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DOKTORA PROGRAMI

# BIOTECHNOLOGY PATENT PROTECTION IN THE INFORMATION ERA FROM PATENTS TO EDUCATION, FROM EDUCATION TO INNOVATION

DOCTORAL DISSERTATION

Elena JANKOSKA
200002946

İSTANBUL, 2023

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DOCTORAL DISSERTATION

Elena JANKOSKA
20000294

Danışman: Doç. Dr. Ebru ŞENSÖZ MALKOÇ

İSTANBUL, 2023

# ETHICS STATEMENT

I hereby state that my thesis ‘Biotechnology Patent Protection in the Information Era: From Patents to Education, from Education to Innovation’ is an original work and has been prepared in accordance with the Graduate Regulations of YÖK and Istanbul Commerce University. In addition, scientific ethical rules have been fully followed during this study; I declare that I have cited all the sources I have used and that I have not quoted in detail from any source. All matters contained in this thesis are my personal opinion and do not reflect the official view of Istanbul Commerce University.

Student Name, Surname:
ELENA JANKOSKA

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ABSTRACT

Doctoral Dissertation

BIOTECHNOLOGY PATENT PROTECTION IN THE INFORMATION ERA

FROM PATENTS TO EDUCATION, FROM EDUCATION TO INNOVATION

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Supervisor: Doç. Dr. Ebru Şensöz Malkoç

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## Abstract

Biotechnology has proven to be one of the most complicated fields of technology the patent law system has been facing ever since its emergence in the late 20th century. This is due to both its novelty and complexity, and this work examines that clash between the two disciplines in an attempt to contribute into the long-sought-after balance of rights. By providing comparative analysis of biotechnology patent protection in the United States, the European Union and Türkiye as well as looking into the manner in which such protection is internationally provided by the TRIPS Agreement, the dissertation aims at bringing together the issues occurring in all jurisdictions. Biotechnology patents and access to healthcare are the focus of the work, which is looking to provide an alternative, rather indirect solution that might improve the whole IPRs environment and ease the longstanding strife between access to health and patent protection. It argues that increase of the overall standard in developing and least developed countries through provision of better education, in turn, supported by IPRs resources, can contribute to better access to healthcare and novel patented medicines.

For this purpose, an analytical method is used going through various approaches to IPRs ranging from human rights, public-private interests, information and patents, individualism and IPRs as well as looking into the concept of knowledge economy. It concludes with the findings that IPRs contribution to education might be beneficial for both IPRs holders and the general society.

**Key words:** Patents, biotechnology, IPRs, access to health, knowledge economy.

ÖZET

Doktora Tezi

BİLGİ DÖNEMİNDE BİYOTEKNOLOJİ PATENT KORUMASI
PATENTTEN EĞİTİME, EĞİTİMDEN İNOVASYONA

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**Özet**

Biyoteknoloji, 20. yüzyılın sonlarında ortaya çıkışından bu yana patent hukuku sisteminin karşı karşıya kaldığı en karmaşık teknoloji alanlarından biri olduğunu kanıtlamıştır. Bunun nedeni hem yeniliği hem de karmaşıklığıdır ve bu çalışma, uzun süredir aranan haklar dengesine katkıda bulunmak amacıyla iki disiplin arasındaki bu çatışmayı incelemektedir. Tez, Amerika Birleşik Devletleri, Avrupa Birliği ve Türkiye'deki biyoteknoloji patent korumasının karşılaştırmalı analizini sunmanın yanı sıra bu korumanın TRIPS Anlaşması tarafından uluslararası olarak nasıl sağlandığını inceleyerek, tüm yargı alanlarında ortaya çıkan sorunları bir araya getirmeyi amaçlamaktadır. Biyoteknoloji patentleri ve sağlık hizmetlerine erişim, tüm fikri mülkiyet hakları ortamını iyileştirebilecek ve sağlığa erişim ile patent koruması arasında uzun süredir devam eden çekişmeyi hafifletebilecek alternatif, oldukça dolaylı bir çözüm sunmayı amaçlayan çalışmanın odak noktasıdır. Çalışma, gelişmekte olan ve en az gelişmiş ülkelerde daha iyi eğitim sağlanması yoluyla genel standardın yükseltilmesinin ve bunun da fikri mülkiyet hakları kaynaklarıyla desteklenmesinin, sağlık hizmetlerine ve yeni patentli ilaçlara daha iyi erişime katkıda bulunabileceğini savunmaktadır.
Bu amaçla, insan hakları, kamu-özel çıkarları, bilgi ve patentler, bireycilik ve fikri mülkiyet hakları gibi fikri mülkiyet haklarına ilişkin çeşitli yaklaşımların yanı sıra bilgi ekonomisi kavramını da inceleyen analitik bir yöntem kullanılmaktadır. Çalışma, fikri mülkiyet haklarının eğitime katkısının hem fikri mülkiyet hakları sahipleri hem de genel toplum için faydalı olabileceği bulgularıyla sonuçlanmaktadır.

**Anahtar kelimeler:** Patentler, biyoteknoloji, fikri mülkiyet hakları, sağlığa erişim, bilgi ekonomisi.

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LIST OF ACRONYMS AND ABBREVIATIONS

| | |
|---|---|
| ACT | Access to COVID-19 Tools |
| AIDS | Acquired immunodeficiency syndrome |
| BIRPI | United International Bureaux for the Protection of Intellectual Property |
| BRCA | BReast CAncer |
| Cas9 | CRISPR-associated protein 9 |
| CEPI | Coalition for Epidemic Preparedness Innovations |
| CESCR | Committee on Economic, Social and Cultural Rights |
| CJ | Courts of Justice |
| CJEU | Court of Justice of the European Union |
| COVAX | COVID-19 Vaccines Global Access |
| COVID | Coronavirus disease |
| CRISPR | Clustered Regularly Interspaced Short Palindromic Repeats |
| CVC | University of California, the University of Vienna, and Emmanuel Charpentier |
| DNA | Deoxyribonucleic acid |
| EBA | Enlarged Board of Appeal |
| EC | European Commission |
| EFW | Education Finance Watch, UNESCO |
| EIU | Economist Intelligence Unit |
| EPC | European Patent Convention |
| EPO | European Patent Office |
| GAEIB | Group of Advisers on the Ethical Implications of Biotechnology to the European Commission |
| GATT | General Agreement on Tariffs and Trade |
| GDP | Gross domestic product |
| HIV | Human immunodeficiency virus |
| ICESCR | International Covenant on Economic, Social and Cultural Rights |
| ICT | Information and communications technology |
| IP | Intellectual Property |
| LDC | Least Developed Countries |
| LNP | Lipid nanoparticle |
| MERS | Middle East Respiratory Syndrome |
| MOH | Ministry of health |
| NPP | Named Patient Programme |
| OECD | Organisation for Economic Co-operation and Development |
| PCR | Polymerase chain reaction |
| PCT | Patent Cooperation Treaty |
| PGS | Plant Genetic Systems |
| PTAB | US Patent Trial and Appeal Board |
| RNA | Ribonucleic acid |
| SARS | Severe Acute Respiratory Syndrome |

| | |
|---|---|
| SGK | Sosyal Güvenlik Kurumu (Social Security Institution) |
| SSI | Social Security Institution |
| TEB | Turkish Pharmacists' Association |
| TRIPS | Agreement on Trade-Related Aspects of Intellectual Property Rights |
| UK | United Kingdom |
| UN | United Nations |
| UNESCO | United Nations Educational, Scientific and Cultural Organization |
| UNHCR | United Nations High Commissioner for Refugees |
| UPC | Unitary Patent Court |
| US | United States of America |
| USA | United States of America |
| USPTO | United States Patent and Trademark Office |
| WARF | Wisconsin Alumni Research Foundation |
| WHO | World Health Organisation |
| WIPO | World Intellectual Property Organization |
| WTO | World Trade Organisation |

# PART I BASIC ASPECTS AND PATENT LEGISLATION THROUGHOUT JURISDICTIONS

## 1. INTRODUCTION

### 1.1. Hypotheses

Advancements in biotechnological sciences and artificial intelligence in the 21st century have opened the door to immense possibilities furthering human quality of life as well as allowing global dissemination of knowledge thus, enabling new biotechnological inventions to reach everyone around the globe. Whilst the first part of the above statement is accurate enough, the second one concerning **dissemination of knowledge and global access to advanced biomedical products** will be the main goal of this research as it is very far from achieved.

The first hypothesis is that **strong patent protection no longer provides the incentive for further innovation** since innovation depends on access to information from practical and massive use of existing inventions. While moral and ethical aspects contribute to the truthfulness of the first hypothesis, this work disproves it and goes on to examine different approaches to achieving the abovementioned goal.

The second hypothesis is that **by rebalancing the patent system, it can indeed continue to serve its historical purpose of disseminating knowledge** and not only contribute to the scientific and technological development of society, but it can also **obtain a social role, more suitable for our time**.

### 1.2. Goals and Methodology

The research **challenges the long-standing promise that intellectual property protection, specifically patent protection, promotes and incentivises technological development** in an attempt to prove that in the digital, knowledge-based era, patent protection in its current form, though founded on the premise of sharing knowledge for protection, as well as any limitation to data flow can only **impede rather than advance technological as well as economic development**. The purpose is to prove that patent protection of biotechnological inventions is not compatible with the

scientific, societal, and economic developments in the 21st century on more than just ethical grounds.

The research is approached form three aspects in order to examine the viability of patent protection of biotechnological inventions. The first includes review of patent protection of biotechnology in the US, the European Union and Türkiye. Comparative legal examination is used to consider national and international regulation of patenting biotechnological inventions and provides recommendations for further consideration accordingly. Progress made and development achieved by the introduction of the abovementioned legislation is compared by conducting statistical analysis on patented inventions in these jurisdictions. Comparative method is used to compare the findings.

### 1.3. Grounds for Further Research of Biotech Patents

This work is an attempt to address the imbalance between public and private interests in patents, which drastically increased with the rise and development of life sciences. As the products of life sciences save lives and patents make these life-saving products inaccessible, given that patent holders are entitled to the returns of their investment as well as profits, the lives which are saved are the lives of those who can afford to buy patented medical products. And this practice is provided for and protected by law. Countless number of academics, policy makers, NGOs, individuals etc., have addressed the issue, fought against it, wrote about it but their efforts have so far brought about only very slight changes, if any.

For decades have legal scholars argued that patent protection stifles scientific studies,[1] generally on the argument that licences for patented inventions were too expensive, and without a licence, the mere study of a patented invention would represent a breach of patent protection.[2] Today, patent law contains exemption for research purposes in this regard and huge efforts have been made in this direction in order to facilitate

[1] Jorge L. Contreras, "The anticommons at 20: Concerns for research continue." *Science* 361, no. 6400 (2018): 335-337. Available at https://dc.law.utah.edu/cgi/viewcontent.cgi?article=1000&context=labs. Last accessed on 2 June 2022.

[2] Research exceptions now allow for free experimental use of patented invention in jurisdictions where they are legally provided for.

further studies of patented inventions, as is the effort across jurisdiction to implement exemption rules[3] for purely scientific purposes.[4]

Yet, biotechnological patents are not as simple as mechanical or chemical patents. These are borderline patents of discoveries, which internationally are considered unpatentable subject matter.[5] On the other hand, economic incentive to monopolise such discoveries have so far prevailed in moulding patent law to step outside its primary confines and provide special kind of protection for biotechnological novelties, too.

The American patent code needed no amendments to provide such protection and it took several decades and a supreme court decision to prevent patenting of genetic material, be that a whole gene or just a genetic sequence.[6] On the other hand, advances in biotechnology achieved in the US and Japan during the gene patenting era encouraged the European Union to adopt the Biotech Directive in hopes of incentivising biotechnological research and development to catch up with the US advances in the said field. Hence, biotech patents were available throughout the developed world for about two decades. With the Myriad Supreme Court decision in 2013, patent drafters only needed to become more inventive to circumvent the newly introduced ban on gene patents and go on patenting cDNA instead of DNA.[7]

Patent protection in its contemporary meaning was provided in Türkiye only in the late 20$^{th}$ century, 24$^{th}$ June 1995, by the introduction of the Decree-Law No. 551 pertaining to the protection of patent rights. It was just recently replaced by the new Law No. 6769 on the Protection of Industrial Property rights.[8]

Whilst Türkiye was adopting the 'development-boosting' legislation, the European Union was introducing protection to another kind of technology, the biotechnology,

[3] Article 27(b) of the Luxembourg Convention on the Community Patent of 1975- 1989 ('CPC') provides that 'acts done for experimental purposes relating to the subject matter of the patented invention' do not constitute patent infringement. However, this convention never went into force.
[4] Vincenzo Di Cataldo, "The Experimental Use of the Patented Invention: A Free Use or an Infringing Use?." *Patents and Technological Progress in a Globalized World: Liber Amicorum Joseph Straus* (2009): 87-98.
[5] See *infra* Patentability
[6] See *infra* Part Patentability and Exclusions under US Law
[7] Tallmadge, *infra* note 108, p. 596.
[8] 22/12/2016 tarihli ve 6769 sayılı Sınai Mülkiyet Kanununa

which was already being patented in the US and Japan while lacking protection in the EU and thus, assumingly, impede development in Europe. On the said premises, in 1998, the EU introduced the Directive on the legal protection of biotechnological inventions, Directive 98/44/EC.[9]

By examining the competitive advantages gained since the introduction of the biotech directive and the patent law in the EU and Türkiye, respectively, this work aims to provide arguments against strong patent protection for life-sciences inventions. The research is limited to biotechnology patents with medical implications and their development throughout the relevant jurisdictions, which serves as a backbone to the large question concerning patent protection as a whole. Pharmaceutical patents as largely debated topic in relation to access to medicine and subject to much dispute throughout the past few decades are also discussed as they provide the background of the patents versus health debate.

Furthermore, considering the technological changes ever more so relying on knowledge sharing and data flow, statistics concerning investments and changes in the educational system are analysed so as to determine whether it is the patent protection or the investments in other sectors, particularly education, that further economic developments. This is the second approach to technological and economic development that this research will explore. It also considers whether it would be more beneficial for the global society to provide or deny patent protection for such inventions and provides arguments for and against such protection.

Finally, this research attempts to provide possible solutions or alternatives to the biotechnological inventions' protection. Past practices of biotech patents in other jurisdictions are also considered so as to provide the backdrop for the solutions and the proposals to be provide. This part includes case studies and comparative analysis of legislation in different countries especially focusing on the case law contributing to legislative changes pertaining to biotechnological patents.

The research is dealt in a descriptive way keeping in view the documentary sources readily available and the international and national practices undertaken regarding the

[9] Directive 98/44/EC of the European Parliament and of the Council of 6 July 1998 on the legal protection of biotechnological inventions

legal and biotechnological research. The work focuses on primary sources and secondary information published in national and international periodicals, literatures, books, and other sources are referred to as well.

### 1.4. Structure

The work is divided into two parts. Part I looks at the biotechnology patents in the US, Europe and Türkiye. This introductory chapter covers the general notions of patent law in all tree jurisdiction providing brief comparison between them in order to set up the scene for the further analysis of how these apply to biotechnology in the following three chapters. Chapter 2 focuses on the patenting of the BRCA genes, by looking into *Myriad* and CRISPR litigations and the issues addressed by the courts in the cases, which are taken representatively to discuss the issues of biotechnology patents in the US thus providing an insight in the substantive provisions of the US Patent Act as well as the relevant case law pertaining to biotechnology patents. It also provides a view of some of the judicial doctrines which shape the US patent system. The faith of the BRCA patents in Australia and Europe is also included in this Chapter, showing the different approaches to it across jurisdictions.

Chapter 3 deals with biotechnology patents in Europe and is centred around the Biotechnology Directive as well as its subsequent incorporation in the European Patent Convention. It includes a comparative view of the three layers of patent protection in Europe. As the main concern with biotechnology patents in Europe proved to be the morality of the practice, '*ordre public*' or morality issues before the adoption of the Directive and its interpretation by the EPO Board of Appeal are discussed in detail. Chapter 4 looks at the Turkish patent system and provides a historical view so as to evaluate the conditions in the country when the modern patent system was introduced.

Part II deals with patent protection provided for on international level with Chapter 5 looking into the TRIPS Agreement, the Doha Declaration[10] and their practical application during the COVID-19 pandemic with a special emphasis on the issue of access to affordable medicines. It considers the adoption of the text and the issues with access to medicine countries face after its introduction. Access to medicine is also dealt

[10] World Trade Organization, Ministerial Declaration on the TRIPS Agreement and Public Health of November 14, 2001, 6, WT/MIN(01)/DEC/W/2, 41 I.L.M. 755 (2002)

with in this chapter and the COVID-19 pandemic is taken as a representative example of a current worldwide problem. Finally, Chapter 6 takes a different turn by looking into the primordial balance of rights and considering different approaches to balance the private and public interests. It gives view of possible alternatives to the current patent system and changes so far made to improve it, to finally propose a possible upgrade which could make the system better suited for the contemporary technological, scientific, and societal conditions. Recommendations on legislative changes on international level found to be necessary in order to achieve the much sought-after balance are also included in this Chapter. The Conclusion sums up the findings and gives a reflection on the effects of life-sciences patents on society in order to reaffirm the need for decisive introduction of the proposed legislative amendments. It also gives concrete propositions as to how the findings of this work can be implemented in existing legal texts.

### 1.5. Brief Overview of Contemporary Patent Law Notions

Originating in the Middle Ages, times when innovation was almost non-existent, rulers came to recognize the ingenuity of certain individuals and in their appreciation, granted these individuals exclusive, monopolist rights to exploit their inventions for a brief period of time.[11] These rights extended to three years or, later on, for ten, but the first patent system recorded is the Venetian Patent Statute.[12] Accordingly, the definition of what patent constitutes is similar to the current one. An invention for patent must be novel, must involve and inventive step and must be useful. Depending on separate countries' patent laws, the wording varies but it, more or less, implies the same conditions.

[11] 'Patent' Encyclopaedia Britannica. Available at https://www.britannica.com/topic/patent. Last accessed on 18 April 2022. 'The first recorded patent for an industrial invention was granted in 1421 in Florence to the architect and engineer Filippo Brunelleschi. The patent gave him a three-year monopoly on the manufacture of a barge with hoisting gear used to transport marble.'

[12] Stephen Pericles Ladas, *Patents, trademarks, and related rights: national and international protection*. Vol. 1. Harvard University Press, 1975. pp. 6–7; also Mikulás Teich and Roy Porter, eds. *The industrial revolution in national context: Europe and the USA*. Cambridge University Press, 1996.

### 1.5.1. Subject Mater

Patents are granted for inventions. According to the Glossary of the European Patent Organisation, an invention is a '[n]ew product, process or apparatus or any new use thereof. To be patentable, an invention must be novel, involve an inventive step (i.e., not be obvious to those having ordinary skill in the particular art of the invention) and be susceptible of industrial application'.[13]

The USPTO Glossary defines an invention as 'any art or process (way of doing or making things), machine, manufacture, design, or composition of matter, or any *new* and *useful* improvement thereof, or any variety of plant, which is or may be patentable under the patent laws of the United States'.[14] However, according to Article 100 of the US Patent Act (35 U.S. Code) 'the term "invention" means invention or *discovery'*. Unlike Europe, where discoveries are not patentable subject matter, discoveries could be subject to patent protection in the US.[15]

Article 82 of the Turkish Industrial Property Law[16] (hereinafter 6769 Law) provides for patenting of 'inventions in all fields of technology providing that the invention is *new*, involves an *inventive step* and is *susceptible to industry*'.[17] The wording of this definition is almost identical with the one provided for in the EPC. In this sense, with the introduction of the new Industrial Property Code, Türkiye, as a member of the EPO, is in line with the European standpoint on patentable subject matter. In accordance with the EPC, it also excludes discoveries from patentability.[18]

However, neither of the above definitions really answer the question of what an invention really is. They just provide for the conditions which should be met for an invention to be eligible for patent protection. Patent disputes arise over the validity of

[13] EPO – Glossary, 'Invention' at https://www.epo.org/service-support/glossary.html#i. Last accessed on 3 June 2022.
[14] USPTO – Glossary, 'Invention' at https://www.uspto.gov/learning-and-resources/glossary#sec-I. Last accessed on 22 Apr. 23
[15] Under Art. 52(2)(a) and (3) EPC, discoveries, like scientific theories and mathematical methods, are not patentable.
[16] Law No. 6769 of December 22, 2016, on Industrial Property (22/12/2016 tarihli ve 6769 sayılı Sınai Mülkiyet Kanununa)
[17] Industrial Property Law of Türkiye No. 6769 (English translation) available at https://www.turkpatent.gov.tr/TURKPATENT/resources/temp/4D59A7D3-A564-40A1-9C96-DB1E3D157E90.pdf. Emphasis added by author.
[18] Article 82(2)a of 6769 Law.

patents based on the argument that a patented subject matter does not constitute patentable subject matter at all.[19]

From a social aspect, the purpose of patent protection is, in a matter of speaking, data sharing. That is, having been granted exclusive rights over inventions, patent holders are obliged to disclose the details of the protect invention with the public. Such disclosure includes the patent claims, outlining the exact segment exclusivity is sought for, and patent description, providing information on the existing problem the invention claimed solves as well as the manner in which the solution is provided and details of how the invention could be reconstructed. Patent protection, thus, is in line with the goal of dissemination of knowledge and information and as such, more than suitable for a data-based era.

This is converted and formalised in a patent application. A patent application is a form which should be comprised of invention description and graphic representation of the invention, that is, the patent specification. This part is envisaged to include details on the prior art, define the problem for which the invention, for which protection is sought, provides solution and give explanation on how the product or process being patented can be replicated, built, or used by a person skilled in the art without undergoing any further experimentation.

The patent application further needs to contain one or more claims which would constitute a single sentence. The claims of the patent are meant to provide the actual area for which exclusivity is sought. Whereas the description gives the full scope of the invention, claims denote the actual novel, inventive part of the said invention. The manner in which the invention would be used could be given in the description or in the claims. The debate on whether claims should be interpreted in light of the description or independently of it is a long lasting one and continues to be a thorny topic of biotechnology patents, too.

[19] According to Articles 52 to 57 EPC the patent is not patentable or that the patent does not disclose the
invention in a manner sufficiently clear and complete for it to be carried out by a person skilled in the art, or that
the subject matter of the patent extends beyond the content of the application as originally filed.

A patent application must include a description of the invention and patent claims. There is a disagreement concerning which one of these should contain the characteristics that prove the invented subject matter is patentable.[20] The claims define the extension (scope of exclusivity) to which the monopoly is granted, and the description gives the details on what is new about the claimed invention, how it differs from the existing state of the art (inventive step) and what industrial applicability it has got.

### 1.5.2. Novelty

Novelty is provided for by Article 54 of the EPC. Accordingly, an invention is considered to be novel if 'it does not form part of the state of the art'.[21] The same article defines 'state of the art' as 'everything that has been made available to the public by means of a written or oral description, by use, or in any other way, before the date of filing of the European patent application'.[22]

The US Patent Code provides for the conditions under which an invention will not be eligible for protection. Thus, it outlines the limitations of what would be considered as new. Or in other words, it provides the conditions of what is considered to be prior art. Similar to the EPC, it defines prior art as anything 'patented, described in a printed publication, or in public use, on sale, or otherwise available to the public'.[23]

Likewise, the Turkish IP Law considers an invention to be novel if it does not form a part of the state of the art.[24] Further on, Article 83 of the said law provides for the condition of what constitutes the state of the art. Thus, it can be concluded that novelty is generally defined in the same manner throughout jurisdictions and that the new Turkish IP Law is in line with the standards of what is new in the US and in Europe.

[20] For a detailed discussion see Cotropia A. Christopher, "What Is the" Invention"?, 53 Wm. & Mary L." *Rev* 1880 (1855): 2012.. Available at https://scholarship.law.wm.edu/wmlr/vol53/iss6/2. Last accessed on 2 June 2022.
[21] Article 54(a) EPC
[22] Article 54(b) EPC
[23] Article 102(a)(1) of the 35. US Code. (35 U.S.C. 102a)
[24] Article 83(1) of 6769 Law.

