsory licensing. Charging high prices, refusing to grant access to essential facilities, or engaging in exclusionary conduct would be difficult to use as grounds for compulsory licensing under the TRIPS agreement. The second interesting aspect of this case is the conditions of the settlements and the commitments accepted by GSK. The different commitments mirror the developments in the framework of the Doha Declaration with regard to pharmaceuticals, with the introduction of a mechanism of licensing for export to countries without sufficient manufacturing capacities. In Doha, in addition to the declaration on IP and public health, a new mechanism allowing countries without sufficient manufacturing capacities to issue compulsory licenses for imports was introduced. Although in theory the mechanism would enhance access to medicines, in practice it proved difficult to render it operational, as the only instance in which it was tested illustrates.[222] It is interesting to note that in the GSK case in South Africa, the Doha mechanism, which allows countries to

[222] The mechanism was put into test in a case between Canada and Rwanda and it proved very difficult to operationalize.

issue compulsory licenses for exportation to countries without manufacturing capacities, was triggered through competition law enforcement. Hence, in its commitments, GSK agreed to permit licensees to export the relevant ARVs to sub-Saharan African countries, which do not have manufacturing capacities. In addition, GSK agreed, where the licensee did not have manufacturing capacity in South Africa, to permit the importation of the ARV medicine for distribution in South Africa only, provided that the regulatory approval was obtained. Those commitments, which constitute the essence of Article 31bis of the TRIPS Agreement, were obtained not through importing mechanisms set up by the Doha Declaration, which turned out to be difficult to use, but by using competition law. Moreover, a price cap of 5 per cent of the net sales of the relevant ARVs allows the control of the prices charged by GSK to licensees. The terms of the commitments go beyond what has been agreed upon in the framework of the Doha Declaration. In addition, enforcing the Doha measures involves a heavy administrative burden, whereas, in this case, the Competition Commission can easily monitor whether GSK actually fulfills its commitments. This case the effectiveness of using competition law in addition to IP flexibilities. Competition law can be more effective and easier to enforce than IP stricto sensu flexibilities.

The Aspen case in Italy

Facts: In the EU, the Aspen case on excessive pricing handled by the Italian Competition Authority has attracted significant attention. Ongoing investigations both in the EU and in South Africa illustrate what could be considered as an emerging enforcement trend on the application of competition law in the pharmaceutical sector.

Aspen, a pharmaceutical company, had acquired an off-patent cancer drug package from GlaxoSmithKline. The antitumor drugs are considered life-saving and irreplaceable especially in the treatment of children and elderly patients.

After acquiring the rights on the drugs, Aspen initiated negotiations with the Italian Medicines Agency (Agenzia Italiana del Farmaco - AIFA) with the sole aim to obtain a high increase in prices, even in the absence of any necessary economic justifications. An important factual element in the Aspen case is that there was a public procurement process whereby the relevant authority was purchasing the drugs directly from Aspen. Aspen used an aggressive negotiation strategy with the Italian Medicines Agency and threatened the latter to interrupt supply to the Italian market, as a result of which Aspen obtained extremely high increases in its prices ranging between 300% and 1500% compared to the original price levels since the approval of the drug in Italy in 2013.[223]

[223] https://www.competition.org.za/ccred-blog-competition-review/2017/12/20/excessive-pricing-in-the-global-pharmaceutical-industry.

Outcome: The Italian Competition Authority fined Aspen in September 2016 for infringing Article 102 (a) of the TFEU. The Italian Competition Authority considered that Aspen had fixed unfair prices with increases up to 1500%.

Two aspects were considered by the Italian Competition Authority in assessing the excessive pricing conduct by Aspen: First, the disproportion between price and cost; secondly, additional aspects including the "specific context and behavioural factors, such as the inter-temporal comparison of prices, the absence of economic justification for the increase in prices, the absence of any extra-economic benefits for patients, the nature of the drugs, the characteristics of the Aspen group, and the damage caused to the National Health System (Sistema Sanitario Nazionale – SSN)".[224]

The Italian Aspen case illustrates how important it is to have competitive markets in order to make TRIPS flexibilities operational.