### 1.5.3. Inventive Step

The second condition that an invention should meet in order to be patent eligible is the inventive step. There is a slight discrepancy in the wording between the US and Europe when it comes to this condition. Namely, the US patent code adopts the term 'non-obviousness' instead of 'inventive step'. However, the definitions of what an inventive step is and what is non-obvious are similar. Namely, according to article 56 of the EPC, an invention will be patent eligible if it involves an inventive step, that is, the invention would not be obvious to a person skilled in the art. The non-obviousness in the US Patent Code is provided for by Article 103 of the said code and excludes from patentability inventions which would be obvious to a 'person having ordinary skills in the art'.

The Turkish law uses the term 'inventive step' just like the EPC does and the provisions for it are included in Article 83(4) and (5). It provides the invention should not be obvious to an 'expert of the area to which the invention is related'.

There is a difference in the wording in all three pieces of legislation since it would seem that in Europe, the invention should not be obvious to a 'person skilled in the art'; in the US, this person should have just 'ordinary skills in the art'; whereas the Turkish law goes further on and provides that this person should be an 'expert' in the field which the invention relates to. It is arguable that the definition of who the invention should not be obvious to differs a lot from one to another jurisdiction. It begs the question of whether a skilled person in the art is also an expert in the relevant field. On the other hand, the Turkish law obviously departs from the meaning of the US code since the latter specifically states that the skills of the person should be 'ordinary', thus not requiring any expertise on their side.

It is arguable that this could be a question of the meaning of the Turkish term 'uzman' which quite literally translates to 'expert'. Translations of the Decree Law 551 of 1995 have this term translated as 'skilled' person, however, given the existence of another, yetenekli', a more appropriate term for 'skilled', it would seem that the condition for inventive step provided for in the Turkish law is stricter than in the US and Europe. Namely, an invention obvious to an expert in the US would still involve an inventive step since the requirement is for it not to be obvious to a person with ordinary skills.

However, in Türkiye, the threshold seems to be higher since for the invention to involve an inventive step not only does it have to be non-obvious to an ordinarily skilled parson, but to an expert in the art as well.

On the other hand, the choice of words in the Turkish law could be ascribed to its connections to the German law. Namely, the term used for a skilled person in the German law, Fachmanm, could translate to Turkish as 'uzman'.

#### 1.5.4. Industrial Applicability

Coming to the last condition of patentability, the definition of 'industrial applicability' the Turkish law and in the EPC are almost identical. Namely, for an invention to meet this criterion, it must be 'producible and usable in any industrial area' in Türkiye,[25] that is, 'it can be made or used in any kind of industry' in Europe.[26] Both texts specifically note that, in this context, 'agriculture' is considered as an industry, too.

The US patent code departs from the wording of the former two since it couples novelty with utility in Article 101. It does not contain a specific provision concerning industrial applicability. Nor do the previous two set a condition for utility per se. Instead, even if the invention can be only made, not specifically used, it is considered to have met the industrial applicability condition. However, this patent law doctrine is meant to prevent from patenting fantastic or hypothetical devices[27]. Hence, utility and industrial applicability are considered synonyms in patent law context.

#### 1.5.5. Patent Term

Throughout jurisdictions, patent protection is provided for a period of 20 years, with the pharmaceutical industry enjoying 25 years of protection in certain jurisdictions justified by the lengthy process of developing pharmaceuticals as well as obtaining marketing permissions from national governments.[28] This was proven to be sufficient

[25] Article 83(6) of 6769 Law.
[26] Article 57 EPC
[27] Robert P. Merges, *Patent law and policy: Cases and materials*. Michie, 1992.
[28] Supplementary Protection Certificates (SPCs) are granted for the purpose of offsetting the loss of patent protection for pharmaceutical products that is due to the lengthy testing and clinical trials required for these products to obtain regulatory marketing approval. For more details, see EC, 'Supplementary protection certificates for pharmaceutical and plant protection products.' Available at https://ec.europa.eu/growth/industry/strategy/intellectual-property/patent-protection-eu/supplementary-protection-certificates-pharmaceutical-and-plant-protection-

period for marketing and capitalization of an inventive product in the 20th century and the public seem to have benefited from the disclosure of patent specification and subsequently of the free access to the product upon expiration of the patent protection. However, given the current trend of extremely fast-paced technological development and obsoletion of currently novel invention only after several years, this period of patent protection is proving to be too long since patented invention get to the public domain way too late when the said protection will have expired. No longer does the public benefit from the public domain invention since they are no longer applicable when protection is not afforded.

The goal is to determine if patent protection is beneficial only for highly developed countries, where modern patent protection has been provided for since the 18th century,[29] thus rendering them ever more so developed, in comparison to developed/developing countries, as is Türkiye, where the contemporary patent protection has been provided for only since the end of the 20th century.[30]

However, biotechnological patents have attracted a lot of attention since the rise of patented inventions seem to have curbed the field for further research. In order for an invention to be examined and further developed, researchers are obliged to acquire expensive patent licences. Universities are not known for the large funding at their disposal; hence academia is left with either violating a patent and build on existing inventions or abandoning the research due to lack of access to patented products. This issue has already been addressed in Europe and exemptions to use of patented inventions for educational and research purposes have been introduced.[31]

products_en#:~:text=Supplementary%20protection%20certificates%20(SPCs)%20are,been%20authorised%20by%20regulatory%20authorities. Last accesses on 9 June 2022.

[29] The history of patent law in Europe goes even further back to 1474, when the Venetian Patent Statute was introduced.

[30] Decree-Law No. 551 of 24 June 1995 on the Protection of Patent Rights, OG No: 22326, 27.06.1995 (551 Sayılı Patent Haklarının Korunması Hakkında Kanun Hükmünde Kararname)

[31] Please see Hans-Rainer Jaenichen and Friederike Stolzenburg, "The European Patent Office will now grant generic claims for transgenic plants: G1/98," Plants/NOVARTIS"." *Biotechnology Law Report* 19, no. 4 (2000): 401-404. Available at https://www.vossiusandpartner.com/fileadmin/Redakteure/Archiv/2000_Practice_in_the_different_EPC.pdf for details on how research exemptions are dealt with throughout Europe; Article 13(3)(b) of the Biotech Directive allows the use of a sample of a patented invention for experimental purposes.

## 1.6. Biotechnology and Patents

Generally, biotechnology makes use of living organisms to produce goods and conduct processes.[32] Production of beer and cheese is subject to fermentation processes used since ancient times; however, it became a subject to science only in the 20th century when genetic engineering technology was developed, and genetic manipulation of living organisms became possible. Human gene isolation came on stage in the late 1970' and its application in preventing and curing diseases generated great scientific interest.[33]

The word 'biotechnology' was first introduced by Karl Ereky in his book titled 'Biotechnology of the meat, fat and milk production in agricultural large concerns for scientific sophisticated farmers.'[34] The book was published as early as 1919 in Berlin. At the time, Karl Ereky was the director of the cattle utilization cooperative and Hungarian great landowner, who later became Hungarian Food minister.[35] His idea to produce goods by making use of living organisms was nothing new, but the word biotechnology was new. The word biotechnology derives from the Greek words – **bios** – life, **technos** – art, skill, craft in work; a system or method of making or doing, and **logia** – 'a speaking, discourse, treatise, doctrine, theory, science.'[36]

As a relatively new science covering, or rather intertwining with, many fields of study, an attempt has been made for the different subcategories of biotechnology to be categorized so as to be better understood. First such categorisation is made by Dr. Rita R. Colwell in 2003.[37] She introduces ten colours, each ascribed to a different branch of biotechnology (Table 1). The most developed biotech branches are 'red,' 'blue,'

[32] Silvia Salazar, "Intellectual property and the right to health." *Intellectual Property and Human Rights* (1998): 65.. Available at http://193.5.93.81/edocs/pubdocs/en/intproperty/762/wipo_pub_762.pdf#page=72. Last accessed on 20 April 2022.
[33] National Human Genome Research Institute. '1976: First Genetic Engineering Company' Available at https://www.genome.gov/25520305/online-education-kit-1976-first-genetic-engineering-company. Last accessed on 20 April 2022.
[34] Karl Ereky, *Biotechnologie der Fleisch-, Fett-, und Milcherzeugung im landwirtschaftlichen Grossbetriebe: für naturwissenschaftlich gebildete Landwirte verfasst*. P. Parey, 1919.
[35] Ursula Steiner, *Fachenglisch für BioTAs und BTAs*. Springer Spektrum, 2020, p. 3-80
[36] Online etymology dictionary 'biotechnology', available at https://www.etymonline.com/word/biotechnology#etymonline_v_27147. Last accessed on 22 Apr. 23
[37] Rita R. Colwell, *The Flag of Biotechnology*, 2003. https://www.nsf.gov/news/speeches/colwell/rc030625usectask.htm

'green,' 'white,' and 'grey' biotechnology. Biotechnology relating to the medical field of study is represented by the colour red. The subject of its study include gene therapy (defective gene replacement by a healthy gene), stem cell research (aiming at leukaemia treatment), genetic engineering (use of recombinant DNA technology to alter the genetic composition of an organism) as well as development of new drugs and vaccines in medicine.[38] Furthermore, red biotechnology deals with tissue engineering, that is, cultivating cells for tissue implantation as well as production of artificial skin, cartilage and disc replacement. Mutations and amplifications of genes to cure degenerative diseases is another research field in which biotechnology finds its application. The cross section of biotechnology with pharmaceuticals comes to light in the field of drug development where biotechnology contributes to production of individualised medicines necessary for some individuals who have different genetic disposition. As other biotechnology branches fall outside the scope of this work, they are just given in table 1 below as reference.

***Table 1-1.1. Biotechnology classifications by colours***[39]

| **Colour** | **Industries** |
|---|---|
| Red | Biomedicine, Biopharmaceutics, Diagnostics |
| Yellow | Food Biotechnology, Nutrition Science |
| Blue | Aquaculture, Coastal and Marine Biotechnology |
| Green | Agricultural Biotechnology, Bioenergetics (Biofuels), Biofertilizers, Bioremediation, Geomicrobiology |
| Brown | Arid Zone and Desert Biotechnology |
| Black | Bioterrorism, Biowarfare, Biocriminology, Anticrop Warfare |
| Violet | Patents, Publications, Inventions, Intellectual Property Rights (Legal, Ethical and Philosophic Issues) |
| White | Industrial Biotechnology |
| Gold | Bioinformatics, Nanobiotechnologies |
| Grey | Environmental (Ecological) Biotechnology |

[38] Steiner, *supra* note 35

[39] Edgar J. DaSilva, "The colours of biotechnology: science, development and humankind." *Electronic journal of biotechnology* 7, no. 3 (2004): 01-02. Available at: https://www.scielo.cl/scielo.php?script=sci_arttext&pid=S0717-34582004000300001. Last Accessed on 17/11/2021.

An important hallmark in biotechnology was the Human Genome Project, which was initiated in the early 1990' and considered essentially completed in 2003, when 92%[40] of the human genome[41] was identified, mapped and sequenced.[42] It was supported by many countries around the world and the work was conducted by an international team of researchers.[43] In March 2022, the research of the completed sequence of the human genome was published in *Science*.[44]

### 1.6.1. Biotechnology vs Pharmaceuticals

Biotechnology patents are separately regulated from pharmaceuticals in some jurisdictions. The reason for this is mainly the novelty of the science itself and the moral dilemma it started causing when first patent applications were filed. Therefore, it is important to mention some of the difference in these two industries, which further on are elaborated in more detail through the prism of patents.

As noted above, biotechnology makes use of living organisms for the development of biotechnological products while pharmaceuticals imply use of chemical compounds for the production of pharmaceutical products. Patenting in the field of chemistry and hance in the pharmaceutical industry has a long tradition but just as biotechnological products which aim at human health, they have been subject to fearsome debate pertaining to access to medications. With the rise of biotechnology, this debate has converged to include access to products deriving from both biotechnological and pharmaceutical industry. And rightly so, since the potential market for both involves human health, that is, it is dependent on current diseases humans face.

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[40] Nearly two decades since, scientists have struggled to decipher the remaining 8%. See CNN, *Scientists sequence the complete human genome for the first time*. Available at https://edition.cnn.com/2022/03/31/health/first-complete-human-genome-sequence/index.html?utm_medium=social&utm_term=link&utm_content=2022-03-31T21%3A31%3A08&utm_source=twCNN. Last accessed on 20 April 2022.

[41] The genome is the complete set of information carried by an organism's DNA. See Bruce Alberts, Alexander Johnson, Julian Lewis, Martin Raff, Keith Roberts, and Peter Walter. "The structure and function of DNA." In *Molecular Biology of the Cell. 4th edition*. Garland Science, 2002. Available at https://www.ncbi.nlm.nih.gov/books/NBK26821/. Last accessed on 20 April 2022.

[42] National Human Genome Research Institute, 'The Human Genome Project' Available at https://www.genome.gov/human-genome-project. Last accessed on 20 Apr. 22.

[43] *Ibid*

[44] Sergey Nurk, Sergey Koren, Arang Rhie, Mikko Rautiainen, Andrey V. Bzikadze, Alla Mikheenko, Mitchell R. Vollger et al. "The complete sequence of a human genome." *Science* 376, no. 6588 (2022): 44-53. Available at https://www.science.org/doi/10.1126/science.abj6987. Last accessed on 20 April 2022

Patenting of living organism begins as early as the 1970s, but the first biotechnological patent was granted in the USA in 1981 after the US Supreme Court decided in the case of *Diamond vs Chakrabarty*[45] that living organisms are patentable subject matter if they are truly manmade. Henceforth follows the ongoing debate of whether or not genetically engineered organisms should be patentable subject matter.

The topic becomes even more so interesting when the question of discoveries vs inventions comes forth. As discussed above, discoveries are not considered patentable subject matter in some jurisdiction while patentable in others. The application of the newly discovered natural law is normally un-patentable if its application relies on elements already known in that art. These issues need to be considered by many biotech companies to ensure that their result is patentable otherwise they may risk wasting a huge amount of funding on research when their product cannot be patented.[46] Which would further mean that inventions are encouraged but discoveries are un-patentable as are undiscovered laws of nature. That is to say that manipulating the existent knowledge is rewarded, however, discovering novel phenomena is side-lined. Innovation and progress can go just as far as researchers are encouraged to delve into the new, not only come up with ways to apply the existing.

According to a study by Tufts Centre for the Study of Drug Development, the average cost to develop a new medicine is over $800 million (£648 million). The ability of a company to recoup these costs is highly dependent on their ability to control the supply of their development and sale.[47]

One of the questions which may be raised is whether these companies really need 20 years or more to recuperate the high development costs spent on a given drug. While the study provides the average cost to develop a new medicine, it fails to provide information on how big the average profit for these companies is.

Generic pharmaceuticals become a threat to pharmaceutical companies with patent expiry. The premise that generic drugs are a threat to pharma companies is short-

[45] *Diamond v. Chakrabarty*, 447 U.S. 303 (1980).
[46] Patsnap.com, 'Pharmaceutical vs biotech (chemistry vs biology)' available at https://www.patsnap.com/resources/blog/pharmaceutical-vs-biotech-chemistry-vs-biology/. Last accessed on 22 Apr. 23
[47] *Ibid*

sighted since only after the product becomes generic, that is, the patent protection lapses, can the products become widely available to the public as they finally become within easy reach and serve the purpose they had been developed to serve.

The identification and sourcing of DNA have helped the industry make great leaps. Companies in this sector have developed pest-resistant crops, created biofuels like ethanol, and developed gene cloning.[48] However, science is just as good as its promise to improve and enrich human lives. The more of them it touches, the stronger it keeps its promise. Improvement and great leaps in a single industry do not necessarily mean improvement of human life as a whole, quite the contrary. Patents impede access, thus the keeping of the aforementioned promise is delayed by at least 20 years, that is, the lifetime of a patent.

In recent years, biotechnology start-ups have sprouted alongside computer technology companies in Silicon Valley. The aim of most is to use biotechnology processes to create breakthrough drugs. Unlike computer technologies, which have touched the lives of billions in the past two decades, biotechnological products, being subject to patent protection, again, unlike computer technologies, which are subject to copyright protection, are not as accessible just yet. Biotechnology companies generally have very high operating costs as they are involved in research, development, and testing that takes years to complete. The result could be a historic breakthrough or utter failure. Investors in their stocks are along for the ride, up or down.

Historic breakthroughs get patented and by the time they come to serve their purpose become old new products. Utter failures in biotech just mean that they do not meet the patenting requirements and the investors 'fail' to profit from the research. This may or may not be true for the public. An unpatentable product can potentially affect more lives since there is no legal obstacle to access.

[48] Varsha Gupta, Manjistha Sengupta, Jaya Prakash, Baishnab Charan Tripathy, Varsha Gupta, Manjistha Sengupta, Jaya Prakash, and Baishnab Charan Tripathy. "An introduction to biotechnology." *Basic and Applied Aspects of Biotechnology* (2017): 1-21. Available at https://www.ncbi.nlm.nih.gov/pmc/articles/PMC7119977/. Last accessed on 3 June 2022.

Also, this industry may find roadblocks to the development of new products if the research or end product is controversial. As an example, several countries ban genetically modified plants and products.[49]

Then again, it is not only patents which impede access to newly developed biotech product but also mindset and lack of understanding of advantages and disadvantages of such products. While moral grounds can be sometimes legitimately stated as contrary to patent protection of biomedical products, the same grounds can be used to prevent such product to enter markets where they can make real difference to people's lives.

### 1.7. Cons and Pros Biotech Patent Protection

Biotechnology brought about lifesaving and life-changing inventions at the price of shifting the commonly accepted human values, norms and ethics. The prevalent grounds for the fast development and improvement of our technology-driven world are that patents create incentive[50] for research and development and as such are essential for furthering the human quality of life. Accordingly, patents have become available for biotechnological products and processes, including genes and gene sequences, and are treated just as mechanical and chemical patents.[51] Given the structure of genetic material, it is patentable as a chemical compound isolated from its natural environment.[52] 'Purified' and 'isolated', considered as non-existent in nature

[49] France, Germany, Austria, Greece, Hungary, the Netherlands, Latvia, Lithuania, Luxembourg, Bulgaria, Poland, Denmark, Malta, Slovenia, Italy and Croatia have chosen a total ban. Wallonia, the French-speaking region of Belgium has opted out, as well as Scotland, Wales and Northern Ireland. The Flemish region of Belgium, England and Romania are open to GMOs. See 'Several European countries move to rule out GMOs' European Green Capital at https://ec.europa.eu/environment/europeangreencapital/countriesruleoutgmos/#:~:text=Several%20countries%20such%20as%20France,Scotland%2C%20Wales%20and%20Northern%20Ireland. Last accessed on 18 April 2022.

[50] Karen I. Boyd, "Nonobviousness and the Biotechnology Industry: A Proposal for a Doctrine of Economic Nonobviousness." *Berkeley Tech. LJ* 12 (1997): 311. Available at https://www.btlj.org/data/articles2015/vol12/12_2/12-berkeley-tech-l-j-0311-0344.pdf. Last accessed on 29 November 2018. Also, Kshitij Kumar Singh. "Implications of Genetic Patents on Human Genetic Resources: Issues of Ownership, Benefit Sharing and Informed Consent." *Biotechnology and Intellectual Property Rights: Legal and Social Implications* (2015): 195-228. Also, WIPO website, *Economic Development and Patents*, https://www.wipo.int/patent-law/en/developments/economic.html Accessed 29 November 2018.

[51] Graham Dutfield, *Intellectual property rights and the life science industries: a 20th century history*. Ashgate, 2003.

[52] *Diamond vs Chakrabarty* 447 U.S. 303 (1980)

as such, discoveries became patentable subject matter and gave rise to the dawn of biotechnological patents.[53]

Given the expansion of the patentable subject matter concerning biomedical products and methods,[54] the clash between the existing ethical norms and the rights to patents is ever stronger. In a competition driven economy,[55] monopolies create discriminating environment in which only those who can afford the products, specifically innovative medications, can have access to them. With the ongoing debate on what and how precisely can health be defined, though recognized as fundamental human right,[56] the right to access to medications is still brought into question.[57]

Furthermore, the plethora of patents pose a significant issue for scientist when developing their products and their concerns whether their invention will infringe of someone else's patent, regardless of how wide its scope might be. Acquiring patent licences can be very expensive[58] and affordable only by major R&D corporations, which, indeed, impedes the work of smaller laboratories and academia, who could potentially bring about ground-breaking inventions furthering individual as well as collective health and wellbeing. Empirical evidence demonstrates real fear on behalf of clinical laboratory directors and researchers based on the belief that patent holders can and will prevent them from conducting their research.[59]

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[53] Jorge A. Goldstein and Elina Golod, "Human gene patents." *Academic Medicine* 77, no. 12 Part 2 (2002): 1315-1328.. Available at https://journals.lww.com/academicmedicine/Fulltext/2002/12001/Human_Gene_Patents.3.aspx. Last accessed on 3 June 2022.

[54] *Ibid* at p. 195. Before 1980, living organisms did not constitute patentable subject matter and were considered products of nature.

[55] Stephen Yelderman, "Do patent challenges increase competition." *U. Chi. L. Rev.* 83 (2016): 1943.. Available at https://papers.ssrn.com/sol3/papers.cfm?abstract_id=2731216. Last accessed on 6 June 2022. Also, Saeed Ahmadiani and Shekoufeh Nikfar, "Challenges of access to medicine and the responsibility of pharmaceutical companies: a legal perspective." *DARU Journal of Pharmaceutical Sciences* 24 (2016): 1-7. Available at https://link.springer.com/article/10.1186/s40199-016-0151-z. Last accessed on 2 June 2022.

[56] WHO recognizes the right to health as a fundamental right, which is reaffirmed by the Ottawa Charter for Health Promotion of 1986.

[57] Marion Habersack and Gero Luschin. "WHO-definition of health must be enforced by national law: a debate." *BMC medical ethics* 14, no. 1 (2013): 1-3. Available at https://bmcmedethics.biomedcentral.com/articles/10.1186/1472-6939-14-24. Last accessed on 29 November 2018.

[58] Nigel Borshell and Taskin Ahmed, eds. *Approaches to valuation of pharmaceutical licensing deals*. PharmaDeals, 2012.

[59] Richard E. Gold and Julia Carbone. "Myriad Genetics: In the eye of the policy storm." *Genetics in Medicine* 12, no. 1 (2010): S39-S70. Available at

Legislation and practices regarding biotech patents differs throughout the world. While patenting gene-related patents was not acceptable practice in Europe, the Unite States allowed such inventions to be patented. Europe responded to the trend by introducing the Biotech directive, however, still not granting such a wide patent scope as did the US.[60] Isolated, albeit identical to the naturally occurring, genes and gene sequences are now patentable subject matter in the EU, but no longer in the US.[61] The importance of the gene is not per se in its material qualities as it is in its informational content. It is then arguable that the chemical composition of the gene, regarded as patentable subject matter, should instead be regarded as information, and non-patentable subject matter as such.[62] Nonetheless, things in the USA started changing with the *Mayo Collaborative Services v. Prometheus Laboratories, Inc*.[63] and especially after *Association for Molecular Pathology v. Myriad Genetics, Inc.*[64] decisions in the US when 'products of nature' were exempt of patent protection. After years long litigation,[65] Myriad Genetics' patents on BRCA1 and BRCA2 mutations, responsible for causing breast and ovarian cancer, were partially invalidated by the US Supreme Court holding that "naturally occurring DNA segment is a product of nature and not patent eligible merely because it has been isolated."[66]

'The era of Old intellectual property – the overuse of patents, copyrights and trade-marks – is ending' said Dr. Richard Gold from McGill CIPP. The Report[67] submitted by the International Expert Group on Biotechnology, Innovation and Intellectual Property recommends replacement of the 'Old IP' involving construction of

http://www.nature.com/gim/journal/v12/n1s/full/gim2010142a.html#aff1. Last accessed on 29 November 2018.

[60] Unlike in the EU, public order and moral aspects of patenting genes are not criteria to be considered when patents are granted in the USA.