Case law on reverse payment settlements or pay for delay[225]

Cartels, bid rigging and boycotts are conventional behaviours, which aim to fix prices or share markets and earn monopoly profits. These are "traditional" types of anticompetitive practices that affect markets, including the pharmaceutical sector. In addition to these anticompetitive practices, there is a particular type of anticompetitive agreement in the pharmaceutical industry, which has drawn the attention of competition law enforcers in recent years: The practice commonly known as a "pay for delay" agreement; or, since it often involves a payment from the patent holder to the alleged infringer, a "reverse payment" settlement agreement. Basically, it concerns situations where a brand-name pharmaceutical company, as patent holder, and a generic producer agree to settle either a patent infringement suit or a dispute concerning the validity of the patent under agreed terms. The agreed terms would require that, firstly, the generic manufacturer not to produce and/or distribute the patented product until the expiration of the patent, and secondly, the patent holder to "compensate" the generic company for staying out of the market.

Both in the United States and in Europe, the competition agencies and national/regional courts have perceived such arrangements as an attempt to allocate markets and preserve monopolistic conditions;[226] and have condemned them as

[224] For additional developments on the case see Mor Bakhoum, Intellectual Property Rights (IPRs), Competition Law and Excessive Pricing of Medicines, in, Access to Medicines and Vaccines
Implementing Flexibilities Under Intellectual Property Law, Carlos M Correa et Reto M Hilty (eds), 2022, pp 277-296, available at: https://library.oapen.org/handle/20.500.12657/51469.

[225] Mor Bakhoum, Intellectual Property Rights (IPRs), Competition Law and Excessive Pricing of Medicines, in, Access to Medicines and Vaccines
Implementing Flexibilities Under Intellectual Property Law, Carlos M Correa et Reto M Hilty (eds), 2022, pp 277 296, available at: https://library.oapen.org/handle/20.500.12657/51469.

[226] Announcing the Commission's decision on the *Servier* case, the then Competition Commissioner Joaquín Almunia stated "Servier had a strategy to systematically buy out any competitive threats to make sure that they stayed out of the market. Such behavior is clearly anti-competitive and abusive. Competitors cannot agree to share markets or market rents instead of competing, even when these agreements are in the form of patent settlements. Such practices

clear violations of competition law.[227] In the United States, the Supreme Court has already had the opportunity to pronounce on the legal assessment of this kind of patent settlements.[228]

In July 2013, the European Commission fined Lundbeck and several producers of generic medicines for delaying generic market entry of Citalopram.[229] In December 2013, the Commission fined Novartis and J&J,[230] which concluded an agreement to delay the market entry of cheaper generic version of Fentanyl, a painkiller. This was a straightforward pay-for-delay case as it did not involve any patent dispute or litigation.

In the US, the Actavis decision of the Supreme Court[231] sets the legal standard for assessing pay-for-delay cases. After contradictory decisions from lower courts, the Supreme Court concluded that the rule of reason should be applied to reverse payment settlements.

directly harm patients, national health systems and taxpayers". See European Commission, Press Release of 9 July 2014, IP/14/799. http://europa.eu/rapid/press-release_IP-14-799_en.htm. Accessed 23 October 2014.

[227] In Europe, see European Commission, Press Release of 19 June 2013, IP/13/563 (Antitrust: Commission fines Lundbeck and other pharma companies for delaying market entry of generic medicines). http://europa.eu/rapid/press-release_IP-13-563_en.htm?locale=en; Press Release of 10 December 2013, IP/13/1233 (Antitrust: Commission fines Johnson & Johnson and Novartis € 16 million for delaying market entry of generic pain-killer fentanyl). http://europa.eu/rapid/press-release_IP-13-1233_en.htm; Press Release of 9 July 2014, IP/14/799 (Antitrust: Commission fines Servier and five generic companies for curbing entry of cheaper versions of cardiovascular medicine). http://europa.eu/rapid/press-release_IP-14-799_en.htm. All press releases accessed 23 October 2014. At the time of writing this contribution, no public version of these decisions was yet available. For an overview of the FTC's practice see Cook, A. (2001). Pharmaceutical Patent Litigation Settlements: Balancing Patent & Antitrust Policy Through Institutional Choice. *Michigan Telecommunications and Technology Law Review*, 17(2), pp. 417-458, pp.437 et seq. (commenting particularly on *In re Schering-Plough Corp.*, 136 F.T.C. 956 (2003); *FTC v. Watson Pharm., Inc.*, 611 F. Supp. 2d 1081 (C.D. Cal. 2009) and *FTC v. Cephalon, Inc.*, 551 F. Supp 2d 21 (D.D.C. 2008)).

[228] See *Actavis* decision, https://unctad.org/ippcaselaw/sites/default/files/ippcaselaw/2020-12/FTC%20v.%20Actavis%20570%20U.S.%20Supreme%20Court%20%282013%29.pdf.