[61] See *infra* PATENTING BRCA

[62] Stephen A. Merrill and Anne-Marie Mazza. "Reaping the benefits of genomic and proteomic research: intellectual property rights, innovation, and public health." (2006). https://ncbi.nlm.nih.gov/books/nbk19865.

[63] *Mayo v. Prometheus*, 566 U.S. 66 (2012)

[64] *Association for Molecular Pathology v. Myriad Genetics, Inc.* 569 U.S. 576 (2013)

[65] On May 12, 2009, the Association for Molecular Pathology challenged Myriad Genetics' patents on BRCA1 and BRCA2 genetic mutations, responsible for causing breast and ovarian cancer, on the grounds of unconstitutionality and invalidity of the patents. All challenged claims were firstly invalidated by the United States District Court for the Southern District of New York only the decision to be twice overturned by the Court of Appeals for the Federal Circuit.

[66] Opinion of the Supreme Court of the United States on *Association for Molecular Pathology vs Myriad Genetics* Available at https://www.supremecourt.gov/opinions/12pdf/12-398_1b7d.pdf. Last accessed on 5 June 2022.

[67] Full report can be found at http://www.theinnovationpartnership.org/en/ieg/report/

'increasingly higher walls around knowledge and controlling it tightly'[68] with 'New IP' based on 'sharing and collaboration instead of increased protection'. Gene patents opponents' arguments tend to be in accordance with the Report conclusion. Even as far back as the early 2000, Gert Matthijs and Dicky Halley[69] as well as Luigi Palombi[70] claimed that genes cannot be patented because they are discoveries, not invention. IPWatchdog.com had a paper published in 2013, during the time when the biopatents had the utmost public attention in light of *Myriad*, arguing that granting a monopoly over an isolated gene sequence tends to disincentivise innovators, as it creates an unjustified barrier to entry for any future application involving that sequence.[71] *Throughout the past two decades, the ethics in patenting* human body parts has been rigorously questioned by academia and practitioners alike.[72] However, others argue that human genes are patentable subject matter in all countries in which disputes over *Myriad*'s genes arose[73] and that '[w]ithout the incentive of patents, there would be less investment in research, and scientists might not disclose their new technologies to the public'.[74] Data protection, on the other hand, provides further restriction on dissemination of information since information is comprised of data. Clinical trial

[68] Richard E. Gold, Wendy A. Adams, Louise Bernier, Tania Bubela, Luc Cassivi, David Castle, Ghislaine Cleret de Langavant et al. "Toward a New Era of Intellectual Property: From Confrontation to Negotiation-A Report by the International Expert Group on Biotechnology, Innovation and Intellectual Property." *Pamela Jane, Toward a New Era of Intellectual Property: From Confrontation to Negotiation-A Report by the International Expert Group on Biotechnology, Innovation and Intellectual Property (September 9, 2008)* (2008), p. 7. Available at https://papers.ssrn.com/sol3/papers.cfm?abstract_id=1260099. Last accessed on 2 June 2022.

[69] Gert Matthijs and Dicky Halley. "European-wide opposition against the breast cancer gene patents." *European Journal of Human Genetics* 10, no. 12 (2002): 783-785. Available at http://www.nature.com/ejhg/journal/v10/n12/full/5200924a.html. Last accessed on 4 June 2022.

[70] Luigi Palombi, *The patenting of biological materials in the context of the agreement on trade-related aspects of intellectual property rights*. University of New South Wales, 2004. Available at http://www.austlii.edu.au/au/journals/UNSWLawTD/2004/5.pdf. Last accessed on 5 June 2022.

[71] Lennon J., Brodzik G.J. Myriad: Positive Implications for Genetic Research, but Some Questions Remain Unanswered. Available at http://www.ipwatchdog.com/2013/06/20/myriad-positive-implications-for-genetic-research-but-some-questions-remain-unanswered/id=42020/

[72] Cynthia M Ho, "Splicing morality and patent law: Issues arising from mixing mice and men." *Wash. UJL & Pol'y* 2 (2000): 247. Available at https://lawecommons.luc.edu/cgi/viewcontent.cgi?article=1300&context=facpubs. Last accessed on 2 June 2022. Also see Matthew Rimmer, *Intellectual property and biotechnology: biological inventions*. Edward Elgar Publishing, 2008., also Singh, *supra* note 50 and Nuffield Council on Bioethics. *The ethics of patenting DNA: A discussion paper*. Nuffield Council on Bioethics, 2002, USPTO website, *The Drastic Rise in Patent Litigation* (2000-2015). Available at https://www.uspto.gov/learning-and-resources/ip-policy/economic-research/drastic-rise-patent-litigation-2000-2015

[73] Stephen A. Merrill and Anne-Marie Mazza. "Reaping the benefits of genomic and proteomic research: intellectual property rights, innovation, and public health." (2006). Available at https://www.ncbi.nlm.nih.gov/books/NBK19865/pdf/Bookshelf_NBK19865.pdf. Last accessed on 5 June 2022.

[74] John J. Doll, "The patenting of DNA." *Science* 280, no. 5364 (1998): 689-690.

results are protected by data protection legislation[75] thus further limiting the flow of information which is the major asset for development and market competitiveness.

[75] Regulation (EU) 2016/679 of the European Parliament and of the Council of 27 April 2016 on the protection of natural persons with regard to the processing of personal data and on the free movement of such data, and repealing Directive 95/46/EC (General Data Protection Regulation) (Text with EEA relevance). See also European Patent Forum, *The new EU Regulation on the protection of personal data: what does it mean for patients?* Available at http://www.eu-patient.eu/globalassets/policy/data-protection/data-protection-guide-for-patients-organisations.pdf. Last accessed on 22 Apr. 23.

## 2. PATENTING BRCA AND CRISPR

The mid-twentieth century saw a rise in our understanding of molecular mechanisms of life when James Watson and Francis Crick first discovered the structure and function of DNA.[76] This discovery was followed by a vast increase in biological knowledge, which evolved into a new industry, biotechnology, and caught the eye of the existing pharmaceutical industry. To support development of this emerging technology, the US developed a patent-friendly political environment and encouraged expansion of the scope of patentable subject matter.[77] The Courts followed suit in their consideration that 'ingenuity should receive a liberal encouragement,' referencing Thomas Jefferson's philosophy embodied in the US Constitution.[78] Gene patents sprung up from the political and judicial support received at the time and thrived for decades before being challenged. [79]

Patenting biotechnology was very much encouraged in its early days. A prevalent approach of '[t]he more, the better' boosted the practice of gene patenting[80] and went on until 2010 when the first gene patents were challenged. Gene patents faced real opposition only after thousands of gene patents had already been granted and the technology of isolating and sequencing DNA had become routine. Concerns about the negative impact of gene patents on research and development also increased at this time.[81] Consequently, the political support gene patents had enjoyed started to diminish. This was evident from the measures taken by US Congress to prohibit or narrow down the scope of gene patents.[82] Despite the lack of success of these

[76] James D. Watson and Francis Crick, "Molecular structure of nucleic acids; a structure for deoxyribose nucleic acid." *Nature* 171, no. 4356 (1953): 737-738. Available at https://dosequis.colorado.edu/Courses/MethodsLogic/papers/WatsonCrick1953.pdf. Last accessed on 20 April 2022.
[77] Samantak Ghosh, "Patenting human genes in the United States." In *Research Handbook on Intellectual Property and the Life Sciences*, pp. 41-55. Edward Elgar Publishing, 2017, p. 41.
[78] *Diamond vs Chakrabarty*, 447 U.S. 303, 309 (1980).
[79] Samantak Ghosh, "Prometheus and the Natural Phenomenon Doctrine: Let's Not Lose Sight of the Forest for the Trees." *J. Pat. Off. Soc'y* 94 (2012): 330, p. 342. Available at https://papers.ssrn.com/sol3/papers.cfm?abstract_id=2145063. Last accessed on 20 April 2022.
[80] *Application of Bergy*, 596 F.2d 952, 985 (Fed. Cir. 1979).
[81] Linda J. Demaine and Aaron Xavier Fellmeth. "Reinventing the double helix: A novel and nonobvious reconceptualization of the biotechnology patent." *Stanford Law Review* (2002): 303-462, p. 303; also Michael A. Heller and Rebecca S. Eisenberg. "Can patents deter innovation? The anticommons in biomedical research." *Science* 280, no. 5364 (1998): 698-701, p. 698; Eileen M. Kane, "Splitting the gene: DNA patents and the genetic code." *Tenn. L. Rev.* 71 (2003): 707, p. 718.
[82] H.R. 3967: The Genomic Research and Diagnostic Accessibility Act of 2002, was introduced 'to provide for non-infringing uses of patents on genetic sequence information for purposes of research

congressional efforts, the US Supreme Court eventually adopted decisions which drastically narrowed down the patent scope of composition of matter and methods alike. The relevant cases are discussed further in this Chapter.

This Chapter on BRCA reviews the cases in the US, Australia, and the EU and demonstrates the global importance of patenting biotechnology and the impact it is considered these patents to have on the global society, not only the in low-to-middle income countries but developed countries as well. The Chapter first looks in the US practice, past and present, of patenting genes, it goes on to review aspects taken by the Australian courts in the same regard and finishes with the similar European cases, which unlike the other two jurisdictions, do not address exactly the same issues, but serve to exemplify a global problem with gene patents. The discussion on the CRISPR patent disputes, also found in the US and Europe alike, contributes to the meaning and complexity of the 'inventive step' requirement, which is not as specifically addressed in the BRCA case. The chapter concludes that these cases demonstrate disparity between patent protection and the right to health as a human right, which is more broadly discussed in Chapter 6.

### 2.1. Technology Description

Subject to biotechnology are not genes exclusively, although they get the most attention when patents are concerned. Molecular biology distinguishes vast spectrum of nucleotide-based molecules, generally referred to as genetic material. The different treatment of gene patents received by the courts stems from the differences in the molecules subject to patent protection. Though the genes themselves enjoy the widest popularity, a wide range of nucleotide-based molecules are subject to research and patenting practices. To better understand the differences between these molecules, this part provides some explanation of their structure and functionality.

As a hereditary material, DNA (desoxyribonucleic acid) is comprised of four building blocks, called nucleotides, which are made up of bases: adenine (A), thymine (T),

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and genetic diagnostic testing.' Available at https://www.congress.gov/bill/107th-congress/house-bill/3967/text?r=77&s=1. Last accessed on 31 March 2022; H.R. 977: the Genomic Research and Accessibility Act, introduced by Congressman Xavier Bacerra on 9 Feb 2007, would have prohibited the patenting of human genetic material. Available at https://www.congress.gov/bill/110th-congress/house-bill/977/text?r=42&s=1. Last accessed on 31 Mar. 22.

guanine (G) and cytosine (C).[83] They are the code in which DNA information is stored and are bound together by covalent bonds to form polymer (polynucleotide) DNA.[84] Compact structures called chromosomes[85] are formed of proteins wrapped around the DNA. In each chromosome, two strands of DNA polymers form a spiral in a helical manner[86] by pairing of nucleotides from one strand to their complementary nucleotides of the other strand.[87] A sequence of these nucleotides is called a gene and the synthesis of proteins is directed by such sequences.[88] Protein synthesis takes place when DNA sequences replicate into a polymeric molecule called RNA (ribonucleic acid), preceded by unwinding of the DNA strands, and DNA bases pair bind with complementary RNA bases.[89] After the replication of DNA into RNA, a molecule called messenger RNA (mRNA) is formed when some parts (introns) are cut off from the RNA molecule and the other parts (exons) are combined together.[90] The process is known as splicing. Thus created mRNA then directs the synthesis of proteins.[91] The building blocks of proteins are called amino acids, which are produced by translation of the nucleotide sequences into amino acid sequences.[92]

When the ribonucleic sequences from the mRNA are, in turn, copied into DNA sequences, the resulting nucleotide sequences produce complementary DNA or cDNA.

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[83] 'What is DNA?' MedilinePlus. Available at https://medlineplus.gov/genetics/understanding/basics/dna/#:~:text=DNA%2C%20or%20deoxyribonucleic%20acid%2C%20is,body%20has%20the%20same%20DNA. Last accessed on 31 March 2022.
[84] *Ibid*
[85] 'What is a Chromosome?' MedilinePlus .Available at https://medlineplus.gov/genetics/understanding/basics/chromosome/#:~:text=In%20the%20nucleus%20of%20each,histones%20that%20support%20its%20structure. Last accessed on 31 March 2022.
[86] *Ibid*
[87] *Ibid*
[88] 'A Brief Guide to Genomics' National Human Genome Res. Inst. Available at https://www.genome.gov/about-genomics/fact-sheets/A-Brief-Guide-to-Genomics. Last accessed on 31 March 2022.
[89] 'How do genes direct the production of proteins?' MedilinePlus. Available at https://medlineplus.gov/genetics/understanding/howgeneswork/makingprotein/#:~:text=Most%20genes%20contain%20the%20information,tightly%20controlled%20within%20each%20cell. Last accessed on 31 March 2022.
[90] 'Splicing' National Cancer Institute. Available at https://www.cancer.gov/publications/dictionaries/genetics-dictionary/def/splicing. Last accessed on 31 March 2022.
[91] *Ibid*
[92] Suzanne Cla and William Brown. "Translation: DNA to mRNA to." *Nature Education* (2008). Available at https://www.nature.com/scitable/topicpage/translation-dna-to-mrna-to-protein-393/. Last accessed on 31 March 2022.

cDNA differs from genomic DNA in that it does not contain introns, which are removed during the process of forming the mRNA.[93]

Primers are short nucleotide sequences complementary to a targeted nucleotide sequence whose replication is initiated by the primers when they bind to it.[94] An amplification process called polymerase chain reaction (PCR) can be used to multiply these targeted nucleotide sequences or target polynucleotide sequences can be identified by synthetically generated primers.[95]

Probes, like primers, are short nucleotide sequences which are synthetically generated to 'probe' a target nucleotide sequence to hybridise only DNA sequences with corresponding probes and help in the identification of natural DNA sequences.[96]

All these comprise the genetical material which is subject to patenting since it demands a lot of research needed to identify mutations in the genetic sequences which, in turn, result in diseases like cancer. The need for therapeutic solutions for these disease drives such research and consequently the pursuit of patents.

### 2.2. Patentability and Exclusions under US Law: Natural Phenomena, Products of Nature, Isolated and Purified

The history of patent protection in the US begins with its Constitution. Intellectual property protection in the US is a constitutional right governed by Article 1, section 8 of the US Constitution. The importance of patent protection was recognized by the framers of the U.S. Constitution when they gave Congress the power '[t]o promote the Progress of Science and useful Arts, by securing for limited Times to Authors and Inventors the exclusive Right to their respective Writings and Discoveries.'[97] Accordingly, 'any new and useful process, machine, manufacture, or composition of

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[93] 'cDNA Production' Davidson.edu. Available at https://bio.davidson.edu/genomics/method/cDNAproduction.html. Last accessed on 31 March 2022.
[94] 'Primer' *Nature*. Available at https://www.nature.com/scitable/definition/primer-305/. Last accessed on 31 March 2022.
[95] *Ibid*
[96] 'DNA Probes' *Nature*. Available at https://www.nature.com/subjects/dna-probes. Last accessed on 31 March 2022.
[97] Michele Wales and Eddie Cartier, "The Impact of Myriad on the Future Development and Commercialization of DNA-Based Therapies and Diagnostics." *Cold Spring Harbor Perspectives in Medicine* 5, no. 12 (2015): a020925. Available at https://perspectivesinmedicine.cshlp.org/content/5/12/a020925. Last accessed on 11 May 2023.

matter, or any new and useful improvement' was defined as patentable subject matter under 35 U.S.C. §101.[98] This provision has been constant since the 1793 Patent Act, save the replacement of the archaic term 'art' with its modern equivalent, 'process.'[99]

The United States is a leader in biotechnology due to its strong patent protection, among all else. However, similar to the European patent protection legislation, patentable subject matter is a subject to certain exclusions from patentability, though they are not *per se* provided for by law but derive from judicial interpretation, thus, making them a matter of doctrine, rather than law. Likewise, judicial interpretations of statutory provision providing for patentability requirements shed light as to why abstract ideas,[100] laws of nature,[101] and products of nature are declared unpatentable exclusions from otherwise patentable subject matter.[102] Exceptions to exclusions of patentability are a further similarity of the systems, however, despite the significant exception to the natural product exclusion developed by the judiciary, that is, the patent eligibility of composition of matter of a natural product, isolated and purified from nature, this exception has been eliminated by the U.S. Patent and Trademark Office ('USPTO') *vis-a-vie* the *Association for Molecular Pathology v. Myriad Genetics*[103] (hereinafter *Myriad*) decision.[104] On the other hand, patenting the use of a given natural product,[105] patenting of new material produced using the insight gained from that natural product,[106] or the patenting of a method of production of that material[107] is not precluded by the prohibition of patenting natural products. The debate on whether the

[98] 35 U.S.C. § 102 (July 19, 1952).
[99] Patent Act of 1793, 1 Stat. 318-23. The 1793 Act replaced the first U.S. Patent Act of 1790, which allowed patents for "any art, manufacture, engine, machine or device." Patent Act of 1790, 1 Stat. 109-12. "Process" entered the statute in 1952. *See* Act of July 19, 1952, ch. 950, Pub. L. No. 82-593, 66 Stat. 792, § 101. (66 Stat. 792 - An Act to revise and codify the laws relating to patents and the Patent Office, and to enact into law title Sb of the United States Code entitled "Patents")
[100] *Alice Corp. Pty. Ltd. vs CLS Bank Int'l,* 134 S. Ct. 2354 (2014).
[101] See, e.g., *Mackay Radio & Tel. Co. vs Radio Corp. of Am.,* 306 U.S. 86, 94 (1939).
[102] See, e.g., *Diamond vs Diehr,* 450 U.S. 175, 186 (1981). Also, *Bilski vs Kappos*, 130 S. Ct. 3218, 3225 (2010) (citing *Diamond vs Chakrabarty*, 447 U.S. 303, 309 (1980)).
[103] *Association for Molecular Pathology vs Myriad Genetics, Inc.,* 133 S. Ct. 2107, 2119 (2013).
[104] Memorandum to the Patent Examining Corps from Andrew H. Hirshfeld, Deputy Commissioner for Patent Examination Policy, to Patent Examining Corps (Mar. 4, 2014), Available at https://perma.cc/3HLZ-5X84. Last accessed on 4 June 2022.
[105] *See, e.g., Amgen Inc. vs Hoechst Marion Roussel, Inc.,* 314 F.3d 1313 (Fed. Cir. 2003).
[106] *Mackay Radio & Tel. Co. vs Radio Corp. of Am.,* 306 U.S. 86, 94 (1939) ("While a scientific truth, or the mathematical expression of it, is not patentable invention, a novel and useful structure created with the aid of knowledge of scientific truth may be.").
[107] *Cf. Association for Molecular Pathology vs Myriad Genetics, Inc.,* 133 S. Ct. 2107, 2119 (2013).

*Myriad* decision should be interpreted in such a manner is significant and ongoing in legal literature[108] and among practitioners.[109]

Current statutory requirements of patentability are clearly divided into separate conditions: patent-eligible subject matter (found in 35 U.S.C. §101), utility (§101), novelty (§102); nonobviousness (§103), and sufficiency of disclosure (§112). It may be that question of patentable subject matter is the area of the law most shaped by non-statutory common-law edicts.[110] The scope of §101 exclusions is determined by the reasoning of older cases and must be accepted by both patentees and lower courts. One strand of patent law, long curated by the late Judge Giles Rich (one of the drafters of the 1952 Act), insisted on a strict separation between the functions and content of novelty, non-obviousness, utility, and patent-eligible subject matter.[111] The district

[108] *See, e.g.*, David Knapp, "The Fate of Small-Molecule Natural Products After Myriad Genetics." *AIPLA QJ* 43 (2015): 595, in Evan H. Tallmadge, "Patenting natural products after myriad." *Harv. JL & Tech.* 30 (2016): 569. Available at https://jolt.law.harvard.edu/assets/articlePDFs/v30/30HarvJLTech569.pdf. Last accessed on 2 June 2022. Sean Brennen, *After Myriad: A Herd of Elephants in the Room*, PATENT DOCS (July 3, 2013), Available at http://www.patentdocs.org/2013/07/after-myriad-a-herd-of-elephants-in-the-room.html. Last accessed on 5 June 2022; Dennis Crouch, *Twenty Thoughts on the Importance of Myriad*, PATENTLY-O (June 14, 2013), http://patentlyo.com/patent/2013/06/myriad.html [https://perma.cc/RXY9-JANW].

[109] See, e.g., Stephen H. Schilling and W. Murray Spruill. "PTO Subject Matter Eligibility Guidance: An Ill-Advised Overextension of Myriad." *Biotechnology Law Report* 33, no. 3 (2014): 120-132..; also, Chenghua Luo and Jorge Goldstein, Patenting Purified Natural Products by Specific Activity: Eligibility and Enablement, BLOOMBERG BNA LIFE SCI. LAW & INDUS. REP. (May 29, 2015). Available at https://static1.squarespace.com/static/5c899ec09b7d151febd5660e/t/5d1bc87a84af9d000170e76c/1562101883315/romance.pdf. Last accessed on 27 May 2022; Warren D. Woessner, "Isolated" Natural Products Still in Purgatory Post-PTO Guidance?, PATENTS4LIFE (Apr. 28, 2015). Available at http://www.patents4life.com/2015/04/isolated-natural-products-still-in-purgatory-post-pto-guidance/. Last accessed on 6 June 2022.

[110] For example, the definition of patentable subject matter in § 101 of the Patent Act says nothing about the "well established" exceptions for "laws of nature, physical phenomena, and abstract ideas." *Bilski*, 130 S. Ct. at 3226; 35 U.S.C. § 101 (2012). See also John F. Duffy, "Rules and Standards on the Forefront of Patentability." *Wm. & Mary L. Rev.* 51 (2009): 609. Available at https://scholarship.law.wm.edu/cgi/viewcontent.cgi?article=1015&context=wmlr. Last accessed on 3 June 3, 2022. On patent law as a "hybrid" field combining statutory and common-law requirements, with the Patent Act as a "common law enabling statute," see, e.g.: Craig Allen Nard, "Legal forms and the common law of patents." *BUL Rev.* 90 (2010): 51. Available at https://scholarlycommons.law.case.edu/cgi/viewcontent.cgi?article=1569&context=faculty_publications. Last accessed on 2 June 2022; Rochelle Cooper Dreyfuss, "In Search of Institutional Identity: The Federal Circuit Comes of Age." *Berkeley Tech. LJ* 23 (2008): 787:803. Available at https://btlj.org/data/articles2015/vol23/23_2/23-berkeley-tech-l-j-0787-0828.pdf. Last accessed on 5 June 2022.

[111] *See, e.g.*, *In re* Bergy, 596 F.2d 952, 960-64 (C.C.P.A. 1979) ('Achieving the ultimate goal of a patent under those statutory provisions involves, to use an analogy, having the separate keys to open in succession the three doors of sections 101, 102, and 103'); see also *Diamond vs Diehr*, 450 U.S. 175, 189-90 (1981) (citation omitted) (noting that while it had been argued that 'novelty is an appropriate consideration under § 101,' '[t]he question . . . of whether a particular invention is novel is

court in *Myriad* noted Judge Rich's caution that 'statements in the older cases must be handled with care lest the terms used in their reasoning clash with the reformed terminology of the present statute.'[112] Even so, nobody involved has shown an inclination to limit the terms of argument to post-1952 concepts.[113]

The exclusion of products of nature from the broad protection provided by §101 relies on the finding that natural products do not constitute a new machine, manufacture, or composition of matter, or any new and useful improvement thereof.[114] Judicial justification rests on the premise that phenomena of nature, and thus natural products, are not novel, as they have always been a part, albeit undiscovered, of the storehouse of knowledge, and only new applications of them are patentable. The Court has thus held that:

> [P]atents cannot issue for the discovery of the phenomena of nature. The qualities of these bacteria, like the heat of the sun, electricity, or the qualities of metals, are part of the storehouse of knowledge of all men. They are manifestations of laws of nature, free to all men and reserved exclusively to none. He who discovers a hitherto unknown phenomenon of nature has no claim to a monopoly of it which the law recognizes. If there is to be invention from such a discovery, it must come from the application of the law of nature to a new and useful end.[115]

The Supreme Court, though, has stated that subject matter eligibility is to be determined strictly pursuant to §101 and not by more rigid application of §102, §103, or §112.[116]

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'wholly apart from whether the invention falls into a category of statutory subject matter') cited in Christopher Beauchamp, "Patenting nature: a problem of history." *Stan. Tech. L. Rev.* 16 (2012): 257, p.263. Available at https://brooklynworks.brooklaw.edu/cgi/viewcontent.cgi?referer=www.google.com/&httpsredir=1&article=1460&context=faculty. Last accessed on 18 April 2022.

[112] *Association for Molecular Pathology*, 702 F. Supp. 2d at 220 (quoting *In re* Bergy, 596 F.2d 952, 959 (C.C.P.A. 1979)).

[113] Beauchamp, *supra* note 111 p. 266

[114] *Diamond vs Chakrabarty*, 447 U.S. 303, 309 (1979) ('The laws of nature, physical phenomena, and abstract ideas have been held not patentable.'). See also U.S. PATENT & TRADEMARK OFFICE, MANUAL OF PATENT EXAMINING PROCEDURE § 706.03(a) (8th ed. July 2010) ('[A] thing occurring in nature, which is substantially unaltered, is not a "manufacture." A shrimp with the head and digestive tract removed is an example.') (citing *Ex parte Grayson*, 51 U.S.P.Q. (BNA) 413 (Bd. App. 1941)).

[115] *Funk Bros. Seed Co. vs Kalo Inoculant Co.*, 333 U.S. 127, 130 (1947) (internal cita-tions omitted).

[116] *Mayo Collaborative Servs. vs Prometheus Labs., Inc.*, 132 S. Ct. 1289, 1303 (2012) ("The relevant cases rest their holdings upon [S]ection 101, not later sections").

A line of cases have contributed to the shaping of the 'product of nature' exclusion denying patent protection to naturally occurring metals,[117] new combinations of existing bacteria,[118] and plant extracts.[119] A significant exception to this doctrine was made by courts allowing for patent protection of natural products which have been isolated and purified.[120] The isolated and purified exception originates from *Parke-Davis & Co. v. H.K. Mulford Co.*[121] in which Judge Learned Hand held that adrenaline, isolated and purified from animal glands, was eligible for a patent despite it being a natural product.[122] In his own words:

> E]ven if it were merely an extracted product without change, there is no rule that such products are not patentable. Takamine [the inventor] was the first to make it available for any use by removing it from the other gland-tissue in which it was found, and, while it is of course possible logically to call this a purification of the principle, it became for every practical purpose a new thing commercially and therapeutically. That was a good ground for a patent.[123]

In light of this judgment, the rate of patenting of isolated and purified natural products drastically increased after 1911.[124]

The classical patent transaction rests on the premise that '[p]atent protection strikes a delicate balance between creating "incentives that lead to creation, invention, and discovery" and "imped[ing] the flow of information that might permit, indeed spur, invention."'[125] The public benefit is larger if a monopoly is narrower as it is less harmful.[126] This is true if the incentive to innovate is completely ignored as a basis for patent grant.[127] Thus, there seem to be two concerns due to which judges are prone to

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[117] *Gen. Elec. Co. vs De Forest Radio Co.,* 28 F.2d 641, 642 (3d Cir. 1928).
[118] *Funk Bros. Seed Co. vs Kalo Inoculant Co.,* 333 U.S. 127 (1948).
[119] *Ex parte* Latimer, 1889 Dec. Comm'r Pat. 123.
[120] *See* Utility Examination Guidelines, 66 Fed. Reg. 1092, 1093 (Jan. 5, 2001) ("Thus, an inventor's discovery of a gene can be the basis for a patent on the genetic composition isolated from its natural state and processed through purifying steps that separate the gene from other molecules naturally associated with it.").
[121] *Parke-Davis & Co. vs H.K. Mulford Co.*, 189 F. 95 (C.C.S.D.N.Y. 1911).
[122] *Ibid*
[123] *Ibid*
[124] Beauchamp, *supra* note 111, p.262.
[125] *Myriad,* 133 S. Ct. at 2109 (alteration in original) (quoting *Mayo Collaborative Servs. vs Prometheus Labs., Inc.,* 132 S. Ct. 1289, 1305 (2012)).
[126] Oskar Liivak, "Maintaining Competition in Copying Narrowing the Scope of Gene Patents." *UC Davis L. Rev.* 41 (2007): 177:183. Available at https://scholarship.law.cornell.edu/cgi/viewcontent.cgi?article=1125&context=lsrp_papers. Last accessed on 5 June 2022. See also Janet Freilich, "The Uniformed Topograhy of Patent Scope." *Stan. Tech. L. Rev.* 19 (2015): 150 in Tallmadge, *supra* note 108
[127] *Ibid*, Tallmadge

prohibit patenting of natural product: grant of monopolies constraining further scientific inquiry into broad swaths of the natural world[128] and whether an invention meets the novelty criterion if it was first created by nature instead of the claimant.[129] However, unlike the European legislator[130] explicitly excluding discoveries from patentability, 35 U.S.C. §101, indeed, provides for patent protection of such subject matter. On the other hand, the question of novelty governed by 35 U.S.C. §102 brings discoveries into question since anything already in existence does not meet the novelty criterion. Available case law, however, departs from this reasoning in argument that as long as the claimant is first to make the discovery, and not merely the use of it, then such discovery could still be subject to a patent grant.[131]

Looking into the 'isolated and purified' exclusion introduced with the *Myriad* decision, a consideration should be given to the fact that DNA is carrying information while molecules subject to the past isolated and purified exception do not. Thousands of gene patents have been issued under the isolated-and-purified rubric in the past twenty years.[132] However, there is a strong conviction among the broad patent protection advocates that the practice of patenting genetic materials is under attack.

Christopher Beauchamp finds that the canon of precedent utilised against patentability of isolated and purified subject matter is as follows: two Supreme Court cases from the late nineteenth century dealing with purification of natural materials; a decision by the Commissioner of Patents in 1889, *Ex parte* Latimer, rejecting a patent for extracted plant fibre; a group of similar cases from the 1920s and 1930s rejecting patents for

[128] *Mayo*, 132 S. Ct. at 1293 ("[M]onopolization of those tools through the grant of a patent might tend to impede innovation more than it would tend to promote it.").
[129] *Pennock vs Dialogue*, 27 U.S. (2 Pet.) 1, 23 (1829)
[130] See *infra* BIOTECH PATENTS IN EUROPE.
[131] See, e.g., *Kuehmsted vs Farbenfabriken of Elberfeld Co.*, 179 F. 701 (7th Cir. 1910).
[132] See, e.g., *Association for Molecular Pathology vs U.S. Patent & Trademark Office*, 653 F.3d 1329 (Fed. Cir. 2011) [hereinafter *Association for Molecular Pathology I*] (citations omitted) ("It is estimated that the PTO has issued 2,645 patents claiming 'isolated DNA' over the past twenty-nine years, and that by 2005, had granted 40,000 DNA-related patents covering, in non-native form, twenty percent of the genes in the human genome"). The source for most such estimates is a now-dated quantitative study of gene patents. See Kyle Jensen and Fiona Murray. "Intellectual property landscape of the human genome." *Science* 310, no. 5746 (2005): 239-240.. The notion that patents "cover" twenty percent of the human genome is disputed in also Christopher M. Holman, "Will Gene Patents Impede While Genome Sequencing: Deconstructing the Myth that 20 of the Human Genome is Patented." *IP Theory* 2 (2011): 1. Available at https://www.repository.law.indiana.edu/cgi/viewcontent.cgi?article=1009&context=ipt. Last accessed on 2 June 2022.

pure metals; and three further Supreme Court decisions: *American Fruit Growers v. Brogdex* (1931), rejecting a patent for fruit treated with mold-resistant coating, *Funk Brothers v. Kalo Inoculant Co.* (1948), invalidating a patent for a combination of natural bacteria, and *Diamond v. Chakrabarty* (1980), approving a patent for a man-made bacterium.[133]

A major case on which the *Myriad* decision relied on was *Mayo vs Prometheus* (hereinafter *Mayo*).[134] The Supreme Court decision in *Mayo* (2012) was reached shortly before the *Myriad* decision in 2013. The patent in *Mayo* claimed a method of medical treatment, which simply consisted of certain observed natural correlations in patients' metabolite levels after a drug had been injected. Namely, certain concentrations of thiopurine drugs were effective when certain concentrations of the drug metabolites formed within the body. The method claims involved administration of the thiopurine drug, measuring the blood concentration levels of thiopurine based on which the doctor could determine the drug dosage.[135] The Court's unanimous decision was that patents effectively claimed a law of nature and as such were invalid. Even though case law mainly prohibits patenting of law of nature, with a few decisions also finding product of nature patent ineligible, the Court's reasoning was heavily grounded in *stare decisis*,[136] so as to avoid 'monopolization' of 'basic tools of scientific and technological work'.[137]

[133] Beauchamp, *supra* note 111, p. 266
[134] *Mayo Collaborative Services vs Prometheus Laboratories, Inc.*, 566 U.S. 132 S. CT. 1289 (2012).
[135] 'The patent claims here set forth processes embodying researchers' findings that identify correlations between metabolite levels and likely harm or ineffectiveness with precision. Each claim recites (1) an "administering" step—instructing a doctor to administer the drug to his patient—(2) a "determining" step—telling the doctor to measure the resulting metabolite levels in the patient's blood—and (3) a "wherein" step—describing the metabolite concentrations above which there is a likelihood of harmful side-effects and below which it is likely that the drug dosage is ineffective, and informing the doctor that metabolite concentrations above or below these thresholds "indicate a need" to decrease or increase (respectively) the drug dosage.'
[136] *Mayo*, 132 S. Ct. at 1302 (stating that "[t]he presence here of the basic underlying concern that these patents tie up too much future use of laws of nature simply *reinforces* our conclusion that the processes described in the patents are not patent eligible, while eliminating any temptation to depart from case law precedent" (emphasis added)).
[137] *Mayo*, 132 S. Ct. at 1293.

## 2.3. The *Myriad* Saga

In 1990, Mary-Claire King discovered that a single gene located on Chromosome 17q21, now known as BRCA1, was responsible for a large number of early-onset breast cancers.[138] In 1994, a research team at the University of Utah was the first to clone and sequence BRCA1 successfully.[139] Over a year later, Michael Stratton at the Institute of Cancer Research in the United Kingdom identified another gene linked to early-onset breast and ovarian cancer, which he named BRCA2.[140] Mark Skolnick's team from the University of Utah published a complete sequence of BRCA2 only months after Stratton published a truncated BRCA2 sequence.[141]

At the same time when their papers on BRCA1 and BRCA2[142] were published, the Utah researchers applied for seven patents to protect their work in a variety of forms. These patents covered three groups of technologies related to BRCA1 and BRCA2:

[138] Jeff M. Hall, Ming K. Lee, Beth Newman, Jan E. Morrow, Lee A. Anderson, Bing Huey, and Mary-Claire King. "Linkage of early-onset familial breast cancer to chromosome 17q21." *Science* 250, no. 4988 (1990): 1684-1689. Available at https://njc.rockefeller.edu/pdf4/Class8-King1990.pdf. Last accessed on 9 March 2022.

[139] Yoshio Miki, Jeff Swensen, Donna Shattuck-Eidens, P. Andrew Futreal, Keith Harshman, Sean Tavtigian, Qingyun Liu et al. "A strong candidate for the breast and ovarian cancer susceptibility gene BRCA1." *Science* 266, no. 5182 (1994): 66-71. Available at https://www.researchgate.net/profile/Jeffrey-Swensen/publication/15653070_A_Strong_Candidate_for_the_Breast_and_Ovarian_Cancer_Susceptibility_Gene_BRCA1/links/568f4eb608aead3f42f088dc/A-Strong-Candidate-for-the-Breast-and-Ovarian-Cancer-Susceptibility-Gene-BRCA1.pdf. Last accessed on 5 June 2022.

[140] Richard Wooster, Graham Bignell, Jonathan Lancaster, Sally Swift, Sheila Seal, Jonathan Mangion, Nadine Collins et al. "Identification of the breast cancer susceptibility gene BRCA2." *Nature* 378, no. 6559 (1995): 789-792. Also, Richard Wooster, Susan L. Neuhausen, Jonathan Mangion, Yvette Quirk, Deborah Ford, Nadine Collins, Kim Nguyen et al. "Localization of a breast cancer susceptibility gene, BRCA2, to chromosome 13q12-13." *Science* 265, no. 5181 (1994): 2088-2090.

[141] Tavtigian, S. V., J. Simard, J. Rommens, F. Couch, D. Shattuck-Eidens, S. Neuhausen, S. Merajver et al. "The complete BRCA2 gene and mutations in chromosome 13q-linked kindreds." *Nature genetics* 12, no. 3 (1996): 333-337.

[142] National Cancer Institute. *BRCA1 and BRCA2: Cancer Risk and Genetic Testing*, (reviewed November 2020), available at https://www.cancer.gov/about-cancer/causes-prevention/genetics/brca-fact-sheet. Last accessed on 9 March 2022.

the isolated forms of BRCA1 and BRCA2;[143] the related cDNAs,[144] primers, and probes useful in sequencing the two genes; and methods of using BRCA1 and BRCA2 sequencing to predict early-onset breast and ovarian cancer risk.[145] The patents were granted to the University of Utah, which later licenced the patents to Myriad Genetics Inc.,[146] a Utah-based diagnostics company that Skolnick and Peter Meldrum had founded in 1991. In 1998, Myriad began to enforce its intellectual property against several high-profile clinicians performing BRCA1- and BRCA2-based cancer risk assessments.[147] The licences Myriad offered were expensive and their enforcement aggressive. While numerous other gene patents were issued at the same time, the licences offered for these gene patents were reasonable and rarely actively enforced.[148] On 12 May 2009, the Association for Molecular Pathology ('AMP')[149] together with several hospitals, doctors, and patients brought suit against Myriad, challenging the validity of their patents under § 101 before the United States District Court for the Southern District of New York.[150]

#### 2.3.1. *Myriad* Litigations in the US

In a 152-page opinion, Judge Robert W. Sweet of the United States District Court for the Southern District of New York declared all of Myriad's patent claims invalid for lacking patentable subject matter. By rejected the notion that *Parke-Davis* concerned itself with patentable subject matter, he potentially casted doubt on the classical reading of *Parke-Davis*, and tied the decision to patent law's novelty standards,

[143] U.S. Patent No. 5,747,282 claim 1 is representative of both the DNA and cDNA composition of matter claims across *Myriad*'s patent portfolio. Ass'n for Molecular Pathol-ogy vs U.S. Patent & Trademark Office, 702 F. Supp. 2d 181, 212 (S.D.N.Y. 2010), as amended (Apr. 5, 2010), *aff'd in part, rev'd in part*, 653 F.3d 1329 (Fed. Cir. 2011), *cert. granted, judgment vacated sub nom*. Ass'n for Molecular Pathology vs *Myriad* Genetics, Inc., 566 U.S. 902, 132 S. Ct. 1794 (2012), *opinion vacated, appeal reinstated*, 467 F. App'x 890 (Fed. Cir. 2012), *aff'd in part, rev'd in part*, 689 F.3d 1303 (Fed. Cir. 2012).

[144] cDNA is produced by transcribing RNA produced in the cell (which would normally be translated into the coded protein) back into DNA. This results in a DNA strand without any of the non-coding regions found in the chromosomal DNA. *Id.* at 198–99.

[145] *Association for Molecular Pathology vs Myriad Genetics.* 2011. 653 F.3d 1329 (Fed. Cir.) in Jacob S. Sherkow, and Henry T. Greely. "The history of patenting genetic material." *Annual Review of Genetics* 49 (2015): 161-182. Available at https://papers.ssrn.com/sol3/papers.cfm?abstract_id=2713761. Last accessed on 9 March 2022.

[146] *Hereditary Breast Cancer*, MYRIAD, available at https://myriad.com/patients-families/disease-info/breast-cancer. Last accessed on 9 March 2022.

[147] Sherkow, J. S. (2015) p. 172

[148] *Ibid*.

[149] *About AMP*, ASS'N FOR MOLECULAR PATHOLOGY, https://www.amp.org/about/in-dex.cfm

[150] *Ass'n for Molecular Pathology*, 702 F. Supp. 2d at 227–28.

currently subject to §102. Judge Sweet found that 'DNA represents the physical embodiment of biological information, distinct in its essential characteristics from any other chemical found in nature' thus concluding that DNA's existence in an 'isolated' form alters neither this fundamental quality of DNA as it exists in the body nor the information it encodes.' Accordingly, Judge Sweet ruled that the patents at issue directed to 'isolated DNA' containing sequences found in nature are unsustainable as a matter of law and are deemed unpatentable subject matter under 35 U.S.C. §101.[151] Furthermore, with respect to *Myriad*'s 'composition of matter' claims covering the sequence of the isolated BRCA genes and their known cancer-associated variants, he held that '[i]n light of DNA's unique qualities as a physical embodiment of information, none of the structural and functional differences cited by Myriad . . . render the claimed DNA "markedly different"' than naturally-occurring DNA.[152] In response to Myriad's claims covering methods 'for diagnosing a predisposition for breast cancer in a human subject'[153] by comparing a patient's BRCA gene to the sequence of known BRCA mutations, Judge Sweet held that such comparisons were 'mental processes and abstract intellectual concepts'[154] that were also ineligible for patent protection under the Supreme Court's recent decision in *Bilski v. Kappos*.[155] Finally, regarding one claim covering '[a] method for identifying potential cancer therapeutics' by observing the effect of a drug candidate on cancer cells containing mutated BRCA genes, Judge Sweet held that the claimed process was nothing more than 'the scientific method itself' and thus ineligible subject matter for patent protection.[156]

Myriad appealed to the Court of Appeals for the Federal Circuit, where the case was heard by a three-judge panel and on 29 July 2011, the Federal Circuit issued an opinion authored by Judge Lourie.[157] In addressing the substantive evaluation of Myriad's claims, the Federal Circuit panel unanimously affirmed the District Court's rejection of *Myriad*'s diagnostic method claims, finding them to be directed to 'abstract mental

[151] *Ass'n for Molecular Pathology vs USPTO*, 702 F. Supp. 2d 181, 185 (S.D.N.Y. 2010)
[152] *Id*. at 229.
[153] *Id*. at 236 (citation omitted).
[154] *Id*. at 232 (quoting Gottschalk vs Benson, 409 U.S. 63, 67 (1972))
[155] See *id*. at 236–37 (citing *In re Bilski*, 545 F.3d 943, 952 (Fed. Cir. 2008)).
[156] See *id*. at 237
[157] *Ass'n for Molecular Pathology vs U.S. Patent and Trademark Office*, 653 F.3d 1329, 1344–48 (Fed. Cir. 2011).

processes' and thereby ineligible for patent protection under the Supreme Court's precedent in *Bilski*.[158] However, with respect to Myriad's therapeutic screening claim, the District Court decision was reversed upholding the claim since it included sufficiently 'transformative steps,' thus being patent-eligible under *Bilski*.[159] Coming to the composition of matter claims, the judges did not all agree to the rejection of the District court. In an explanation by Judge Lourie in the name of the majority, he stated that the BRCA genes were chemically and structurally different from any DNA found in the human body when they are isolated and extracted from the cellular nucleus and as such constitute a man-made product of 'human ingenuity', thus patent protection eligible under the Supreme Court's precedent in *Chakrabarty*.[160] Judge Bryson, however, dissented from this court's opinion reasoning that Myriad was merely one of many researcher groups working to identify the BRCA sequence , that Myriad did not make the most significant breakthrough, and that it used known techniques to sequence the BRCA genes. Judge Bryson concluded that Myriad's discovery of the sequence for the BRCA genes was not an 'invention' that was eligible for patent protection.[161] As a result of this, the plaintiffs filed a petition for *certiorari* to the Supreme Court.[162]

In the meantime, the Supreme Court had decided *Mayo Collaborative Services vs Prometheus Laboratories, Inc.*,[163] and in light of its decision limiting the patentability of diagnostic methods under Section §101, it granted *certiorari* in *Myriad* and remanded the case to the Federal Circuit.[164] Upon rehearing the arguments in *Myriad*, the Federal Circuit's opinion largely echoed its 2011 decision.

Following the second petition for *certiorari* with the Supreme Court on 25 September 2012, with a unanimous decision, the Supreme Court reversed the Federal Court decision on 13 June 2013. By prefacing its decision in *Mayo*, the Court reaffirmed that courts have 'long held that [35 U.S.C. §101] contains an important implicit exception:

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[158] See *id*. at 1355
[159] See *id*. at 1357 (quoting *Research Corp. Techs., Inc. vs Microsoft Corp*., 627 F.3d 859, 868–69 (Fed. Cir. 2010)).
[160] See *id*. at 1351–52 (quoting *Diamond vs Chakrabarty*, 447 U.S. 303 (1980). The question before the Court in Chakrabarty was whether living organisms fell into the group of patent-ineligible subject matter: laws of nature, physical phenomena or abstract ideas.)
[161] See *id*. at 1373 (Bryson, J., dissenting).
[162] Petition for Writ of Certiorari at 25, 31, *Ass'n for Molecular Pathology vs Myriad Genetics, Inc.*, 566 U.S. 902 (2012) (No. 11-725).
[163] *Mayo Collaborative Servs. vs Prometheus Labs., Inc*., 566 U.S. 66 (2012).
[164] *Ass'n for Molecular Pathology vs Myriad Genetics, Inc*., 556 U.S. 902 (2012)

Laws of nature, natural phenomena, and abstract ideas are not patentable.'[165] However, it also stated that 'rule against patents on naturally occurring things is not without limits, however, for 'all inventions at some level embody, use, reflect, rest upon, or apply laws of nature, natural phenomena, or abstract ideas,' and 'too broad an interpretation of this exclusionary principle could eviscerate patent law.'[166] The Court's analysis began by stating that Myriad did not create or modify any of the information encoded in the genes and that the nucleotides existed in nature before Myriad discovered them,[167] thus Myriad's discovery of the BRCA genes — even if it involved substantial time, expense, and skill — was not 'an act of invention.'[168] Similar to Judge Sweet, the court minimised Myriad's technical contribution stating that 'before Myriad's discovery of the BRCA1 and BRCA2 genes, scientists knew that heredity played a role in establishing a woman's risk of developing breast and ovarian cancer' and that 'Myriad's principal contribution was uncovering the precise location and genetic sequence of the BRCA1 and BRCA2 genes within chromosomes 17 and 13.'[169] Addressing the main question, 'are the isolated segments of DNA patent-eligible,'[170] the Court held that despite the breaking of the chemical bonds to isolate the genes, thus theoretically creating a new molecule, the claims were 'simply not expressed in terms of chemical composition, nor do they rely in any way on the chemical changes that result from the isolation of a particular section of DNA.'[171] Consequently, the patenting of isolated genes in the US was cut short and this resulted in changes in the USPTO patenting guidelines on patentable subject matter.[172] On the other hand, the Court ruled cDNA to be patent-eligible subject matter finding it to be exclusively man-made and not naturally occurring as its counterpart gDNA since '[i]ts creation results in an exons-only molecule, which is not naturally occurring.'[173] Even though the order of the exons is dictated by nature, the Court found that the removal

[165] *Ass'n for Molecular Pathology vs Myriad Genetics, Inc*., 133 S. Ct. 2107, 2116 (2013) (quoting *Mayo Collaborative Servs. vs Prometheus Labs., Inc.*, 132 S. Ct. 1289, 1293 (2012)).
[166] *Id*. (quoting *Mayo*, 132 S. Ct. at 1293).
[167] *Ass'n for Molecular Pathology*, 133 S. Ct. at 2116.
[168] *Ass'n for Molecular Pathology vs Myriad Genetics, Inc.*, 569 U.S. 576, 591 (2013)
[169] *Ass'n for Molecular Pathology*, 133 S. Ct. at 2116.
[170] *Id*. at 2118
[171] *Ibid*
[172] USPTO, 2014 Interim Guidance on Patent Subject Matter Eligibility (2014). Available at https://www.federalregister.gov/documents/2014/12/16/2014-29414/2014-interim-guidance-on-patent-subject-matter-eligibility. Last accessed on 6 June 2022.
[173] *Ass'n for Molecular Pathology vs Myriad Genetics, Inc.*, 569 U.S. 576, 577 (2013)

of the introns[174] from a DNA sequence is an unquestionable creation of something new.[175] However, the ruling that an isolated sequence is not patent-eligible since the bonds which are cut during the isolation process do not contribute to the functioning of the DNA sequence can be compared to the removal of the introns, which also play no role in the function of the DNA sequence due to their non-coding nature. The Supreme Court did not take this comparison into consideration, nor did it consider the instances of naturally occurring cDNA.[176]

Myriad's story in the US did not end with the invalidation of its isolated gene patents. Within one month of Supreme Court's gene patent ruling, Myriad brought lawsuits against several companies which started to offer less expensive versions of Myriad's BRCA genetic tests.[177] Myriad alleged infringement on ten claims in the patents-in-suit relating to 'primers' and diagnostic methods for analysis of BRCA1 and BRCA2 genes and requested a preliminary injunction to prevent sales or offers to sell the tests by the defendants.[178] Finding it unlikely for Myriad to succeed on the merits of their claims, the District court denied Myriads motion for preliminary injunction.[179] The composition claims involved were DNA primers,[180] which Myriad claimed to be synthetically generated rather than extracted from nature. However, in interpreting the decision in *Myriad* and considering the much shorter length of primers than the naturally occurring exon-only regions, the Court concluded that claimed primers had the same sequence as the naturally occurring BRCA DNA.[181] In addition, finding that

[174] 'An intron is a portion of a gene that does not code for amino acids. Most gene sequences are broken up by one or more introns. The parts of the gene sequence that are expressed in the protein are called exons, while the parts of the gene sequence that are not expressed in the protein are called introns, because they come in between the exons. Exons are the sequences coding for proteins that are present between either the untranslated regions or two introns.' in Microbe Notes, Introns Vs Exons- Definition, 12 Major Differences, Examples. Available at https://microbenotes.com/introns-vs-exons/#:~:text=Introns%20are%20the%20non%2Dcoding,that%20code%20for%20specific%20proteins.&text=Introns%20are%20present%20between%20two,untranslated%20regions%20or%20two%20introns. Last accessed on 29 March 2022

[175] *Ass'n for Molecular Pathology vs Myriad Genetics, Inc.,* 569 U.S. 576, 577 (2013)

[176] Jorge L. Contreras, "Association for Molecular Pathology v. Myriad Genetics: A Critical Reassessment." *Mich. Tech. L. Rev.* 27 (2020): 1, at 36. Available at https://dc.law.utah.edu/cgi/viewcontent.cgi?article=1226&context=scholarship. Last accessed on 17 May 2022.