[229] Press release Commission: http://europa.eu/rapid/press-release_IP-13-563_en.htm?locale=en Information of General Court upon time of completion not available (July 2015).

[230] See press release of Commission: http://europa.eu/rapid/press-release_IP-13-1233_en.htm; full text of judgment available at http://ec.europa.eu/competition/antitrust/cases/dec_docs/39685/39685_1976_7.pdf.

[231] Federal Trade Commission v. Actavis Inc 570 U.S. 136 Supreme Court (2013), https://unctad.org/ippcaselaw/federal-trade-commission-v-actavis-inc-570-us-136-supreme-court-2013; https://unctad.org/ippcaselaw/sites/default/files/ippcaselaw/2020-12/FTC%20v.%20Actavis%20570%20U.S.%20Supreme%20Court%20%282013%29.pdf.

MODULE 5

IP Related Provisions in Free Trade Agreements (FTAs)

5 IP-RELATED PROVISIONS IN FREE TRADE AGREEMENTS[232]

5.1 THE RATIONALE FOR FREE TRADE AND OTHER BILATERAL/ REGIONAL AGREEMENTS ON TRADE

The period from the year 2000 onwards saw an increase in the number of free trade agreements (FTA). This was a response to the slow progress in multilateral trade negotiations.[233] Before the TRIPS Agreement was finalized, it was difficult (or sometimes impossible) to reach a consensus on the amendment of major Conventions (Paris and Berne) to cover substantial issues on the approach to development and trade liberalization.[234] This led to the frustration of industrialized countries and IPR holders, which ultimately led to the creation of FTAs. USA began negotiating with East Asian countries and some Eastern European States for high levels of IP protection.[235]

The proliferation of FTAs became more prominent in the post-TRIPS period. This is attributed to the minimum standard approach and the flexibilities in the TRIPS Agreement. Countries opted to negotiate stricter IP protection beyond the standards set out under the TRIPS Agreement. FTAs gave countries the opportunity to negotiate and agree on issues they would otherwise not agree, at least effectively, at the multilateral level. Some notable FTAs include those between the United States and Australia, Republic of Korea, Peru, Jordan, Singapore, Colombia and Chile. Those involving the European Union include EC-CARIFORUM Economic Partnership Agreement (EPA), SADC-EU EPA and EPAs with African, Caribbean and Pacific (ACP) countries, as well as with Republic of Korea and Singapore in Asia, and with Chile, Colombia, Ecuador and Peru in Larin America.

5.1.1 OPPORTUNITIES/ BENEFITS UNDER FTAs[236]

- **Motivation to include TRIPS-plus provisions in FTAs**
  - **Trade-Offs**
    - Trade-offs between those countries that are opposed to higher level of IP protection and others that are in favour of the same: Developed countries are in favour of obtaining high-level of IP protection for their firms in developing countries.
    - Trade-offs can be negotiated on a bilateral or regional level to gain preferential access to the markets of FTA partners.

[232] Session 8
[233] Jakkrit Kuanpoth 'TRIPS-Plus Rules under Free Trade Agreements: An Asian Perspective' Heath and Sanders (n 102) 27.
[234] Kur and Dreier (n 5) 24.
[235] Ibid.
[236] Heath and Sanders (n 102).

- Developed countries can offer developing countries preferential market access in core sectors such as commodities, textiles and apparel in exchange for more IP protection.

- **Incentives for Foreign Direct Investment**
  - Stronger IPR protection may attract FDI which leads to securing investment and may, in some instances, enhance technology transfer.
- **Difficulty of achieving consensus on a TRIPS-plus agenda at the multilateral level.**
- **Pro-TRIPS-plus interpretation and implementation of TRIPS.**
  - Interpretation of 'inventive step' and 'capable of industrial application' under Art 27.1 TRIPS interpreted in most US party FTAs as being synonymous with 'non-obvious' and 'useful'. Non obviousness and usefulness are not necessarily synonym of inventive step and capable of industrial application.
- **Implementation of the entire trade agenda of a country is difficult under multilateral agreements.**

  - A bilateral approach brings more flexibility for a developed country to make a developing country follow their standards. *"The United States has worked with Thailand on intellectual property rights issues under the Trade and Investment Framework Agreement (TIFA). While some progress has been made, bringing Thailand's intellectual property regime up to the standards set in other recent FTAs that the United States has negotiated will be a high priority of these negotiations"*[237]
- **Effectively prevents amendment of national laws.**
  For example, the FTA between US and Australia includes data exclusivity as a TRIPS-plus standard. The FTA guarantees that this IP protection remains in place even though this concession was already available under Australian law.
- **Implementation of minimum standards under TRIPS can be achieved through FTAs.**

[237] Letter of Notification of USTR to US Congress of Intent to Initiate Free Trade Agreement Negotiations with Thailand, 12 February 2004, https://ustr.gov/archive/Document_Library/Press_Releases/2004/February/USTR_Notifies_Congress_of_Intent_to_Initiate_FTA_Negotiations_with_Thail.html.