[177] *Univ. of Utah Research Found. v. Ambry Genetics Corp. (In re Brca1- & Brca2- Based Hereditary Cancer Test Patent Litig.),* 3 F. Supp. 3d 1213, (D. Utah 2014)

[178] *Ibid*, 1219

[179] *Ibid*

[180] "A primer is a short, synthetic, single-stranded DNA molecule that binds specifically to an intended target nucleotide sequence" *In re Brca1* 3 F. Supp. 3d 1213, 1224 (D. Utah 2014)

[181] *Ibid*, 1264

primers function like natural DNA during replication, the Court found that they were not 'markedly different' from their natural counterparts, in structure and function alike and thus, patent ineligible.[182]

Similar faith had the probes claimed in the methods for screening for alterations in BRCA genes. As they are also short synthetically generated nucleotide sequences,[183] and in light of *Mayo*, the court found no inventive concept in the claims other than the patent ineligible BRCA sequences.[184]

With the Federal Circuit affirming the lower court's finding, and its own finding that the primers are not distinguishable from isolated patent ineligible DNA but dissimilar to the patent eligible cDNA,[185] it also found that primers have no significant structural or functional difference from natural occurring DNA.[186] The method claims were met with similar outcome as the Federal Circuit found them invalid under 35 U.S.C. §101.[187]

These decisions suggest that without additional inventive concept, primers and probes may be patent-ineligible subject matter.[188]

### 2.3.2. Impact of *Myriad*

The *Myriad* decision brought about major changes in the patent scope concerning gene patents and was praised and criticised alike. Questions have been raised as to what degree have the gene patens been narrowed down. Jessica Lai[189] addresses this question considering both *Mayo*[190] and *Myriad* together since the former concerns methods while the latter, products. In *Mayo*, determining the correct dosage of a medication by means of diagnostic method using metabolite thresholds was found to

[182] *Ibid*, 1266-1267
[183] DNA probes, *supra* note 96
[184] *In re BRCA1-, BRCA2-Based Hereditary Cancer Test Patent Litigation*, 3F. Supp. 3d 1213, 1269 (D. Utah 2014)
[185] *In re BRCA1-, BRCA2-Based Hereditary Cancer Test Patent Litigation (In re BRCA (Fed. Cir.))*, 774 F.3d 755, 760 (2014).
[186] *Ibid*, 761
[187] *Ibid*, 767
[188] Grosh, *supra* note 77, at p. 53
[189] Jessica C. Lai, "Myriad GENETICS and the BRCA patents in Europe: the implications of the US Supreme Court decision." *UC Irvine L. Rev.* 5 (2015): 1041, at p. 1067.
[190] *Mayo Collaborative Services vs Prometheus Laboratories, Inc*, *supra* note 134

be mere recitation of a natural law and thus, not patent eligible.[191] This decision was applied to *Myriad* and resulted in invalidation of the claimed method of analysing BRCA sequences with subsequent comparison with a normal sequence so as to identify cancer-disposing mutations. This method was ruled to be just a recitation of an abstract idea not part of the process of comparing two sequences claimed by Myriad.[192] On the other hand, the transformative nature of the steps for comparing cell growth rates and growing the transformed cells rendered the method for screening potential cancer therapeutics patent-eligible subject matter.[193]

The narrowing of the patent scope was confirmed by the statement issued by the USPTO in its 2014 Guidelines stating that 'the correlation between the presence of misfolded protein ABC in blood and degenerative disease X is a natural principle.'[194] Isabelle Huys *et al.* argue that the link between a mutation and a disease is correctly considered 'a fact derived from nature, and the activity of identifying and making this link constitutes a mental act (or even a discovery) rather than an invention.'[195] For Lai, this narrowing goes too far since as per *Myriad* 'mutations… would be difficult to patent, as the mutations themselves would be mere natural products,' while as per *Mayo*, mutations causing cancer would be considered natural laws.[196]

In Europe, however, patentability of method claims is much broader as claims for detecting a disease or mutation or comparing genetic sequences are allowed.[197] On the other hand, patentability of method claims is broader in the US in terms of methods for medical treatment as these are not patent-eligible in Europe.[198] Consequently, such narrowing of the method claims could cause companies, both in the US and in Europe,

[191] *Ibid* at 1297
[192] *Ass'n for Molecular Pathology vs USPTO*, 689 F.3d 1303, 1333–35 (Fed. Cir. 2012).
[193] *Ibid* at 1335-37
[194] USPTO, *supra* note 172
[195] Isabelle Huy, Gert Matthijs, and Geertrui Van Overwalle. "The fate and future of patents on human genes and genetic diagnostic methods." *Nature Reviews Genetics* 13, no. 6 (2012): 441-448, p. 445.
[196] Lai, *supra* note 189, at p. 1068
[197] Huys et al., *supra* note 195, at 444; Isabelle Huys, Geertrui Van Overwalle, and Gert Matthijs. "Gene and genetic diagnostic method patent claims: a comparison under current European and US patent law." *European Journal of Human Genetics* 19, no. 10 (2011): 1104-1107.
[198] European Patent Convention, art. 53(c), Oct. 5, 1973, 1065 U.N.T.S. 199 (as amended Nov. 29, 2000).

to resort to trade secrets, which are a common practice among companies before and after the narrowing of the patent scope with *Myriad* and *Mayo*.[199]

Given that the case received enormous public attention, ethics of parenting of human genetical material[200] as well as the impact of the practice on further research and development were widely commented topics.[201]

### 2.3.3. Patenting BRCA in Australia

The Myriad patents did not lack of public attention in Australia either. The High Court of Australia's oral hearing took place in June 2015, and it received a significant media coverage.[202] This story began in 2010 when Cancer Voices Australia and Yvonne D'Arcy launched an action in the Federal Court of Australia against the validity of a BRCA1 patent[203] – held by Myriad Genetics Inc., the Centre de Recherche du Chul, the Cancer Institute of Japan and Genetic Technologies Limited.[204]

The argument of the applicants was that '[t]he isolation of the BRCA1 gene mutation from the human body constitutes no more than a medical or scientific discovery of a naturally occurring phenomenon and does not give rise to a patentable invention.'[205]

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[199] Rochelle C. Dreyfuss and James P. Evans. "From Bilski back to Benson: preemption, inventing around, and the case of genetic diagnostics." *Stanford law review* (2011): 1349-1376. Available at https://www.nature.com/articles/ejhg201176.pdf. Last accessed on 29 Mar. 22. Myriad Genetics had an immense and secret database of mutations, related clinical outcomes, and patient data relating to breast cancer.

[200] Marilyn Martone, "The ethics of the economics of patenting the human genome." *Journal of Business Ethics* 17, no. 15 (1998): 1679-1684, p. 1679; David B. Resnik, "DNA patents and human dignity." *Journal of Law, Medicine & Ethics* 29, no. 2 (2001): 152-165, p. 153; David K. Chan, "Should Human Genes Be Patented?." *Philosophy in the Contemporary World* 12, no. 2 (2005): 30-36.

[201] Samantak Ghosh, "Are All Genes Equal." *BUJ Sci. & Tech. L.* 20 (2014): 1, p. 7-9.

[202] Dan Harrison, 'Genetic Patents: Grandmother Yvonne D'Arcy Takes on Global Giant *Myriad* Genetics' (The Sydney Morning Herald, 16 June 2015). Available at https://www.smh.com.au/politics/federal/genetic-patents-grandmother-yvonne-darcy-takes-on-global-giant-myriad-genetics-20150616-ghphvj.html. Last accessed on 1 April 2022; Elizabeth Byrne, 'Breast Cancer Gene: High Court to Hear Whether *Myriad* Genetics' Gene Patent Stands' (ABC News, 16 June 2015). Available at https://www.abc.net.au/news/2015-06-16/high-court-hears-landmark-test-case-on-patenting-human-genes/6547954. Last accessed on 1 April 2022; Tracy Bowden, 'Brisbane Grandmother in Legal Battle against US Biotech Company *Myriad* Genetics Over Human Gene Ownership' (ABC 7:30 Report, 16 June 2015). Available at https://www.abc.net.au/news/2015-06-16/grandmother-sues-biotech-company-over-gene-ownership/6550600. Last accessed on 1 April 2022.

[203] Australian Patent number 686004, 'In vivo mutations and polymorphisms in the 17q-linked breast and ovarian cancer susceptibility gene' (1994).

[204] *Cancer Voices Australia et al. vs Myriad Genetics Inc. et al.* (2010), Federal Court of Australia, Statement of Claim, 8 June.

[205] *Ibid*

It was further argued that 'the alleged invention is not a patentable invention in that, so far as claimed in claims 1–3, it is not a manner of manufacture within the meaning of s 6 of the Statute of Monopolies 1624' and that 'the alleged invention is a mere discovery.'[206] The issue in the case was presented by Nicholas J of the Federal Court of Australia. In considering the importance of 'patentability of genes, or gene sequences, and the practice of 'gene patenting' he stated that 'the issue to be decided is whether under the Patents Act 1990 (Cth) (the Act), a valid patent may be granted for a claim that covers naturally occurring nucleic acid – either deoxyribonucleic acid (DNA) or ribonucleic acid (RNA) – that has been "isolated"' where 'the word "isolated" implies that naturally occurring nucleic acid found in the cells of the human body, whether it be DNA or RNA, has been removed from the cellular environment in which it naturally exists and separated from other cellular components also found there.' [207]

The Federal Court held that Myriad Genetics' patent claims were a 'manner of manufacture' under s 6 of the Statute of Monopolies and s 18(1)(a) of the Patents Act 1990 (Cth). The appeal to the Full Court of the Federal Court of Australia was dismissed in favour of Myriad Genetics Inc. with the observation that '[t]he claim is to an invention within the meaning of s 18(1) of the Act'. [208] These two decisions did not dismay the applicants to lodge an Appeal[209] to the High Court of Australia in March 2015. The High Court of Australia heard oral arguments over the matter in June 2015.[210]

### 2.3.4. *Myriad* before the High Court of Australia

To outline the case, the High Court Judges first considered the history of the interpretation of 'manner of manufacture' pointing out that it is a centuries old terminology relating to patentability of an invention, which, as claimed, must be a 'manner of manufacture' within the meaning of s 6 of the Statute of Monopolies

[206] *Ibid*
[207] *Cancer Voices Australia vs Myriad Genetics Inc.*, [2013] FCA 65, 1–2.
[208] *D'Arcy vs Myriad Genetics Inc.* [2014] FCAFC 115 (5 September 2014), para 218.
[209] 'Appellant's Submissions in *D'Arcy vs Myriad Genetics Inc.*', the High Court of Australia, 10 March 2015. Available at https://www.hcourt.gov.au/assets/cases/s28-2015/DArcy_App.pdf. Last accessed on 1 April 2022.
[210] *D'Arcy vs Myriad Genetics Inc & Anor* [2015] HCATrans 146 (16 June 2015); and *D'Arcy vs Myriad Genetics Inc & Anor* [2015] HCATrans 147 (17 June 2015).

1624.[211] They considered the interpretation of 'manner of manufacture' in *National Research Development Corporation v Commissioner of Patents ('NRDC')*[212] where it was emphasised that "'manner of manufacture" taken from s 6 of the *Statute of Monopolies 1624* was to be treated as a concept for case-by-case development.'[213]

Contrary to the interpretation of the Full Court of the Federal Court of Australia, the High Court Judges maintained that '[d]espite the formulation of the claimed invention as a class of product,' Myriad's claims are substantially 'information embodied in arrangements of nucleotides' pointing out that 'information is not "made" by human action but rather discerned.'[214] In considering how the claimed invention fits within the concept of 'manner of manufacture,' the Judges clarify that 'within the meaning of s 6 of the Statute of Monopolies 1624, an invention is something which involves "making,"' something 'brought about by human action' and should be characterised as an 'artificially created state of affairs.'[215]

In the opinion of judges, rights which 'involve far-reaching questions of public policy and to affect the balance of important conflicting interests, the question must be asked whether that application is best left for legislative determination.'[216] They find that 'patentability of nucleotide sequences derived from human DNA is in that category.'[217]

Considering the breadth of claims for an isolated nucleic acid coding for a specified polypeptide, the judges observe that they could lead to an exorbitant and unwarranted de facto monopoly:

> Claims 1 to 3 include the products of applying any process, known or unknown, to the cells of a human being which extracts or replicates from them nucleotides which code for mutant or polymorphic BRCA1 in the sequences specified in the Patent, whether or not the isolate contains other components and sequences. The size of the class of the products as defined is large. No upper limit was suggested in argument. The boundaries of the class are not defined by a limiting range of chemical formulae. There is a real risk that the chilling effect of the claims, on the use of any isolation process in relation to the BRCA1 gene,

[211] *D'Arcy vs Myriad Genetics Inc.* [2015], para 4.
[212] *National Research Development Corporation vs Commissioner of Patents* [1959] HCA 67 (6 December 1959).
[213] *D'Arcy vs Myriad Genetics Inc.* [2015], para 5.
[214] *Ibid*, para 6.
[215] *Ibid*
[216] *Ibid*, para 7.
[217] *Ibid*, para 7.

> would lead to the creation of an exorbitant and unwarranted de facto monopoly on all methods of isolating nucleic acids containing the sequences coding for the BRCA1 protein. The infringement of the formal monopoly would not be ascertainable until the mutations and polymorphisms were detected. Such a result would be at odds with the purposes of the patent system.[218]

The judges conclude that '[t]hose features of the invention as claimed in Claims 1 to 3, and its substance as an invention relating to sequence information, lead to the conclusion that its patentability would not serve the purposes of the concept of "manner of manufacture" in s 18(1)(a) of the Act or of the Act itself.'[219] To support this, the Judges cite Cornish, Llewelyn, and Aplin observing that '[a] patent over a single gene may prove to set up a barrier against its use in a quite distinct genetic procedure for a different medical condition which is worked out only subsequently'.

In considering the applicants engagement with 'the finding by the Full Court that the isolated nucleic acids were patentable as 'an artificially created state of affairs,' French CJ examines the 'application of categories such as "products of nature" versus "artificially created products"' and even though finding this consideration may be destructing from the central issue, he finds that 'the fact of the existence of the requisite mutations or polymorphisms is a matter of chance. It is not something "made." It is not "artificially created"'.[220]

In comparing the US 'product of nature' doctrine and the Australian test of 'artificially created state of affairs,' Professor Brad Sherman, cited by Judges Gageler and Nettle JJ, finds the two to be the same question asked from a different perspective, that is 'nature and artifice are flip sides of the same coin'.[221] For a product to be within the limits of patentable subject matter then, it should be either artificial enough or sufficiently different from its counterpart in nature.[222] In considering the product claimed in Claim 1, the two judges observe that '[t]he process of isolating nucleic acid from the cell for the purposes of genetic testing is a matter of longstanding practice

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[218] *Ibid*, para 8.
[219] *Ibid*, para 9.
[220] *Ibid*, para 91.
[221] Brad Sherman, "Before the high court: D'Arcy v Myriad Genetics Inc: Patenting Genes in Australia." *Sydney Law Review, The* 37, no. 1 (2015): 135-146. Available at http://classic.austlii.edu.au/au/journals/SydLawRw/2015/6.html#:~:text=The%20Supreme%20Court%2C%20when%20dealing,the%20product%20of%20nature%20exclusion. Last accessed on 3 April 2022.
[222] *Ibid*

and diagnostic technique,' which pathologist are free to use 'without fear of contravention of any patent to which the first respondent might lay claim'.[223] The judges stress that if the responded claimed a new method of isolation of nucleic acid, such method would, indeed, constitute patentable subject matter, however, this is not disclosed in claim 1.[224] Hence they find that the isolated nucleic acid, notwithstanding that it is 'chemically, structurally and functionally different' from the naturally occurring DNA due to the removal of the histones controlling and executing the exon function in the cell,[225] 'they are naturally occurring and therefore not new.'[226]

In addressing the issue of too broad claims having adverse impact on freedom of research and competition, the Judges maintain:

> That consequence coupled with the very large, indeed unquantified size of the relevant class of isolated nucleic acids, all of which bear the requisite information, raises the risk of a chilling effect upon legitimate innovative activity outside the formal boundaries of the monopoly and risks creating a penumbral de facto monopoly impeding the activities of legitimate improvers and inventors.[227]

In stressing that '[t]he invention as claimed in Claims 1 to 3 does not meet the requirement of s 18(1)(a) and the appeal should be allowed'[228] the judges explain their conclusion that:

> Although it may be said in a formal sense that the invention as claimed, referring to isolated nucleic acids, embodies a product created by human action that is not sufficient to support its characterisation as a manner of manufacture. The substance of the invention as claimed and the considerations flowing from its substance militate against that characterisation. To include it within the scope of a 'manner of manufacture' involves an extension of that concept, which is not appropriate for judicial determination. Further, to include this class of claim within that concept would not contribute to coherence in the law as was the case in *Apotex*. Nor do Australia's international obligations and the differently framed patent laws of other jurisdictions, which were referred to earlier in these reasons, support the conclusion that this class of claim should fall within the concept.[229]

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[223] *D'Arcy vs Myriad Genetics Inc.* [2015], para 157.
[224] *Ibid*, para 158
[225] *Ibid*
[226] *Ibid*, para 169
[227] *Ibid*, para 93.
[228] *Ibid*, para 95.
[229] *Ibid*, para 94.

The joint judgment stressed: 'The invention as claimed in Claims 1 to 3 does not meet the requirement of s 18(1)(a) and the appeal should be allowed.'[230]

In their written submission to the High Court of Australia, Myriad Genetics Inc. argued that 'the legislative history' did not support any 'exclusion' of isolated DNA or RNA sequences from patentability,[231] further pointing out that enactment of such exclusion was expressly declined by Parliament on more than one occasion.[232] The company interpreted the 'silence by the legislator' as an act of 'leaving the field to the Courts for resolution.'[233] In support of its argument, Myriad listed several events which included 'the rejection in the Senate of an amendment to the Patents Bill 1990 (Cth),[234] which would have excluded genes from patentability, whether derived from cells or chemically synthesised', 'the rejection by the Legal and Constitutional Affairs Legislation Committee of the Senate of a Private Members' Bill, the Patent Amendment (Human Genes and Biological Materials) Bill 2010 (Cth),' and the Australian Law Reform Commission report on gene patenting and human health. [235]

Myriad's arguments were rejected in the plurality judgement explaining that 'gene patenting' was not the Courts concern in the appeal 'but with whether the invention as claimed in Claims 1 to 3 falls within established applications of the concept of manner

[230] *Ibid*, para 95.
[231] 'First Respondent's Submissions in *D'Arcy vs Myriad Genetics Inc.*' (the High Court of Australia, 24 March 2005). Available at http://www.hcourt.gov.au/assets/cases/s28-2015/DArcy_Res.pdf. Last accessed on 3 April 2022.
[232] The Australian Parliament, though, did pass a prohibition on patenting human beings in 1990. See Matthew Rimmer, "The attack of the clones: patent law and stem cell research." *Journal of law and Medicine* 10, no. 4 (2003): 488-505. Available at https://papers.ssrn.com/sol3/papers.cfm?abstract_id=603225. Last accessed on 3 April 2022; Matthew Rimmer, "The last taboo: patenting human beings." *Expert Opinion on Therapeutic Patents* 14, no. 7 (2004): 1061-1074.
[233] First Respondent's Submissions, *supra* note 231
[234] Rimmer (2003), *supra* note 232
[235] Senate Community Affairs Reference Committee, 'Gene Patents' (Canberra: Australian Parliament, 2010). Available at http://www.aph.gov.au/senate/committee/clac_ctte/gene_patents_43/report/index.htm. Last accessed on 3 April 2022; Senate Legal and Constitutional Committee, Patent Amendment (Human Genes and Biological Materials) Bill 2010 (Canberra: Australian Parliament, 2011), cited in Matthew Rimmer, "An exorbitant monopoly: the High Court of Australia, Myriad Genetics, and gene patents." In *Research Handbook on Intellectual Property and the Life Sciences*, pp. 56-103. Edward Elgar Publishing, 2017, p. 75.

of manufacture' and that [t]he legislative history does not assist the Court in answering the question posed in this appeal.'[236]

### 2.3.5. BRCA in Europe

Unlike in the US and Australia, the subject matter before the Board of Appeal in Europe was not patentability *per se*. Namely, in Case T 1213/05[237] pertaining to EPO patent EP0705902 '17q-Linked Breast and Ovarian Cancer Susceptibility Gene,' the Board dealt with priority and the question of whether priority could be claimed from a U.S. Patent Application[238] containing an error in the disclosed BRCA1 sequence. The question before the Board was to determine whether the 15 inaccuracies pertaining to nucleotides of the cDNA sequence and found in the priority application affect the claimed priority date in the EPO patent application.[239] In citing previous EBA decision, the Opposition Division and the Board of Appeal found that in order to ensure a proper exercise of priority rights, 'a narrow or strict interpretation of the concept of "the same invention," equating it to the concept of "the same subject-matter" referred to in Article 87(4) EPC,'[240] was necessary and that the argument 'a DNA sequence deviating from the claimed one within the margin of error of the used sequencing method' should be 'entitled to claim priority from an earlier application' was in opposition to the said EBA decision.[241] Consequently, it was establish that *Myriad* was entitle to claim priority from a latter US patent application filed[242] on 24 March 1995.[243]

In 2008, a Myriad patent[244] on BRCA1 concerning mutations indicating a predisposition for breast and ovarian cancer was also narrowed down.[245] Out of 34 mutation, Myriad was entitled to the priority claimed in only one 'frame-shift'

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[236] *D'Arcy vs Myriad Genetics Inc.* [2015], para 37.
[237] Case T 1213/05, *Univ. of Utah Research Found. vs Sozialdemokratische Partei der Schweiz*, ¶ I (EPO Boards of Appeal, 2007). Available at https://www.epo.org/law-practice/case-law-appeals/pdf/t051213eu1.pdf. Last accessed on 3 April 2022.
[238] Filed on 2 September 1994, designated the P2 (US 300266) priority application.
[239] *Id*. ¶ 20, at 27. "Nine of these deviations lead to an amino acid exchange in SEQ ID NO: 2 while six are so-called "silent deviations'".
[240] *Id*. ¶ 21, at 29 citing EBA Opinion G 2/98 (OJ EPO 2001, 413)
[241] *Id*. ¶ 29, at 36
[242] US 409305 (24 March 1995)
[243] *Id*. ¶ 34, at 41.
[244] EP0705903 "Mutations in the 17q-Linked Breast and Ovarian Cancer Susceptibility Gene"
[245] Case T 0666/05, Univ. *of Utah Research Found. vs Institut Curie*, ¶ I, at 1 (EPO Boards of Appeal, 2008).

mutation since the errors found in the prior art document did not affect the detection of that specific mutation, nor the nucleotides in the related probe. [246] Consequently, Myriad had to reduce the scope of the claims to methods for diagnosing a predisposition for breast and ovarian cancer with respect to the frame-shift mutations in order to maintain its patent, which was revoked in 2004 but the decision was revered by the Board of Appeal in 2008 with respect to frame-shift mutations because the exact correct sequence is not required to detect frame-shift mutations.[247]

In all three cases, relevance of economic and ethical consequences of patenting diagnostic methods involving the use of human genetic material was considered by the Board of Appeal and in all of them, the Board affirmed that it is not within the EPO competencies to take into account the economic effects of granting patents and to restrict the field of patentable subject-matter accordingly.[248]

As discussed in the following chapter, patenting of genetic sequences in Europe is regulated by the Biotechnology Directive on EU level and the European Patent Convention. Thus far, validity of gene patents pertaining to human, or animal sequences has not been challenged before the CJEU, nor the Board of Appeal of the EPO, hence no case law is available. Gene patents relating to genetically modified plants and seeds have been address by the CJEU, [249] however, these are outside the scope of this work.

### 2.4. Determining Non-obviousness vis-a-vie CRISPR Patent Dispute

The requirement for non-obviousness under 35 U.S.C. 103 is the requirement for an inventive step in Europe. The patent system when first introduced was not set in stone and as imperfect as it was then, caused a lot of legal, administrative and even philosophical problems.[250] In the mid-19th century, the US courts were charged with the responsibility to determine the validity of inventions to be granted patents requiring

[246] *Id*. ¶ 40, at 27-28.
[247] Case T 0080/05, *Univ. of Utah Research Found. vs Institut Curie* (EPO Boards of Appeal, 2008), in Lai *supra* note 189, at p. 1060.
[248] Case T 1213/05, *Univ. of Utah Research Found*., at ¶ 53, at 51; Case T 0666/05, *Univ. of Utah Research Found. vs Institut Curie*, ¶ 82, at 45-46; Case T 0080/05, *Univ. of Utah Research Found. vs Institut Curie*, ¶ 65, at 39.
[249] Case C-428/08 *Monsanto Technology LLC v Cefetra BV*, 6 July 2010 (Grand Chamber) [2010] ECR I-6765.
[250] This is not to say that it is perfect today.

them to be 'of more ingenuity and skill than that possessed by an ordinary mechanic.'[251]

In 1952, US Congress tasked two patent attorneys, Pasquale Joseph Federico and Giles Sutherland Rich, with giving form to this elusive 'inventiveness' requirement.[252] They reshaped what is today called 'non-obviousness' by prohibiting patents covering inventions for which the 'differences between the claimed invention and the prior art are such that the claimed invention as a whole would have been obvious ... to a person having ordinary skill in the art to which the claimed invention pertains.'[253] The advantage of so defined property of patentable inventions brought focus to the prior art, determined by examining previous patent documentation, the time when the invention was made and the hypothetical person with ordinary skills in the patent's art.[254] Albeit a late comer as a requirement for patentability, in addition to novelty and usefulness,[255] non-obviousness or inventive step is today the most critical condition for patent grant and it is brought into question even after a patent has been granted. As such it is often referred to as the 'final gatekeeper of the patent system,' the 'ultimate condition of patentability,' and 'the heart of the patent law.'[256]

This may have revolutionized the patent system and made easier and more practical to use at the time, however, the rise of new technologies seen in the second half of the 20th century and especially in the past two decades, the answer to the question of what is obvious for a person skilled in the art has become a rather complicated one. Biological systems are much more complex and unpredictable than the mechanical and chemical systems the patent system was designed to support. For example, the development of a biologic compound in one cell system using a particular construct is

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[251] *Graham v. John Deere Co.*, 383 U.S. 1 (1966) citing *Hotchkiss v. Greenwood*, 11 How. 248 (1851)
[252] Jacob S. Sherkow, "Inventive steps: the CRISPR patent dispute and scientific progress: The recent patent decisions about CRISPR tell us a lot about how advances in biology are actually made—and how they are not." *EMBO reports* 18, no. 7 (2017): 1047-1051. Available at https://www.ncbi.nlm.nih.gov/pmc/articles/PMC5494531/. Last accessed on 07 May 2023.
[253] 35 U.S.C. 103
[254] Sherkow (2017), *supra* note 252, at p. 2.
[255] The members of the World Trade Organization are required by treaty to award patents for all inventions that "are new, involve an inventive step and are capable of industrial application." A footnote defines 'inventive step' and 'capable of industrial application' as synonymous with the terms 'non-obvious' and 'useful' respectively.
[256] John F. Duffy, "Inventing invention: a case study of legal innovation." *Tex. L. Rev.* 86 (2007): 1. Available at https://papers.ssrn.com/sol3/papers.cfm?abstract_id=1087067. Last accessed on 07 May 2023.

not a guarantee that it will work in a different cell system.[257] The issue of non-obviousness is here exemplified through the prism of the CRISPR patent dispute, which began in 2013 and was decided only in 2022.

### 2.4.1. CRISPR Background

At about the same time when the US Supreme Court was deciding on whether genes are patentable subject matter or not, the genome-editing technology based on clustered, regularly interspaced, short palindromic repeats (CRISPR) and CRISPR-associated protein 9 (Cas9) had just emerged as a groundbreaking technology with immense potential to change the world. As such, a patent dispute was the inevitable course of action. Genome editing technologies hold great potential for scientific research and society as they provide fast, efficient, precise and relatively inexpensive tools to modify the cells of any living organism. By use of genome editing techniques, chronic and lifelong illnesses could be potentially cured as the technique allows modification of the cells. The great potential of genome editing is its relative simplicity as a tool to change any organism's deoxyribonucleic acid (DNA), thus allowing genetic material to be added, removed or altered in particular locations in the genome. That is, CRISPR-Cas9 allows search, deletion and even replacement of a mutation in the genome.

CRISPR was first described in the work of Jennifer Doudna, at the University of California, Berkeley (UC Berkeley), and Emmanuelle Charpentier, then at Umea University, Sweden (currently the Director and Scientific Member at the Max Planck Unit for the Science of Pathogens), for a method that exploits the genome-editing system *in vitro*.[258] Doudna and Charpentier subsequently received a Nobel Prize in chemistry in 2020 for their troubles, however, their invention did not remain unchallenged in the patent protection realm. Shortly after they filed their 155-claim patent application for CRISPR-Cas9 gene editing in all environments, including bacteria, plant, animal, and human cells,[259] with 25 May 2012 as the priority date, Feng Zhang of MIT received a patent[260] on a method for using CRISPR-Cas9 for genome

[257] Sherkow (2017), *supra* note 252, at p. 3.
[258] Martin Jinek, Krzysztof Chylinski, Ines Fonfara, Michael Hauer, Jennifer A. Doudna, and Emmanuelle Charpentier, "A programmable dual-RNA–guided DNA endonuclease in adaptive bacterial immunity." *science* 337, no. 6096 (2012): 816-821.
[259] US Patent Application No. PCT/ US2013/032589
[260] US Patent No. 8,697,359 (2014).

editing in eukaryotic cells on 15 April 2014.[261] The second patent had the 12 December 2012 as priority date.

The dispute arose between the University of California, the University of Vienna, and Emmanuel Charpentier (known as the CVC group in legal filings) and Broad Institute of MIT and Harvard (known as Broad), with the former currently holding the original patent over the use of CRISPR-Cas9 to edit genes *in vitro* and in prokaryotes while the latter hold the patent on CRISPR-Cas9 to edit genes in eukaryotes.

### 2.4.2. CRISPR First Interference Proceedings

At the heart of the dispute was non-obviousness and priority both in the US and in Europe. In the US, the patent dispute was structured as an 'interference proceeding,' a legal procedure unique to US patent law. Such proceedings aim at ascertaining whether two related patents 'claim patentably indistinct subject matter,' that is, whether they claim the same invention, subsequently determining which party was the first to invent. If the inventions are determined to be different, that is, the subsequent invention was a non-obvious improvement, there is no true interference between the inventions. In the CRISPR interference, heard by the US Patent Trial and Appeal Board (PTAB), the invention in dispute between the University of California and the Broad Institute was defined as a single-guide RNA (sgRNA) CRISPR/Cas9 editing system, specific to plant and animal cells (eukaryotic cells). The criterion used by the PTAB to determine whether the eukaryotic-specific invention was a non-obvious advance over the *in vitro* and prokaryote invention was the 'reasonable likelihood of success'[262] of the latter. That is, whether Doudna and Charpentier's application of CRISPR/Cas9 *in vitro* and in bacterial systems would have had a 'reasonable likelihood of success' in eukaryotic cells. For this purpose, testimonies on the differences among cell systems that could have affected Cas9's binding and nuclease activity: 'gene expression, protein folding, cellular compartmentalization, chromatin structure, cellular nucleases, intracellular temperature, intracellular ion concentrations, intracellular pH, and the types of molecules in prokaryotic versus eukaryotic cells' by various experts was considered

[261] Le F. Cong, Ann Ran, David Cox, Shuailiang Lin, Robert Barretto, Naomi Habib, Patrick D. Hsu et al., "Multiplex genome engineering using CRISPR/Cas systems." *Science* 339, no. 6121 (2013): 819-823.
[262] Regents of the Univ. of Cal. v. Broad Inst., Inc., 903 F.3d 1286, 1294 (Fed. Cir. 2018)

and found that they 'would contribute to this unpredictability [regarding whether the CRISPR-Cas9 system would be operative in eukaryotic cells].'[263] Statements made by Doudna and her team that getting CRISPR to work in eukaryotic cells was an 'exciting possibility' contributed to the PTAB's decision as they implied that it wasn't obvious to them their invention would work in eukaryotic cells. Considering the differences of the system together with the inventors' expressed 'frustration' compelled the Board to conclude that eukaryotic cells invention was not an obvious improvement to the *in vitro* invention. Thus, PTAB ruled in 2017 that the claims in Broad's patents and in CVC's applications concerned different inventions, and that Broad's inventions in eukaryotic cells were not drawn from nor obvious over CVC's work, as the latter only involved experiments in test tubes without any experiments conducted in eukaryotic cells.

Although 'CVC argued that Broad's inventions, for editing genes in eukaryotic cells, were obvious extensions of their work on cutting purified DNA in test-tube environments — and therefore should not be patented,'[264] the important differences between Broad's and CVC's work were described by the PTAB as follows:

> 'Broad provided sufficient evidence to show that its claims, which are all limited to CRISPR-Cas9 systems in a eukaryotic environment, are not drawn to the same invention as UC's claims, which are all directed to CRISPR-Cas9 systems not restricted to any environment. Specifically, the evidence shows that the invention of such systems in eukaryotic cells would not have been obvious over the invention of CRISPR-Cas9 systems in any environment, including in prokaryotic cells or in vitro, because one of ordinary skill in the art would not have reasonably expected a CRISPR-Cas9 system to be successful in a eukaryotic environment. This evidence shows that the parties' claims do not interfere.'[265]

[263] Noonan K., PTAB Decides CRISPR Interference in Favor of Broad Institute -- Their Reasoning, available at https://www.jdsupra.com/legalnews/ptab-decides-crispr-interference-in-47126/. Last accessed on 07 May 2023.
[264] Broad Communications, For journalists: Statements and background on the CRISPR patent process, 28 February 2022. Available at https://www.broadinstitute.org/crispr/journalists-statement-and-background-crispr-patent-process. Last accessed on 16 May 2023.
[265] The Broad Institute, Inc., Massachusetts Institute of Technology, and President and Fellows of Harvard College vs The Regents of the University of California, University of Vienna, and Emmanuelle Charpentier. Patent Interference No. 106,048 (DK), DECISION ON MOTIONS 37 C.F.R. § 41.125(a), Summary. Available at https://www.broadinstitute.org/files/news/pdfs/106048DecisiononMotions.pdf. Last accessed on 08 May 2023.

CVC took the matter to the US Court of Appeals for the Federal Circuit, which reaffirmed the PTAB's judgement of no interference-in-fact and that the 'Board did not err in its determination that there is no interference-in-fact.'[266] Although CVC attempted to take the matter up before the US Supreme Court, the Court rejected the petition to hear the case.[267]

Contrary to the decisions of the US patent authorities, the CRISPR story in Europe and before the EPO Opposition Division took a different turn. Namely, 'EPO opposition division had revoked the [Broad's] patent for lack of novelty in view of intermediate prior art. This prior art became relevant because the opposition division did not acknowledge the patentee's claim to priority from a US provisional application naming more applicants than the subsequent PCT application from which EP 2771468 is derived. Since the omitted applicant had not transferred his rights to the applicants of the PCT application the priority claim was considered invalid.'[268]

The CRISPR patent, as soon as filed, was also challenged on ethical grounds. This is briefly discussed in the following Chapter on BIOTECH PATENTS IN EUROPE.

### 2.4.3. CRISPR Second Interference Proceedings

A second interference involving certain patent applications of CVC and the same Broad-issued patents as in the first interference was initiated in June 2019, when unlike in the first interference from 2017, when only no interference was found, priority date was also determined and found in favour of Broad. The CVC claimed priority date 25 May 2012 was not determined to be the CVC patent application priority date for CRISPR-Cas9 system in eucaryotic cells as such a specific patent application was filed by CVC only on 28 January 2013, little over a month after Broad's priority date from the patent application filed on 12 December 2012. The Board found that the 'CVC inventors' comments tend to indicate that they did not have possession of a functional CRISPR-Cas9 system in eukaryotic cells' on the claimed priority date, thus setting

[266] Regents of the Univ. of Cal. v. Broad Inst., Inc., 903 F.3d 1286, 1296 (Fed. Cir. 2018)
[267] Julian Cockbain and Sigrid Sterckx. "Patenting foundational technologies: Recent developments in the CRISPR patent struggle." *The American Journal of Bioethics* 20, no. 4 (2020): 11-12.
[268] Decision in case T 844/18 on the CRISPR gene editing technology. Available at https://www.epo.org/law-practice/case-law-appeals/communications/2020/20200117.html. Last accessed on 9 May 2023.

Broad as the 'Senior Party' and CVC as the 'Junior Party' of the process.[269] The Board set out to decide 'which party's inventors were the first to invent a CRISPR-Cas9 system with a single guide RNA able to cleave or edit DNA to affect gene expression in a eukaryotic cell' and entered a judgement against CVC.

In practice, the Board's decision brings forth licensing issues with licenses which CVC has already granted. On the other hand, Broad Institute pressed for a joint licensing strategy, or patent pools, even before patents were issued to Broad or the University of California-Berkeley (UCB), hoping to ensure open, equitable, and streamlined access to these transformative tools. Such collaboration can ensure easier access to this revolutionary technology and avoid exclusive and stringent license enforcement as in the case with Myriad Genetic's and their patents on BRCA1 and BRCA2.

### 2.5. Conclusion

When the practice of patenting genes first set off, the science was new, so the boundaries were not yet so well known. After thousands of gene patents issued round the world, these patents were proven by various courts to be well beyond the protection provided by the national laws in the respective jurisdictions. Several court cases in the US contributed to narrowing of the scope of gene patents, however, the question that still remains is whether the current protection provided is as exaggerated as it was in the first thirty years of patenting biotechnology. The science is still new, albeit much more advanced now than it was 40 years ago, and further advancement might prove, yet again, that the patent protection now is still too broad in light of future developments. The profits made and the lives affected by the patents granted during the gene patenting period cannot be rebalanced *post festum*, but current practices should be carefully drafted so as to avoid similar consequences in the future. Chapter 6 provides some alternatives as to tackle this issue.

[269] Patent Interference No. 106,115 (DK): Decision on Priority 37 C.F.R. § 41.125(a). USPTO. February 28, 2022. Available at https://drive.google.com/file/d/1-NxaE-FqWz1spjckk-Q6I_-LuKSzvMg3/view. Last accessed on 09 May 2023.

## 3. BIOTECH PATENTS IN EUROPE

### 3.1. Introduction to Patents in Europe

The Venetian Patent Statute of 1474 is considered to be the first statutory patent system in Europe.[270] The English Statute of Monopolies from 1623,[271] otherwise forbidding monopolies, contains provisions on privileges for new inventions and new procedures[272] and is recognised as the original source of Anglo-American Patent Law.[273] It stayed in force for over two hundred years until it was repelled by the Statute Law Revision Act of 1863.[274] The French patent law of 1791 is the first real patent law in Europe.[275] With the rise of international trade, the need for international patent protection became self-evident. Consequently, in 1873 a Congress was held in Vienna where issues pertaining to international protection of inventions were debated paving the way to the Paris Convention of 1883.[276] This was followed by the establishment of the United International Bureaux for the Protection of Intellectual Property (BIRPI) in 1893, which was succeeded by the World Intellectual Property Organisation (WIPO)

[270] Although earlier examples of grant of privileges for inventions are found and the letters patent issued to John Kemp in 1331 is considered to be the progenitor of the modem patent system. See Ikechi Mgbeoji, "The juridical origins of the international patent system: Towards a historiography of the role of patents in industrialization." *Journal of the History of International Law/Revue d'histoire du droit international* 5, no. 2 (2003): 403-422.

[271] An Act concerning Monopolies and Dispensations with Penal Laws and the forfeitures thereof, 1624, 21 Jac.I, c.3. Available at https://www.ipmall.info/sites/default/files/hosted_resources/lipa/patents/English_Statute1623.pdf. Last accessed on 21 April 2022.

[272] *Ibid*, pursuant to Article 6 'any declaration before mentioned shall not extend to any letters patents (b ) and grants of privilege for the term of fourteen years or under, hereafter to be made, of the sole working or making of any manner of new manufactures within this realm (c ) to the true and first inventor (d ) and inventors of such manufactures, which others at the time of making such letters patents and grants shall not use.' This section formed the foundation for English patent law that lasted until the adoption of the Patents Act 1977. See also EPO, e-courses, 'A brief history (Supplementary reading).' Available at https://e-courses.epo.org/wbts_int/litigation/History.pdf. Last accessed on 21 April 2022.

[273] English Statute 1623, *supra* note 271

[274] The Statute Law Revision Act, 1863 (26 & 27 Vict., c. 125).

[275] The first revolutionary patent acts resulted from a strong lobbying by inventors' societies. The law was adopted based on a report from 30th December 1790 submitted by Stanislas de Boufflers. (S. de Boufflers, Rapport sur la propriété des auteurs de nouvelles découvertes et inventions en tout genre d'industrie, Paris 1791.) in Gabriel Galvez-Behar, "The patent system during the French industrial revolution: Institutional change and economic effects." *Jahrbuch für Wirtschaftsgeschichte/Economic History Yearbook* 60, no. 1 (2019): 31-56.

[276] Paris Convention for the Protection of Industrial Property, as last revised at the Stockholm Revision Conference, Mar. 20, 1883, 21 U.S.T. 1583; 828 U.N.T.S. 305. Available at https://wipolex.wipo.int/en/text/288514. Last accessed on 21 April 2022.

in 1967 with the adoption of the Convention for establishing the World Intellectual Property Organisation in Stockholm.[277]

Europe is the birthplace of patents, and their rise, history, and development are reflected in the complex patent protection provided for on the continent. The complexity stems from the multitude of national laws, which are generally approximated with the European Union (EU) Acquis Communautaire (hereinafter the Acquis) by its Member States, however, as all EU Members are also Members of the European Patent Organisation, national laws pertaining to patents need to be in line with the provision of the European Patent Convention (EPC)[278] as well. The European Patent Organisation also includes countries which are not members of the EU. All of them must abide by the provisions of the TRIPS agreement, the Annex to the Agreement establishing the World Trade Organisation.[279]

These systems are meant to function simultaneously and in synchrony, however, as discussed further in this work, the introduction of the Directive 98/44/EC on the legal protection of biotechnological inventions (hereinafter generally referred to as the Biotech Directive) and its subsequent incorporation in the EPC have brought much uncertainty to patent protection of biotechnological inventions in Europe.

As on international level, so on regional, European level, patent legislation tends towards harmonisation, however, despite the efforts, patent legislation in European countries still differs do a degree and the national character of patents makes it difficult for patentees to keep up with all the legal systems of the countries where protection to their inventions is afforded. Novel technologies have had especially diversified reception throughout these countries and the lengthy adoption process of the legislation pertaining to biotechnological inventions is one example of the complexity of the patent system in Europe. As patent protection in Europe is guaranteed by

[277] Convention Establishing the World Intellectual Property Organization, 14 July 1967 and as amended on 28 September 1979 (WIPO Convention).
[278] Convention on the grant of European patents of 5 October 1973, as revised on 29 November 2000 (European Patent Convention - EPC), 1973. The EPC as revised in November 2000 is also known as EPC 2000 to differentiate it from the original version from 1973 (EPC 1973; Convention on the grant of European patents of 5 October 1973, 1973).
[279] Agreement on Trade-Related Aspects of Intellectual Property Rights, Apr. 15, 1994, Marrakesh Agreement Establishing the World Trade Organization, Annex 1C, 1869 U.N.T.S. 299, 33 I.L.M. 1197 (1994) (hereinafter generally referred to as TRIPS Agreement)

statutory laws, unlike in the US where Common Law judicial decisions[280] are on par with statutory laws, patent legislation is more elaborate and tends to cover more detailed aspects of the protection afforded.[281] Patent protection of biotechnology in Europe is one proof of this civil law diligence, on national as well as on EU level.[282] However, such diligence is not without flaws. It is arguable that the 'law trots behind technological development'[283] and the lengthy adoption process of the Biotechnology directive is contributory to this observation especially in view of the gene patenting practices in the US and Australia *vis-a-vie* the European incentive for the adoption of this piece of legislation. As soon as an existing subject is legally provided for, technology makes a further step forward and the cycle of its legal regulation provision begins again.

### 3.2. Filing Options in Europe

Inventions in Europe can be protected classically on national level by filing a patent application in national patent offices, subject to the requirements of the national law pertaining to patent protection in the filing country. The other option is filing through the European Patent Office,[284] which allows applicants to obtain patent protection in EPO Members States of their choosing.[285] However, upon grant, the European patent[286] is again subject to national laws[287] and out of the hands of the EPO. Thenceforth, national patent protection is enforced in accordance with respective national legislations of the EPO Member States.