In recent years, all four major economic players, that is, the European Union (EU), Japan, the USA, and the countries of the European Free Trade Association (EFTA), have been active in the negotiation of FTAs.

5.1.2 NATURE OF FTAs/ RTAs[238]

- FTAs are wide in scope to cover trade in goods and services, investment, government procurement, environmental protection, labour rights and IP protection.
  - Similar to the **"single undertaking"** approach of the WTO.
  - E.g. Economic Partnership Agreement (EPA) between the European Union and CARIFORUM members (2008). The EU-SADC EPA is also a relevant example.

- IP provisions include TRIPS-plus terms beyond the minimum standards under TRIPS.

- A successful negotiation and conclusion of one FTA usually serves as a model for other FTAs, and may inform multilateral trade negotiations in the future.

5.2 TYPICAL 'TRIPS-PLUS' PROVISIONS IN IP CHAPTERS OF FTAs

5.2.1 NEW AREAS AND LONGER TERMS OF PROTECTION

- **Extension of standards of patentability**
  - Extending patentability subject matter for bio- and pharma patents i.e, plants and animals.
    - Art 27 TRIPS allows for the exclusion from patentability of certain biotechnological inventions, as well as medical methods for the treatment of human and animals.
  - Allowing second use/ second medical indication patents
    - TRIPS does not require second use patents.[239]
    - Medicines that are not patentable as products because of lack of novelty can be patented as second use; as well as new dosages or new combinations of existing drugs.
    - Consequently, there is the potential extension of patent terms.

  - Mandating patent term extensions in case of processing delays at a national patent office or delay during clinical trials etc.

[238] Kur and Dreier (n 5).See also Heath and Sanders (n 102).
[239] See art. 27.3 TRIPS

- Under US law, namely, the Drug Price Competition and Patent Term Restoration Act of 1984, generally known as the Hatch-Waxman Act, such extension is allowed.[240]

- Extension of copyright term from life plus 50 years to life plus 70 years (in line with US Sonny Bono Copyright Extension Act 1998).

  - E.g. US Trade Representative IP text proposed to Thailand during FTA negotiations:

    "Each Party shall make patents available for the following inventions:

    a) plants and animals, and
    b) diagnostic, therapeutic, and surgical procedures for the treatment of humans or animals.

    In addition, the Parties confirm that patents shall be available for any new uses or methods of using a known product".[241]

5.2.2 HIGHER PROTECTION AND ENFORCEMENT STANDARDS

- **Test data exclusivity period**

Certain products, including pharmaceutical and agrochemical products are required to be registered and approved prior to being put on the market. To this end, data on the product quality, efficacy, results on clinical trials etc. must be submitted to the regulatory authority as part of the registration process. This is called the 'Test data'.

By virtue of article 39.3 TRIPS, test data disclosed to regulatory authorities for marketing approval of new chemicals must be protected by WTO members against disclosure and unfair commercial use, but the mode of implementation or protection has been left to Members. Regulatory authorities have therefore the discretion to rely on prior data submitted to them or a foreign country to grant marketing approval for generic companies (or subsequent applications).

This could facilitate and accelerate the entry of generic medicines in the market due to the considerable effort needed to compile test data. Generic companies can show that the generic drug is bio-equivalent to the already approved drug and that they have the capacity to produce the drug by adopting similar quality standards. Generic companies do not have the right to access this information

[240] See the US–Singapore FTA, Arts 16.7 (7)(8) and 16.8 (4).
[241] Kuanpoth (n 233).

prior to the expiry of the patent. This exception for research and regulatory approval purposes (the Bolar exception) depends on each jurisdiction.

Data exclusivity clauses in FTAs may prevent generic drug producers to access test data. In this case, generic companies would have to test their drug independently and submit their own test data to regulatory authorities. This would involve high costs and going through a long approval process, which may delay their entry into the market upon the expiry of the patent. Generic companies, which have compulsory licenses to produce, would have to conduct their own clinical trial in order to obtain marketing approval, which may be as costly as the original patent.

Since access to test data eases the entry of generic drug producing companies in the market, developed countries include data exclusivity clause in the FTAs they negotiate and sign with developing countries, which

- prevents the drug regulatory authority from granting market approval to generic drugs based on bio-equivalence or on a grant of marketing approval in a foreign country of the original product.
- protects all types of data submitted for marketing approval, including data for second use/indication.[242]
- makes it mandatory for patent holders to be notified if generic drug producers attempt to obtain marketing approval prior to the expiry of the patent (**patent linkage**).

This enables the patent holder to bring an infringement action against the generic drug companies if they conduct medical trials and engage in production and stockpiling prior to the patent expiry.

For example, the US is responding to the demand of big pharmaceutical companies to interpret Art 39.3 TRIPS as mandating the protection of data exclusivity by requiring all its FTA partners to enforce data exclusivity for at least five years after the submission of the test data.[243] According to the **US-Singapore FTA**, the parties are required to provide exclusivity for test data submitted to a Government for the purpose of product approval, for a period of five years for pharmaceuticals and ten years in case of agricultural chemicals. The trade agreement between the **US and Vietnam** mandates the parties to prohibit generic companies seeking to introduce generic versions from relying on the test data previously submitted by the originator company in support of an application for product approval, for at least five years after the submission of the test data.

[242] TRIPS requires protection only for new chemicals.
[243] Heath and Sanders (n 102) 14.

The EU did not have such clauses in its earlier FTAs but has started to include data exclusivity provisions in its FTAs.[244]

5.2.3 RESTRICTION OR ELIMINATION OF FLEXIBILITIES UNDER TRIPS

- **Limiting compulsory license**

TRIPS and the Doha Declaration allows countries to use compulsory licenses subject to stated conditions. However, many FTAs limit the grounds for which compulsory licenses may be issued through the imposition of stringent conditions which makes the issuance of compulsory licenses difficult.

E.g. The US-Singapore FTA limits the circumstances under which compulsory licenses may be issued to (1) remedy anti-competitive practices (only after a judicial or administrative process) (2) the case of public non-commercial use, and (3) the case of national emergency or other circumstances of extreme urgency.[245]

Issuing of compulsory licenses for non-working or insufficient working may be prohibited even though this right is allowed under TRIPS, through the PARIS Convention. The patentee may also challenge the issue of the compulsory license If same is applied for through an administrative or judicial process. As a further restriction, a term of the FTA can stipulate that Compulsory license can be issued only to the public sector with the payment of full compensation to the patentee, and no obligation to transfer undisclosed information or disclose any know-how.[246]

- **Limiting parallel importation**

TRIPS allows for WTO members to decide their exhaustion regime or principle(s).[247] International exhaustion prevents the right owner from using the protected IP rights to prevent further distribution of the goods that have been placed on the market anywhere by the rights owner or with the consent of the rights owner. This is clearly not pro-higher protection, hence anti-TRIPS-plus.

Many FTAs allow patent holders to prevent the parallel importation of patented products. This is done by insisting on national exhaustion which does not exhaust

[244] Pedro Roffe and Christoph Spennemann, 'The Impact of FTAs on Public Health Policies and TRIPS Flexibilities' (2006) 1 International Journal of Intellectual Property Management 75.
[245] US-Singapore FTA, Art 16.7(6)
[246] US-Singapore FTA, Art 16.7(6)(a)
[247] TRIPS Art. 6.

the rights of a patentee when goods are legitimately placed on the market of a foreign country.[248]

Patentees may also be given the right to restrain parallel importation through contracts, which will give the patentee the right to take legal action against imports or exports of patented products by a third party.[249]

5.2.4 TRIPS-PLUS PROVISIONS ON OTHER IPRS THAN PATENTS

Box 1: Eroding TRIPS Flexibilities in the EU-Colombia-Peru FTA

- **Copyright**
  - Technological measures and rights management information
  - Recognition of *droit de suite*
- **Trademarks**
  - Protection of sounds as trademarks
  - Obligation to introduce opposition proceedings and provide public electronic applications and registration databases
- **Geographical indications (GIs)**
  - Expanded level of protection for GIs not related to wines and spirits
- **Industrial designs**
  - Increased rights conferred by registration
- **Test data**
  - Exclusivity of 5 years for pharmaceuticals and 10 years for agricultural chemical products
- **Enforcement**
  - Several provisions inspired by the EC Directive on the Enforcement of IPRs (2004/48) and the European Customs Regulation (1383/2003).
  - Liability of online service providers inspired by the EC Directive on E-commerce (2000/31).