The European patent is not a single patent but a so-called 'bundle' of national patents subject to national legislation. On EU level, an attempt was made for the introduction

[280] See 2.3.1 above on US Supreme Court Decision in Myriad and its subsequent implementation in the USPTO Guidelines on patentability.
[281] Although judicial decisions in the EU have no law-making force, the decisions of the CJEU are considered as an important part of the EU Law.
[282] See *infra* Part 3.5
[283] Prof. Jadranka Dabovic Antanasovska on her lectures on Intellectual Property Law
[284] Pursuant to Article 4(2) EPC, the European Patent Office (EPO) and the Administrative Council are the two organs of the European Patent Organisation.
[285] Article 3 EPC
[286] Article 2(1) EPC stipulates that patents granted under the convention shall be called European Patents.
[287] Article 2(2) EPC

of a Community Patent[288] which was to be a single EU patent. The idea for a community patent can be traced back to the 1970s and it is expected to finally come to life as Unitary Patent on 1 June 2023 as all necessary ratification procedures have now been finalised by the required number of EU Member States.[289] The Unitary Patent System is linked to the Unitary Patent Court (UPC), which will have jurisdiction over Unitary Patents and European patents.[290] The EU regulations establishing the Unitary Patent system (No 1257/2012[291] and No 1260/2012[292]) entered into force on 20 January 2013 but will apply only from the date of entry into force of the UPC Agreement, which is set to be 1 June 2023.

Last, but not least option for obtaining a patent in Europe is through the International Patent System established with the Patent Cooperation Treaty (PCT), which enables patent applicants to seek protection in any of its Member States, including a European patent.[293]

### 3.3. The Unitary Patent

On top of the two layers of patent protection provided in Europe comes the Unitary Patent with its Unitary Patent Court (UPC) designed to simplify both patent application and patent enforcement throughout the European Union. Thus far, patent enforcement in Europe fell on national jurisdiction where every patent granted through the EPO, albeit as a bundle of patents for several countries, was a subject to national legislation upon grant. This structure proved expensive and cumbersome for patent applicants since applications are to be translated in all national languages where protection is sought for and respective national legislation thoroughly studied in order make use of the protection provided by the respective countries. The purpose of the Unitary Patent

[288] Proposal, of 1 August 2000 for a Council Regulation on the Community patent. 'EUR-Lex - l26056 - EN - EUR-Lex.' Available at https://eur-lex.europa.eu/legal-content/HR/TXT/?uri=LEGISSUM:l26056
[289] When will the Unitary Patent System start? Available at https://www.epo.org/law-practice/unitary/unitary-patent/start.html. Last accessed on 16/02/2022.
[290] Ibid
[291] Regulation (EU) No 1257/2012 of the European Parliament and of the Council of 17 December 2012 implementing enhanced cooperation in the area of the creation of unitary patent protection OJ L 361, 31.12.2012, p. 1–8 Available at https://eur-lex.europa.eu/legal-content/en/ALL/?uri=CELEX:32012R1257. Last accessed on 16 February 2022.
[292] *Ibid* at p. 89–92.
[293] See WIPO, Overview of the PCT System. Available at https://www.wipo.int/pct/en/faqs/faqs.html#note1. Last accessed on 21 Apr. 22.

is to address and overcome these issues and provide a single union patent, which only includes the countries of the European Union, and provide judiciary patent enforcement by a single Unitary Patent Court. Both Unitary Patents and traditional European patents will be enforceable by the UPC since the UPC jurisdiction will automatically apply to existing European patents as well as the grants of currently pending European applications unless the applicant specifically files a request to opt-out.[294]

The Unitary Patent Agreement will come into force for the countries[295] which have already ratified it. Given that some countries have decided not to participate in the Unitary Patent project, the agreement will come into force under the Enhanced Cooperation procedure,[296] which requires a minimum of 9 EU Member States to set up an advanced integration or cooperation in a particular field within the EU. Except for Spain and Croatia, all Member States are participating in the enhanced cooperation. This allows Unitary Patents to get protection in up to 25 Member States making use of the EPO system through a single patent application. While no changes will take place in the pre-grant procedure, the patent proprietor will be able to request a unitary effect thus acquiring uniform patent protection.[297]

Given that the Unitary Patent protection will be governed by the EPC provisions which incorporate the EU Biotech Directive, being itself an integral part of the EU *acquis*, biotechnology patents should not be specifically affected by the new system. However, commentators find that biotechnology could, indeed, be affected by it worldwide. Given that continuous renewal and the early revocation of biotechnology inventions are two of the hallmarks of the biotechnology industry, there are concerns that granting of broad patent protection can establish oversized monopolies that hinder the

[294] The Select Committee the Preparatory Committee, Unified Patent Court - *An Enhanced European Patent System*, p. 16. Available at https://www.unified-patent-court.org/sites/default/files/enhanced-european-patent-system.pdf. Last accessed on 1 March 2022.
[295] The 17 states in enhanced cooperation which already ratified the Agreements and will participate in the Unitary Patent when it starts are: Austria, Belgium, Bulgaria, Denmark, Estonia, Finland, France, Germany, Italy, Latvia, Lithuania, Luxembourg, Malta, the Netherlands, Portugal, Slovenia, Sweden. EPO – *Unitary Patent*. At https://www.epo.org/law-practice/unitary/unitary-patent.html
[296] Article 20 of the Treaty on European Union and Title III of the Treaty on the Functioning of the EU, EUR-Lex, Glossary of Summaries – Enhanced Cooperation. Available at https://eur-lex.europa.eu/summary/glossary/enhanced_cooperation.html. Last accessed on 1 March 2022.
[297] *Ibid* at 295

advancement of the extremely dynamic biotechnology sector.[298] Furthermore, Europe makes Supplementary Protection Certificates (SPCs)[299] available for biotechnology companies, thus allowing them extension of patent terms to compensate for delays during regulatory review periods. Pharmaceutical products are afforded up to five more years of protection subject to regulatory review, however, the UPC regime did not contain provisions on enforcement or invalidation of SPCs.[300] The European Commission encouraged biotech companies to participate in the Unitary Patent by stating that it will recalibrate certain aspects of patent and SPCs protection.[301] This pledge was upheld when the Commission published its Communication[302] to include SPCs under the UPC, that is, UPC will have exclusive competence on actions for actual or threatened infringements of patents and supplementary protection certificates and related defences, including counterclaims concerning licences.[303] Thus, it seems, the protection of biotechnology inventions in Europe will not be affected by the new system.

[298] Ignacio Belda, Gerardo Penas, Domingo Marquina, and Antonio Santos. "Analyzing the impact of the European unitary patent system on worldwide biotechnology." *Trends in biotechnology* 32, no. 8 (2014): 393-395. Available at https://www.academia.edu/15305984/Analyzing_the_impact_of_the_European_unitary_patent_system_on_worldwide_biotechnology?from=cover_page. Last accessed on 1 March 2022.

[299] Regulation (EC) No 469/2009 of the European Parliament and of the Council of 6 May 2009 concerning the supplementary protection certificate for medicinal products, *OJ L 152, 16.6.2009, p. 1–10.* Available at https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX%3A32009R0469. Last accessed on 1 March 2022.

[300] Unified Patent Court: Supplementary Protection Certificates (SPCs) | All Alerts & Newsletters | Crowell & Moring LLP Available at https://www.crowell.com/NewsEvents/AlertsNewsletters/all/Unified-Patent-Court-Supplementary-Protection-Certificates-SPCs. Last accessed on 1 March 2022.

[301] COMMUNICATION FROM THE COMMISSION TO THE EUROPEAN PARLIAMENT, THE COUNCIL, THE EUROPEAN ECONOMIC AND SOCIAL COMMITTEE AND THE COMMITTEE OF THE REGIONS Upgrading the Single Market: more opportunities for people and business. Available at https://ec.europa.eu/transparency/documents-register/detail?ref=COM(2015)550&lang=en. Last accessed on 1 March 2022.

[302] COMMUNICATION FROM THE COMMISSION TO THE EUROPEAN PARLIAMENT, THE COUNCIL, THE EUROPEAN ECONOMIC AND SOCIAL COMMITTEE AND THE COMMITTEE OF THE REGIONS Making the most of the EU's innovative potential An intellectual property action plan to support the EU's recovery and resilience, COM/2020/760 final

[303] Agreement on a Unified Patent Court, *OJ C 175, 20.6.2013,* p. 1–40. Article 30

### 3.4. Patenting Biotechnology in the European Union

Europe has always had a more restrictive attitude towards patent protection in comparison to the US. When the US allowed software patents,[304] the EU did not provide such protection.[305] When the US provided patent protection to genetic material, the EU considered it contrary to the ethical norms deeply ingrained in the European culture.[306] At the end of the 20th century, however, Europe decided to turn the page and introduce less restrictive legislation which would allow for broader protection of biotechnological inventions in order for it to become more competitive in the rising biotech market.[307] 25 years after the introduction of the Biotech Directive and 10 years after the exclusion of gene patents in the US, the topic is still as current due to the biotechnological developments on these two continents. Given that the EU introduced the Biotech Directive in order to boost its biotechnological development, it is interesting to see to which degree this goal has been achieved and whether or not the narrowing of the genetic sequences patent scope after Myriad has weakened biotechnological patent protection in the US. The following part looks into the statistical data giving a clearer picture of this development.

Of the Union law, only the Biotech Directive addresses the issue of patents directly. The reasons for the introduction of this Directive have been heavily discussed. It was primarily introduced in order for the EU to catch up with the technological development in the field of biotechnology in the US and Japan, where, by the time of the adoption of the Directive, biotechnological invention had been protected for quite

[304] Section 101 of Title 35 of the US Code defines 'eligible subject matter' as "any new and useful, process, machine, manufacture, or composition of matter, or any new and useful improvement thereof" setting the scope of protection rather broad.
[305] Michael Guntersdorfer, "Software patent law: United States and Europe compared." *Duke L. & Tech. Rev.* 2 (2003): 1.. Available at https://scholarship.law.duke.edu/cgi/viewcontent.cgi?article=1075&context=dltr. Last accessed on 19 February 2022.
[306] Bartha Maria Knoppers, "Status, sale and patenting of human genetic material: an international survey." *Nature Genetics* 22, no. 1 (1999): 23-26. Available at https://www.researchgate.net/profile/Bartha-Knoppers/publication/12978517_Status_sale_and_patenting_of_human_genetic_material_An_international_survey/links/562fc94f08aed649430df9d6/Status-sale-and-patenting-of-human-genetic-material-An-international-survey.pdf. Last accessed on 3 June 2022.
[307] Biotechnology in the Community: Communication from the Commission to the Council, COM(83)672 final/2-Annex at 12-13 on the Strategic significance of biotechnology. Available at http://aei.pitt.edu/1241/1/biotechnology_COM_83_672.pdf. Last accessed on 14 March 2023.

a while and the industry seemed to have been booming with progress and development in this field.[308]

With the introduction of the Biotech Directive and its transposition into the EPC rules, the patent protection in Europe has become somewhat hybrid. This will be further intensified with the introduction of the Unitary Patent together with its separate Unitary Patent Court.[309]

### 3.4.1. Trends in EPO Biotechnology Patent

Even though at the time when the Biotechnology Directive was in the making the number of biotechnology patent applications filed under the Patent Co-operation Treaty (PCT) decreased from more than 11 800 in 2000 to 9 481 in 2006, after steady growth in the 1990s, at an average rate of –3.6% a year between 2000 and 2006, compared to an increase of 20.4% over 1995-2000. Conversely, the total number of PCT patent applications increased by an average of 6.5% a year over 2000-06. [310] Consequently, the relative weight of biotechnology in all international patent filings decreased between the mid-1990s and the early 2000s in many countries. On average, biotechnology patents represented 6.7% of countries' patent portfolios over 2004-06, compared to 10.6% in the mid-1990s.[311]

[308] Joe Alper, "The rise of the European bioentrepreneur." *Nature biotechnology* 20, no. Suppl 6 (2002): BE3-BE5. Available at https://www.nature.com/articles/nbt0602supp-BE3.pdf?origin=ppub. Last accessed on 18 Feb. 22; Organisation for Economic Co-operation and Development. (1998). *21st century technologies: promises and perils of a dynamic future*. OECD Publishing. Available at https://www.oecd.org/futures/35391210.pdf . Last accessed on 18 Feb. 22; John M. Marcum, "The technology gap: Europe at a crossroads." *Issues in Science and Technology* 2, no. 4 (1986): 28-37.
[309] Anthony Dearden, Upcoming changes to the European patent system. Gowling WLG, 2022. Available at https://gowlingwlg.com/en/insights-resources/articles/2022/upcoming-changes-to-the-european-patent-system/. Last accessed on 19 Feb. 22; 'Unitary Patent system is an arbitrary and ailing hybrid monster mix' - Kluwer Patent Blog http://patentbl0g.kluweriplaw.c0m/2021/12/09/unitpatent-system-is-an-arbitrary-and-ailing-hybrid-monster-mix/. Last accessed: 19 Feb. 22
[310] OECD, OECD. "Science, Technology and Industry Scoreboard 2001: Towards a Knowledge-based Economy." *OEOD: Paris* (2001).
[311] *Ibid*, p.1

Figure 3.3.4.1.1 Biotechnology PCT patent applications[312]

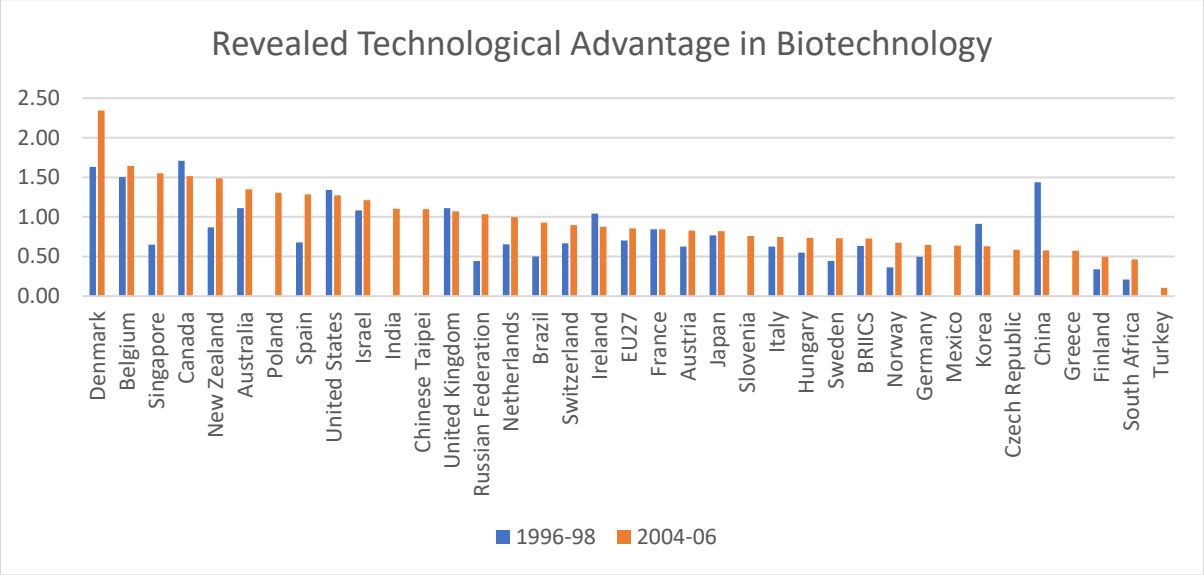



Figure 1: Data relate to patent applications filed under the PCT, at international phase, designating the European Patent Office. Patent counts are based on the priority date, the inventor's country of residence and fractional counts. BRIICS refers to Brazil, China, India, Indonesia, the Russian Federation and South Africa. Source: http://dx.doi.org/10.1787/743558060332

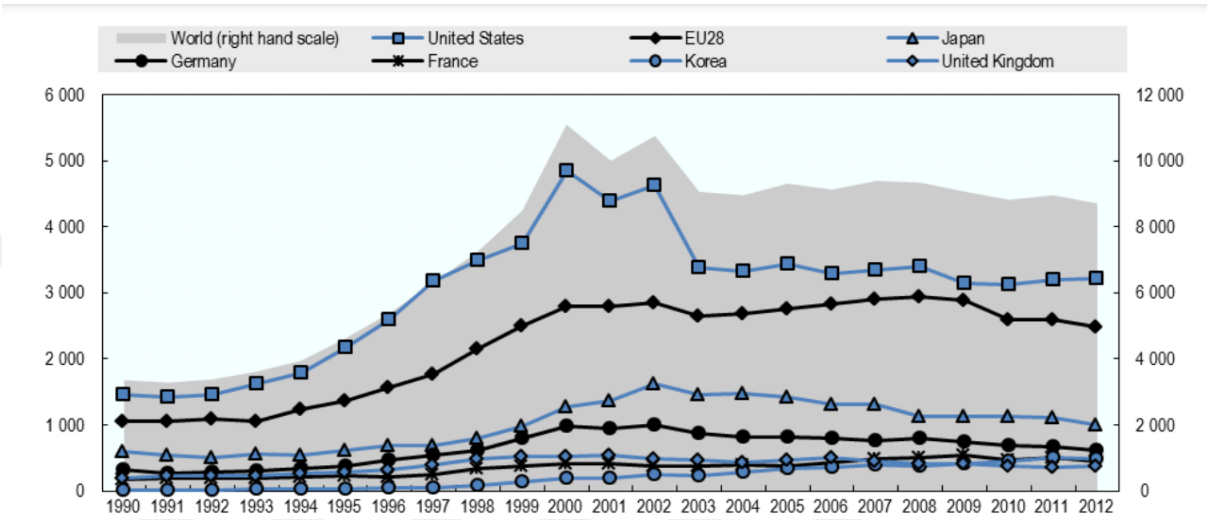
The same trend is observed in the overall world biotechnology patent application in the period between 1990-2012. The overall development of the number of patents in biotechnology from 1990 to 2012 is provided in Figure 2, which illustrates a strong increase in biotech patents in the years 2000 to 2002, observed in the shape of a double-peak. It is largely accounted for by a corresponding increase in patent numbers in the United States only while the European Union (EU28) exhibits a much less pronounced double-peak during this time span. The strong increase in biotechnology patents filed between 1990 and 1999 follows an overall trend in the increase of all patent numbers filed worldwide. Such a strong trend has also been observed for information and communication technology (ICT) patents. In 2014, Kers *et al.* assigned this trend to a dramatic increase in the intention of universities to commercialise their intellectual property.[313] They also attribute the large increase in genetic patent applications until

[312] *Ibid*, p. 2

[313] Jannigje G. Kers, Elco Van Burg, Tom Stoop, and Martina C. Cornel. "Trends in genetic patent applications: the commercialization of academic intellectual property." *European Journal of Human Genetics* 22, no. 10 (2014): 1155-1159. Available at https://www.nature.com/articles/ejhg2013305#citeas. Last accessed on 21 May 2023.

2000 to either investments related to the sequencing of the human genome as well as the large perceived market opportunities for some bioscience engineering products, or the financial support provided by the biotechnology and pharmaceuticals industries, which led to a direct increase in commercialization outcomes.

Figure 3.3.4.1.2 Development in biotechnology patent applications, 1990-2012
Number of IP5 patent families[314] by inventor's country and priority date




Source: Steffi Friedrichs, OECD STI Working Papers, 2018/06

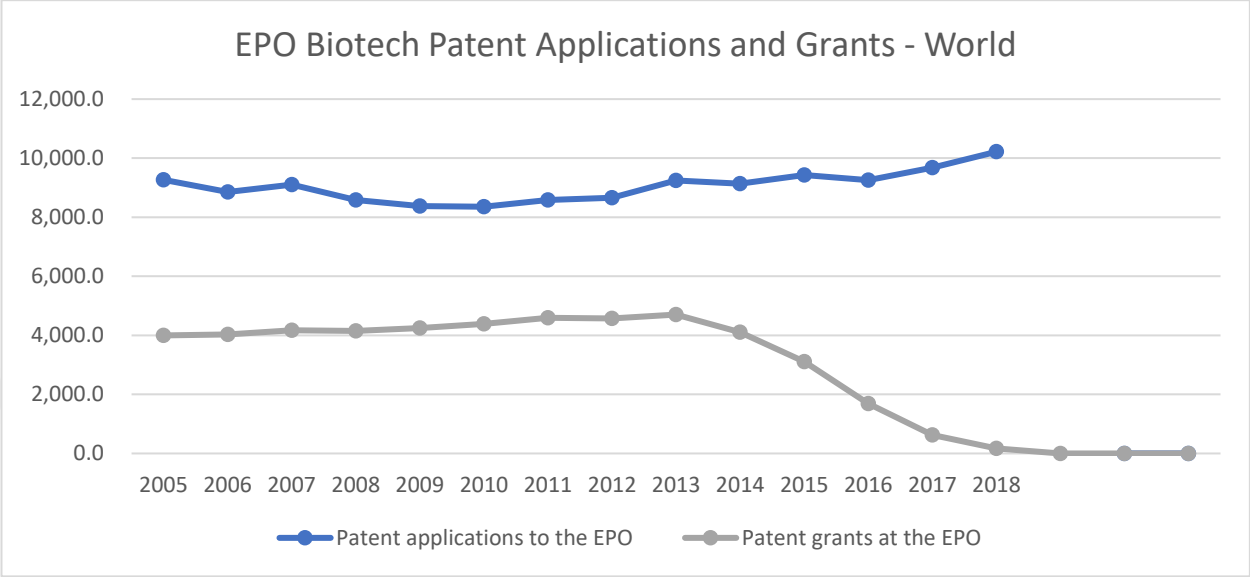
The observed drop in biotechnology patent applications numbers after 2002 is attributed to the completion of the Human Genome Project in 2003, as well as the increasing public debate on genetic engineering in general and the patentability of genes in particular.[315] The subsequent tightening of national rules for the granting of patents on genetic material is considered an explanation for the overall drop in genetic and biotechnology patent applications in recent years.[316]

The same downward trend is observed in EPO biotechnology patent grants, especially after 2013 when the number of granted patents drops from 4703 to 4108 in 2014, with only 188 biotechnology patents granted in 2018. Notwithstanding, patent applications

[314] The five IP5 patent offices are the US Patent and Trademark Office (USPTO), the European Patent Office (EPO), the Japan Patent Office (JPO), the Korean Intellectual Property Office (KIPO), and the National Intellectual Property Administration (CNIPA formerly SIPO) in China.
[315] Kers et al, *supra* note 313, p. 1156; also, Stacy Lawrence, "Patent drop reveals pressures on industry." *Nature Biotechnology* 22, no. 8 (2004): 930-932, p. 930
[316] Brigitte Van-Beuzekom and Anthony Arundel, "Biotechnology patents." *OECD biotechnology statistics 2009* (2009): 103. Available at https://www.oecd.org/sti/inno/42833898.pdf. Last accessed on 21 May 2023.

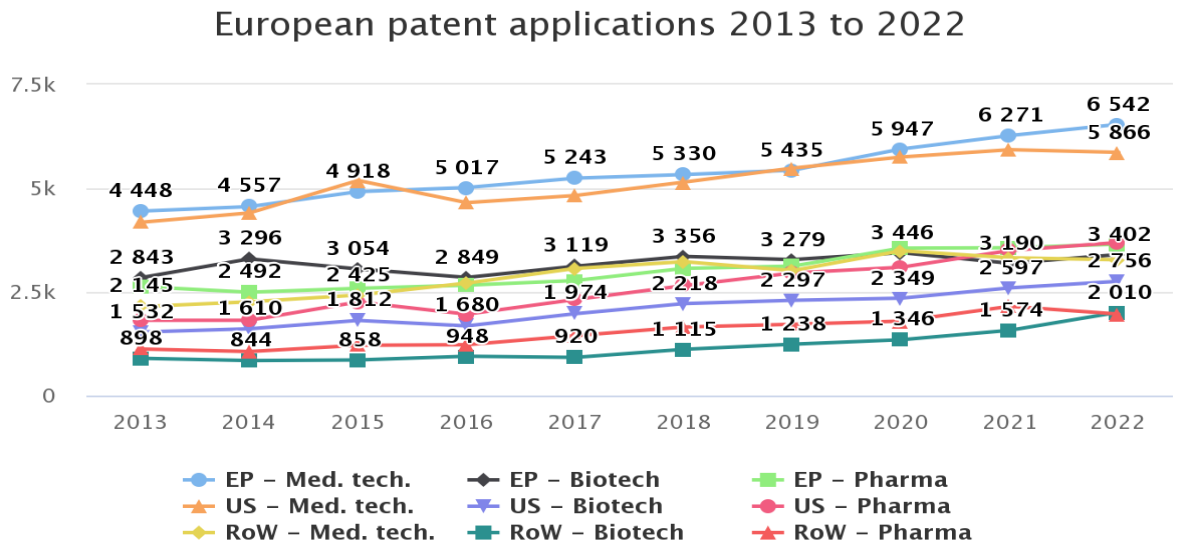
before the EPO maintain a steady course with a gradual annual increase as shown in Figure 3.