Source: based on a comparative table prepared by Souheir Nadde-Phlix, research fellow, Max Planck Institute for Intellectual Property and Competition Law.

5.3 TRIPS-PLUS FTAs AND TRIPS FLEXIBILITIES[250]

Many controversies surround the bilateral agreements which contain TRIPs-Plus provisions and their implications for the flexibilities under TRIPS. Concerns have been expressed that the TRIPS-plus provisions in these agreements reduce the opportunities to use the flexibilities.[251] According to a High-Level Panel on Access to Medicines, convened by the United Nations Secretary-General, there are instances where undue

[248] US-Australia FTA, Art 17.9.4
[249] US–Singapore FTA, Art 16.7(2)
[250] See Roger Kampf "TRIPS and FTAs: A world of Preferential or Detrimental Relations?" Heath and Sanders (n 102) 87.
[251] Roffe and Spennemann (n 244).

political and economic pressure has been used to dissuade governments from using TRIPS flexibilities, and that such pressure violates "the integrity and legitimacy of the system of legal rights and duties created by TRIPS". The panel also emphasized WTO Members' "inalienable duty to protect health", and the need for WTO Members to help safeguard "the legitimate rights of individual Members to adopt and implement flexibilities in the TRIPS Agreement as reaffirmed by the Doha Declaration."[252]

The WHO has emphasized that 'bilateral trade agreements should not seek to incorporate TRIPS-plus protection in ways that may reduce access to medicines in developing countries.'[253]

The United Nations Human Rights Council Special Rapporteur on the Right of Everyone to the Enjoyment of the Highest Attainable Standard of Physical and Mental Health also chimed in to remind member States that:

> '[f]lexibilities were included in TRIPS to allow States to take into consideration their economic and development needs. States need to take steps to facilitate the use of TRIPS flexibilities. …
>
> [de]veloping countries and LDCs should not introduce TRIPS-plus standards in their national laws. Developed countries should not encourage developing countries and LDCs to enter into TRIPS-plus FTAs and should be mindful of actions which may infringe upon the right to health.'[254]

[252] 'Final Report, High-Level Panel on Access to Medicines, 14 September 2016, http://www.unsgaccessmeds.org/final-report.

[253] WHO, Public Health, Innovation and Intellectual Property Rights, Report of the Commission on Intellectual Property Rights, Innovation and Public Health, 2006, Recommendation no: 4.21, https://www.who.int/publications/i/item/9241563230.

[254] Anand Grover, UN Human Rights Council Special Rapporteur on the Right of Everyone to the Enjoyment of the Highest Attainable Standard of Physical and Mental Health, Report of the Special Rapporteur on the Right of Everyone to the Enjoyment of the Highest Attainable Standard of Physical and Mental Health, (A/HRC/11/12), 31 March 2009, https://digitallibrary.un.org/record/652915.

MODULE 6

Policy Considerations in Negotiating and Implementing IPR Related Provisions in RTAs

This part is based on the outcome of a research project conducted at the Max Planck Institute for Innovation and Competition on IP in FTAs. The project aimed to deal with the following research questions:

Why do States accept IP obligations which may not necessarily suit their domestic environment?

Does the development dimension of some EU Agreements make a difference for its rules on IP?

What impact do these agreements have on international IP law?

How are IP provisions implemented in domestic law?

The following principles have been outlined in order to take account of IPRs in RTAs.

PRINCIPLES FOR INTELLECTUAL PROPERTY PROVISIONS IN BILATERAL AND REGIONAL AGREEMENTS[255]

PREFACE

For several years, research at the Max Planck Institute for Intellectual Property and Competition Law (MPI) – in collaboration with experts from all over the world – has examined the trend of bilateral and regional agreements that include provisions on the protection and enforcement of intellectual property (IP) rights. By building on this research, the following PRINCIPLES:

- express core concerns regarding the use of IP provisions as a bargaining chip in international trade negotiations, the increasing comprehensiveness of international IP rules and the lack of transparency and inclusiveness in the negotiating process; and

- recommend international rules and procedures that can achieve a better, mutually advantageous and balanced regulation of international IP.

These principles emanate from several consultations within the MPI and especially from a workshop that was held with external experts in October 2012 in Munich, Germany. They represent the views of those first signatories and are open to signature by scholars who share the objectives of the Principles.

Part One – Observations and Considerations

I. IP as a Trade-off in Bilateral and Regional Agreements

1. Since the early 1990s, the world has witnessed an unprecedented inclusion of IP provisions in trade and other agreements that are outside the traditional domain of international IP law. Those agreements cover a wide range of issues and allow for deals in

255 https://www.ip.mpg.de/fileadmin/ipmpg/content/forschung_aktuell/06_principles_for_intellectua/principles_for_ip_provisions_in_bilateral_and_regional_agreements_final1.pdf.

which IP provisions are agreed in exchange for trade preferences and other advantages. On both sides, these deals are driven by export interests and other objectives external to the IP system rather than the common goal to achieve a mutually advantageous, balanced regulation of IP among the parties. While these agreements may pursue an overall balance of concessions, they usually do not lead to international IP rules that address the interests of all countries affected.

2. Most of these agreements in which IP serves as a trade-off are negotiated on the bilateral or regional level. They are subsequently referred to as bilateral and regional agreements. These agreements increasingly contain provisions on the protection and enforcement of IP that are more extensive than the multilateral standards contained in the Paris and Berne Conventions as well as the WTO TRIPS Agreement.

3. Continuous extension of IP protection and enforcement increases the potential for law and policy conflicts with other rules of international law that aim to protect public health, the environment, biological diversity, food security, access to knowledge and human rights. At the same time, such extension often counters, rather than facilitates, the core IP goal of promoting innovation and creativity.

II. Relevance of the Multilateral Framework

4. The multilateral framework, in particular the TRIPS Agreement and the Berne and Paris Convention rules it incorporates, does not only contain minimum standards of IP protection but also includes norms that provide for policy space in domestic implementation ("flexibilities") and obligations that place limits on IP protection ("ceilings"). The TRIPS Agreement can be understood to pursue a certain balance between those elements. This balance forms part of the negotiated consensus of all WTO Members. It is reflected in the object and purpose of the Agreement, as embodied in Articles 7 and 8 TRIPS. These provisions guide the interpretation and implementation of the TRIPS Agreement.

5. As a multilateral agreement, TRIPS establishes a framework that IP provisions in bilateral and regional agreements amongst WTO Members may not contravene. Based on the safeguards general international law contains against inter se modification, IP standards in such agreements should not affect core TRIPS flexibilities, derogation from which is incompatible with the effective operation of the object and purpose of TRIPS, as embodied in its Articles 7 and 8. Flexibilities crucial for the balance that Article 7 establishes should not be restricted. These are flexibilities that support designing domestic IP systems to be "conducive to social and economic welfare" (Article 7 TRIPS).

III. Eroding Multilateral Policy Space

6. IP protection and enforcement rules in bilateral and regional agreements tend to erode the policy space inherent in the TRIPS Agreement. States bound by such rules are less able to tailor their IP laws to fit their domestic environment and to adapt them to changing

circumstances. These trends also affect current and future multilateral initiatives in international IP law.

7. IP provisions in bilateral and regional agreements have become increasingly detailed and prescriptive. They often transplant specific protection and enforcement standards from the domestic IP system of the IP-demanding country, while disregarding the exceptions, limitations and other checks and balances from that same system. Implementing these transplants will often not suit domestic needs and will further constrain policy space.

8. Given the difficulty to amend or withdraw from international treaties, agreeing to detailed IP obligations in bilateral and regional agreements has far-reaching consequences. Countries risk that these obligations will be cast in stone – with few options to adapt to changing economic, technological or other societal needs on the domestic level.

9. Implementing IP obligations from bilateral and regional agreements often requires the re-allocation of financial and human resources and places additional burdens on the legislative, administrative and judicial infrastructure. It may affect the ability of the implementing country to protect the public interest.

IV. Transparency, Inclusiveness and Equal Participation

10. The current process of negotiating bilateral and regional agreements frequently lacks transparency, inclusiveness and equal participation of stakeholders and the public. These deficits cannot be corrected by parliamentary ratification or implementation processes without a meaningful option to influence the treaty text or its implementation. This is especially acute if detailed and prescriptive transplants are included in these agreements.

Part Two – Recommendations

I. Negotiation Mandate and Strategy

11. Countries demanding additional IP protection should take international principles of development cooperation, the recommendations of the WIPO Development Agenda and the level of development of their negotiating partner into account and adjust their demands accordingly.

12. The text of the negotiation mandate should be openly available to the public in the negotiating countries. There should be a meaningful opportunity to raise concerns and influence the negotiation process.

13. Countries facing IP demands should aim to develop their own pro-active agenda on IP issues in a consultative and participatory domestic process. This may include identifying limits for additional IP protection and enforcement, especially limits motivated by the protection of public interests.

II. Negotiation Process

14. The negotiations should be conducted, as far as their nature makes it possible, in an open and transparent manner. They should allow for participation by all stakeholders in

the negotiating countries that are potentially affected by the agreement in an open and non-discriminatory manner. In particular, right-holder and industry groups should not enjoy preferential treatment over other stakeholders.

15. All stakeholders from the negotiating countries should have meaningful and equal opportunities to comment on draft texts. Publicly elected bodies that have to approve a final text should be consulted during the negotiating process.

16. Each negotiating country should evaluate, for example in the form of impact assessments, the IP demands they face in terms of their implications for public interests, the realization of human rights, and the financial burdens and implementation costs they entail.

17. No country should demand or agree to any IP provision that has not been subject to a public negotiation process in which a full range of stakeholders has had the opportunity to review and comment on the wording of the provision.

III. Negotiated Outcome

18. If parties agree on IP provisions containing stronger protection or enforcement obligations, these provisions should nevertheless be sufficiently flexible to take into account the socio-economic situation and needs of both parties.

19. Countries should consider the long-term consequences for the public interest and their domestic IP system in case they accept IP demands in exchange for obtaining trade preferences or other benefits. They should also be aware that such benefits are progressively eroded whenever their trade partners offer equivalent or greater benefits to third countries.

20. The negotiated outcome should respect all international obligations of the parties, in particular those relating to the protection of human rights, biological diversity, the environment, food security and public health. It should allow countries to adopt exceptions and limitations necessary for giving effect to such concerns.

21. The negotiated outcome should not undermine the ability of WTO Members to rely on the public-interest-related flexibilities in the TRIPS Agreement, including those mentioned in the Doha Declaration on TRIPS and Public Health.

22. IP obligations in bilateral and regional agreements should allow for appropriate transition periods and include a review clause whereby the impact of their implementation is comprehensively assessed. These assessments should focus on the effect on all stakeholders and take their comments into account. Bilateral and regional agreements should include an option for re-negotiating IP provisions in light of an impact assessment.

IV. Interpretation and Implementation

23. IP provisions in bilateral and regional agreements have to be interpreted and implemented in the context of other relevant rules of international law, such as those on

the protection of public health, the environment, biological diversity or human rights, applicable in relation between the parties.

24. The interpretation and implementation of bilateral and regional agreements should further be based on the balancing objective and public interest principles embodied in Articles 7 and 8 TRIPS. Accordingly, IP provisions in bilateral and regional agreements should be constructed to provide sufficient policy space to implement the balance that these Articles call for. When implementing specific provisions serving the interests of right-holders, the implementing country maintains the right to draft exceptions and limitations necessary for restoring the balance of Article 7.

25. The notion of protection and enforcement of IP should be understood to encompass also exceptions, limitations and other rules that balance the interests of right-holders against those of users, competitors and the general public. This wider notion allows for an equally wider understanding of national treatment and most-favoured-nation treatment in international IP law.

26. Countries facing IP demands would then be able to rely on concessions regarding exceptions and limitations obtained by other countries in similar situations: When a country has agreed to a specific exception or limitation to IP protection or enforcement in a bilateral or regional agreement, it should make this available to any other country with which it has concluded a bilateral or regional agreement, if that other country is at a similar stage of development as the country to which the exception or limitation is granted.

27. IP-demanding countries should provide unconditional financial and impartial technical support for implementing IP obligations. This support should in no way attempt to reduce the policy space in deciding how to implement IP provisions.

28. Countries should consult all interested parties through open and transparent processes in order to implement international IP provisions in the light of their domestic needs. To achieve this, they should take into account all available flexibilities to the fullest possible extent.

29. IP-demanding countries should not employ unilateral certification or other assessment processes in order to influence the implementation of IP obligations; nor should those countries unilaterally withhold or withdraw benefits unless an independent process has established a breach of obligations of the bilateral or regional agreement[256].

30. Countries should consider re-negotiating existing bilateral and regional agreements whose IP provisions do not conform with these recommendations; in particular those which undermine recognied TRIPS flexibilities or in which the contracting party makes concessions to other countries at a similar stage of development for additional exceptions and limitations to IP protection and enforcement.

[256] The review of the implementation of the obligations resulting from the bilateral or regional agreement should be conducted through an independent process and not unilaterally by an IP-demanding country.