Figure 3.3.4.1.3 EPO Biotech Patent Applications and Grants - World



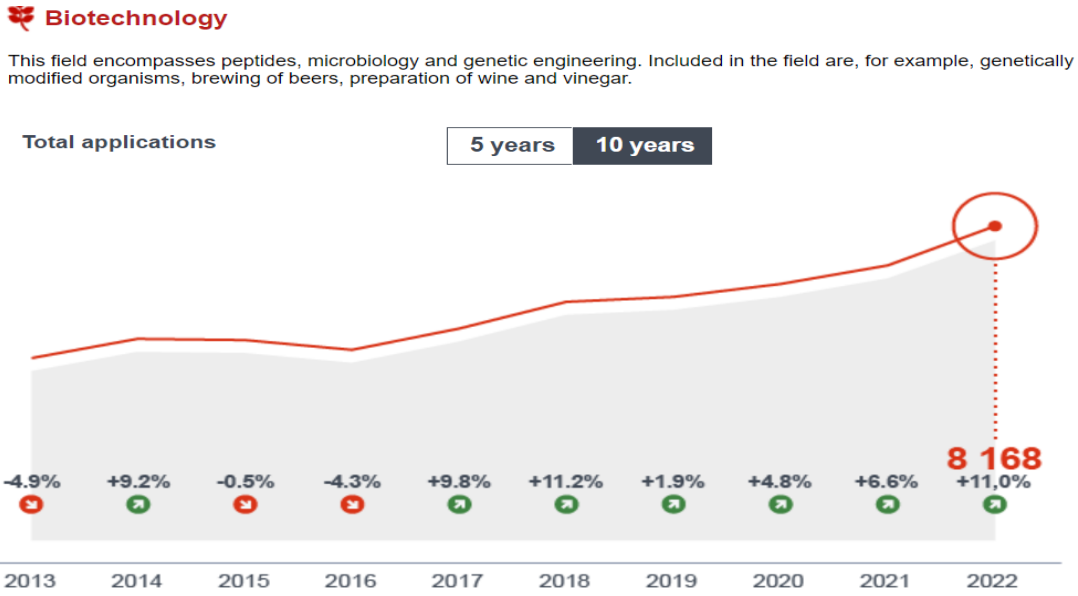

A similar trend of gradual increase in life science patent applications is observed from 2013 to 2022 with a record increase of biotechnology patent applications of 11.0% in 2022 (Figure 5). This trend could be contributed to the medical technologies developed during the COVID pandemic, especially because the rise is significantly larger in the US and EU filings.

Figure 3.3.4.1.4 European patent application 2013 to 2022



Source: EPO Statistics and Trends Centre, at https://new.epo.org/en/statistics-centre#/customchart

Figure 3.3.4.1.5 Total Biotechnology Application 2013 to 2022

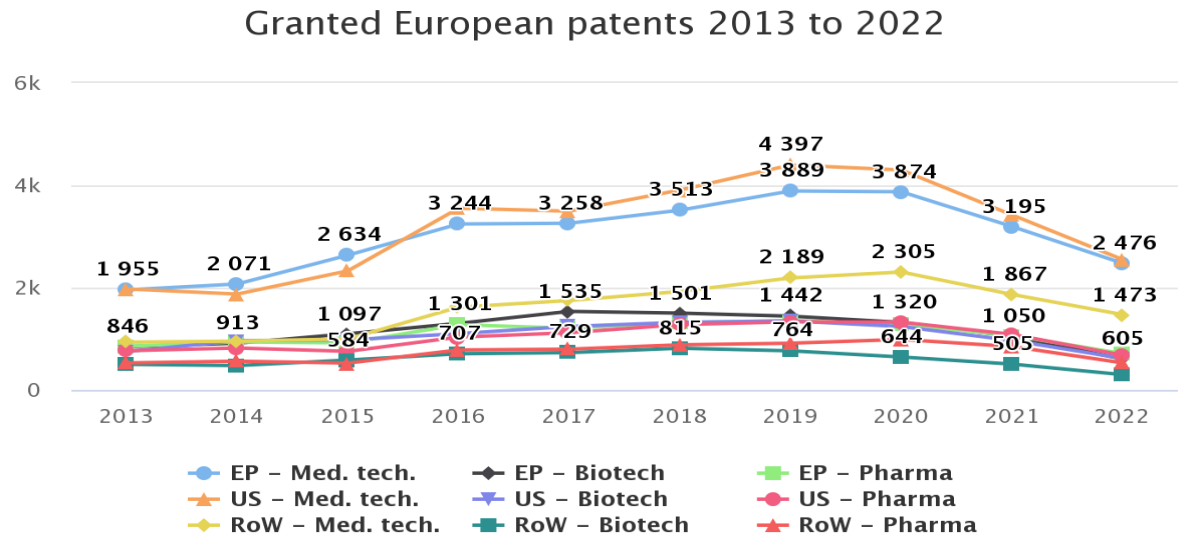



Source: EPO Statistics and Trends Centre, Patent Index 2022, at https://www.epo.org/about-us/annual-reports-statistics/statistics/2022/statistics/patent-applications.html#biotechnology

Despite the increase of patent applications in life science, patent grants do not enjoy the same trend. Beginning in 2019, patents granted for life science innovations are also in decline, nearly reaching the same number of patents granted in 2013. However, this trend is not only characteristic for life science patents but also for the overall patents granted by the EPO.[317] This is particularly true in the field of biotechnology as exemplified in the Figure 7 chart below. Figure 7 also shows that the previous observed dip in 2013, despite the upward trend until 2018, is has reached a new low of the decade.

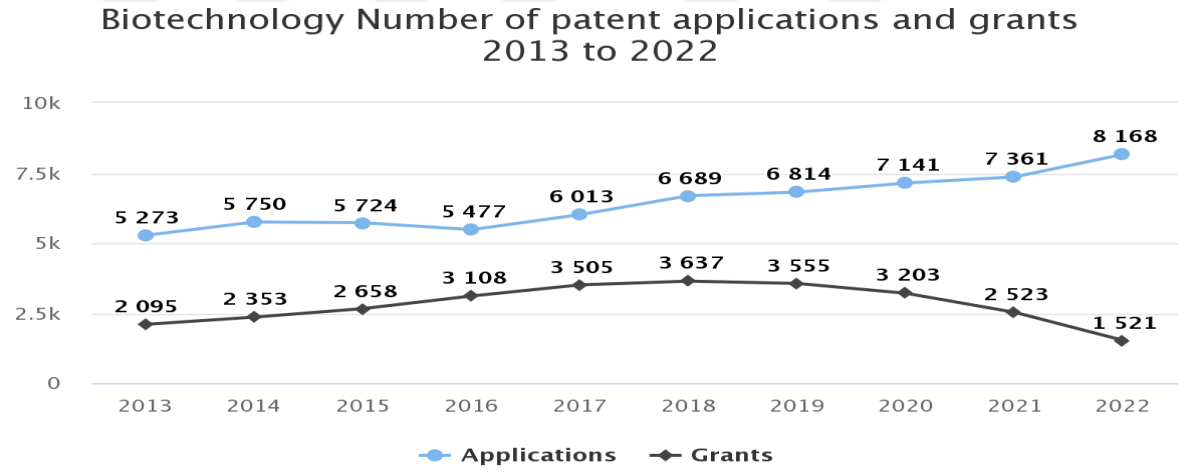
[317] EPO Statistics and Trends Centre, Patent Index 2022, Patents Granted. Available at https://www.epo.org/about-us/annual-reports-statistics/statistics/2022/statistics/granted-patents.html. Last accessed on 21 May 2023.

Figure 3.3.4.1.6 Granted European Patents 2013 to 2022




Source: EPO Statistics and Trends Centre, Patent Index 2022, at https://new.epo.org/en/statistics-centre#/customchart

Figure 3.4.1.7 Biotechnology Number of Patent Applications and Grants 2013 to 2022




Source: EPO Statistics and Trends Centre, Patent Index 2022, at https://new.epo.org/en/statistics-centre#/technologyfields?code=15

### 3.4.2. The Biotech Directive

This part discusses the substantive provisions of the Directive and how these provisions have been so far interpreted by different authors as well as the issues this Directives solves and those it introduces. It will mainly focus on the provisions of Chapters I and II of the Directive.

The Biotech Directive is comprised of two parts. The first one includes the recitals giving the justifications, reasons and purpose of the directive, whereas the second one gives the provisions of the directive themselves.

#### a. Patentability

Patentability of biotechnological inventions is governed by Chapter I of the Directive. Whether or not an invention is patentable depends on whether the invention meets the criteria of Recital 22 by way of Article 1(1) providing for patent protection of biotechnological inventions under national patent laws of European Union Member States[318] and Article 3(1), which in addition to the criteria of being new, involving an inventive step and being susceptible of industrial application, provides protection of products consisting of or containing biological material or a process by means of which biological material is produced, processed or used. Furthermore, Article 3(2) specifically points out that '[b]iological material which is isolated from its natural environment or produced by means of a technical process may be the subject of an invention even if it previously occurred in nature'. Article 1(2) clarifies that the harmonisation of the Directive should be without prejudice to the obligations of the Member States pursuant to international agreements, in particular, the TRIPS Agreement and the Convention of Biological Diversity.

Unlike other patent legislation, the Directive provides definitions of biotechnological terminology through Article 2(1). Thus, 'biological material' is defined as 'any material containing genetic information[319] and capable of reproducing itself or being

[318] Member states are obliged to harmonizing national patent laws with the provisions of the Directive.
[319] The US Equal Opportunity Commission defines genetic information as 'Genetic information includes information about an individual's genetic tests and the genetic tests of an individual's family members, as well as information about the manifestation of a disease or disorder in an individual's family members (i.e., family medical history).

reproduced in a biological system'. Article 2(1)(b) gives the definition for 'microbiological process' and holds that it pertains to 'any process involving or performed upon or resulting in microbiological material'. The 'process for production of plants and animals' is defined as 'essentially biological' provided 'it consists entirely of natural phenomena such as crossing or selection.'[320] Article 2(3) gives the definition for 'plant variety' by referencing Article 5 of the Regulation (EC) No 2100/94.[321]

Article 4 of the Directive excludes plant and animal varieties[322] and 'essentially biological processes for the production of plants or animals'[323] from patentability. The latter is limited by Article 4(3) excluding microbiological processes or other technical processes, or a product obtained by means of such processes. Furthermore, it allows for patent protection if 'technical feasibility of the invention is not confined to a particular plant or animal variety'.[324] Exclusion and exceptions to patentability are briefly discussed below.

Article 5 also governs exclusion to patentability and further restricts the patentable subject matter to exclude '[t]he human body, at the various stages of its formation and development, and the simple discovery of one of its elements, including the sequence or partial sequence of a gene'. This provision indicates that 'sequence or partial sequence of a gene' as elements of the human body cannot constitute patentable subject matter. However, Article 5(2) immediately narrows the scope of this exclusion and stipulates protection of 'sequence or partial sequence of a gene' if they are 'isolated from the human body or otherwise produced by means of a technical process,' they constitute patentable subject matter. It further goes to explain that the similarity

[320] Article 2(2) of the Biotech Directive
[321] Article 5(2) of the Council Regulation (EC) No 2100/94 of 27 July 1994 on Community plant variety rights stipulates that 'variety' shall be taken to mean a plant grouping within a single botanical taxon of the lowest known rank, which grouping, irrespective of whether the conditions for the grant of a plant variety right are fully met, can be: defined by the expression of the characteristics that results from a given genotype or combination of genotypes; distinguished from any other plant grouping by the expression of at least one of the said characteristics, and considered as a unit with regard to its suitability for being propagated unchanged.
[322] Article 4(1)(a)
[323] Article 4(1)(b)
[324] Article 4(2)

between the isolated element and the naturally occurring one would not represent a reason to deny a patent to such an invention. Article 5 reads as follows:

> 1. The human body, at the various stages of its formation and development, and the simple discovery of one of its elements, including the sequence or partial sequence of a gene, cannot constitute patentable inventions.
>
> 2. An element isolated from the human body or otherwise produced by means of a technical process, including the sequence or partial sequence of a gene, may constitute a patentable invention, even if the structure of that element is identical to that of a natural element.
>
> 3. The industrial application of a sequence or a partial sequence of a gene must be disclosed in the patent application.

The provision of Article 5(2) seems to be at odds with the US patent law in terms of patenting sequences or partial sequences of a gene after *Myriad*.[325] Where the EU legislator allows for patent protection of isolated sequences or partial sequences of a gene even if they are identical to the ones occurring in nature, the US legislation has excluded these as patentable subject matter. Namely, after *Association for Molecular Pathology v. Myriad Genetics, Inc.,* 569 U.S. 576 (2013), 'naturally occurring DNA sequences, even when isolated from the body, cannot be patented'[326] leading to changes in the rules for patentability of the USPTO[327] effectively excluding naturally occurring biological material from patentability.

The discrepancy between these two begs the question of whether the EU has accomplished to achieve more competitive advantage compared to the USA due to its wider scope of patentability criteria for biotechnological inventions.

Pursuant to Article 5(3), industrial applicability of sequences or partial sequences of a gene should be disclosed in the patent application. It does not, though, specify if such disclosure should be incorporated in the patent description or in the patent claims.[328]

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[325] See *supra* PATENTING BRCA

[326] Supreme Court of the United States (2013) Syllabus: Association for Molecular Pathology et al. v. Myriad Genetics, Inc., et al. Certiorari to the United States Court of Appeals for the Federal Circuit. No. 12–398, p.1. Available: http://www.supremecourt.gov/opinions/12pdf/12-398_1b7d.pdf. Last accessed on 19 February 2022.

[327] See *supra* PATENTING BRCA

[328] The importance of disclosure comes to light when the boundaries of the claimed invention are set. Patent claims are considered to set these specific boundaries, hence disclosure in the description may or may not be considered to contribute to the patent scope.

### i. Human Body Patents

Patenting of the human body was especially a hot topic during the drafting of the Directive and the provisions of Article 5 were widely debated. According to the preparatory documents of the EU Biotechnology Directive, the European Commission underlined that 'parts of the human body' are parts of the body that are within the body and that a human cell line used in the development of medicines can be patented. Accordingly, the Commission made clear that '[w]ith regard to the unpatentability of the human body or parts of the human body… "parts of the human body" per se means parts of the human body as found inside the body.'[329] It was important for the Commission to spell this out in order 'to remove all possible ambiguity with respect to the position of certain products or parts of the human body which are already covered by patents granted in connection with the development of medicinal products.'[330]

The Common Position adopted by the Council on 7th of February 1994 emphasised that, in the light of the general principle, the ownership of human beings is excluded, that is, 'the human body or parts of the human body as such, for example a gene, protein or cell in the natural state in the human body, including germ cells and products resulting directly from conception, must be excluded from patentability, but isolated parts of the human body should not be unpatentable merely because of their human origin, it being understood that the parts of the human body from which such isolated parts are derived are excluded from patentability.'[331] Some commentators have found that, as per the Directive, the patent regime for human cells is not different from the one for human genes, which, in turn, means that human cells and human stem cells isolated from the human body could be patentable.[332] It is clear, however, that human stem cells from embryonic or foetal origin (so-called embryonic stem cells, embryonic

[329] Amended proposal for a Council Directive on the Legal Protection of Biotechnological Inventions (COM(92)589 final - SYN 159, Brussels, 16 December 1992, p.7.
[330] Ibid
[331] COMMON POSITION (EC) No 4/94 adopted by the Council on 7 February 1994 with a view to adopting European Parliament and Council Directive 94/. . ./EC of . . . on the legal protection of biotechnological inventions, Official Journal C 101 , 09/04/1994 P. 0065. Available at https://eur-lex.europa.eu/legal-content/EN/TXT/HTML/?uri=CELEX:51994AG0409(04)&from=EN . Last accessed on 20 February 2020.
[332] Geertrui Van Overwalle, "Study on the patenting of inventions related to human stem cell research." *European Communities* (2002): 218. Available at https://papers.ssrn.com/sol3/papers.cfm?abstract_id=1720002. Last accessed on 14 May 2022.

germ cells, foetal stem cells) are excluded from patentability since they result directly from conception. However, it could also be understood that human (stem) cells not originating from embryos are not to be excluded from patent protection, whereas embryos isolated as a whole from the human body are to be excluded.[333] According to the Joint Text, the criterion to decide whether or not an element from the human body is patentable, relates to the use of a technical manner in such a way that they can no longer be ascribed to a particular individual. The technical intervention, that is, the artificial process to isolate and reproduce the elements from human origin, are often stressed as one of the major tests to decide whether an element from human origin is patentable.[334]

The explanatory memorandum to the Proposal for a European Parliament and Council Directive on the Legal Protection of Biotechnological Inventions from 25th of January 1996 emphasised that an element of the human body that has not been obtained with the aid of a technological process, but simply detached, removed or collected, may not be regarded as a patentable invention: 'Thus a limb, on organ, or a bodily fluid (e.g., sperm, blood, tears or sweat) cannot be patentable.'[335]

The recitals of the EU Biotechnology Directive from 6th of July 1998 on their turn underline that 'it is important to assert the principle that the human body, at any stage in its formation or development, including germ cells, and the simple discovery of one of its elements or one of its products, including the sequence or partial sequence of a human gene, cannot be patented; whereas these principles are in line with the criteria of patentability proper to patent law, whereby a mere discovery cannot be patented'

[333] On the suggestion of the European Parliament, Recital 10 was to be amended as follows: (10) Whereas, in the light of the general principle that the ownership of human beings is excluded, the human body or parts of the human body as such, for example a gene, protein or cell in the natural state in the human body, including germ cells and products resulting directly from conception, must be excluded from patentability, but isolated parts of the human body should not be unpatentable merely because of their human origin, it being understood that the parts of the human body from which such isolated parts are derived are excluded from patentability; COM(94) 245 final (1994), Opinion of the EU Commission on amendments proposed by Parliament, 9 June 1994 54 in Van Overwalle (2002), *supra* note 332.

[334] Joint Text approved by the Conciliation Committee provided for in article 189 b (4) of the EC Treaty (0159 (COD), PE-CONS 3606/95).

[335] Proposal for a EUROPEAN PARLIAMENT AND COUNCIL DIRECTIVE on the legal protection of biotechnological inventions /* COM/95/0661 FINAL - COD 95/0350 */, *Official Journal C 296, 08/10/1996 P. 0004* Available at https://eur-lex.europa.eu/legal-content/EN/TXT/HTML/?uri=CELEX:51995PC0661&from=SK. Last accessed on 21 February 2022.

(Recital 16). It is also made clear 'that an invention based on an element isolated from the human body or otherwise produced by means of a technical process, which is susceptible of industrial application, is not excluded from patentability, even where the structure of that element is identical to that of a natural element, given that the rights conferred by the patent do not extend to the human body and its elements in their natural environment' (Recital 20). Furthermore, it is underlined that 'an element isolated from the human body or otherwise produced is not excluded from patentability since it is, for example, the result of technical processes used to identify, purify and classify it and to reproduce it outside the human body, techniques which human beings alone are capable of putting into practice and which nature is incapable of accomplishing by itself' (Recital 21).

The Group of Advisers on the Ethical Implications of Biotechnology to the European Commission (GAEIB) took a contrary view in its Opinion on the Ethical Aspects of Patenting Inventions Involving Elements of Human Origin of 25th of September 1996 and argued that 'the traditional distinction between discovery (not patentable) and invention (patentable) involves, in the field of biotechnology, a particular *ethical* dimension.' Accordingly, 'knowledge related to the human body, or its elements is relevant to scientific discovery and cannot be patented.'[336] In their view, patents for inventions issued from the knowledge of a human gene or a partial human gene sequence are acceptable 'only if, on the one hand, the identification of the function attached to a human gene, or a partial human gene sequence allows new possibilities (for instance the production of new drugs), and, on the other hand, if the intended use of the patent is sufficiently specific and identified.'[337] Thus, for GAEIB, the decisive criterion for patent grants for human origin elements is not the mere technical intervention of isolating and reproducing the element, but the fact that the isolation and identification of the element allows *new possibilities*. The new possibilities, however, are already a standard requirement of novelty and industrial applicability, as laid down in the EPC, which also apply to biotech patents. Thus, GAEIB's position is in line with Article 5 approach from the Biotech Directive.

[336] Opinion No 8 of 25 September 1996 [54], on 'The ethical aspects of patenting inventions involving elements of human origin,' para 2.2
[337] Opinion No 8, para 2.5

### ii. Patenting of Cloned Human Beings

Another general difference between the US and the EU legislation concerning patents is that the EU legislator recognises '*ordre public'* and morality as grounds for exclusion from patentability[338] whereas the US patent law does not even address the matter. This was the main reason for the late introduction of the Biotech Directive. While genetic sequences were being patented in the US and Japan for decades before the introduction of the Directive, these inventions were considered unpatentable in Europe being considered against the public order or on grounds of morality. The Directive changed the existing practice in hoping to align the EU legislation with the US and Japanese legislation to include patenting of genetic material by specifying that it does not meet the criteria for exclusion of patentability based on morality grounds.[339]

Article 6 of the Biotech Directive contains the said provision on *ordre public* or morality and under its paragraph 1 stipulates that '[i]nventions shall be considered unpatentable where their commercial exploitation would be contrary to *ordre public* or morality; however, exploitation shall not be deemed to be so contrary merely because it is prohibited by law or regulation.' The same article explicitly declares processes for cloning human beings unpatentable (article 6(2)(a)). According to Recital 40, there is a consensus within the Community that intervention in the human germ line and the cloning of human beings offends against *ordre public* and morality, and it is therefore important to exclude unequivocally processes for modifying the germ line genetic identity of human beings and processes for cloning human beings from patentability.

Article 6(2) gives an exhaustive list of subject matter which is specifically excluded from protection. It includes:

(a) processes for cloning human beings;
(b) processes for modifying the germ line genetic identity of human beings;
(c) uses of human embryos for industrial or commercial purposes;

[338] Article 6(1)

[339] Unlike the US, Europe has dealt with policy issues relating to biotechnology at the legislative level. Much of Europe's substantive law on patentability comes from the Strasbourg Convention of 1963, which was the first serious attempt to harmonise the patent laws of the various European countries. See also Andrew Sheard, "Patenting Stem Cell Technologies in Europe." *Cold Spring Harbor Perspectives in Medicine* 5, no. 3 (2015): a021089. Available at https://www.ncbi.nlm.nih.gov/pmc/articles/PMC4355253/#FN2. Last accessed on 19 February 2022.

(d) processes for modifying the genetic identity of animals which are likely to cause them suffering without any substantial medical benefit to man or animal, and also animals resulting from such processes.

Given that therapeutic cloning could allow an individual's own cells to be used to treat or cure that person's disease, without risk of introducing foreign cells that may be rejected, cloning is vital to realising the potential of stem cell research and moving it from the lab into the doctor's office.[340] The question which rises form Article 6(2)(a) is whether it also applies to cloning cells and what constitutes a 'human being' in the sense of the said article and if so, how it affects cloning for therapeutic purposes. There are different definitions of 'human being' employed in current national legislations. The Biotech Directive itself does not provide such a definition, however, the Council in its Common Position explains that the words 'human beings' referred to the 'human being from the embryonic state.'[341] Furthermore, the Council emphasises that the word 'reproductive' was deliberately omitted as in 'reproductive cloning', since the adjective 'reproductive' could be too restrictive.[342] The National Research Council defines reproductive cloning as 'deliberate production of genetically identical individuals.'[343] However, the position adopted by bioethicist John Harris[344] as well as the esteemed British philosopher Grayling[345] that human reproductive cloning should not be necessarily banned based on the moral grounds only since it should be considered as a legitimate medical treatment for adults afflicted with non-viable gametes who want to have a genetically related child, for example. Hence, it can be

[340] The Value of Therapeutic Cloning for Patients – Biotechnology Innovation Organisation, available at https://archive.bio.org/articles/value-therapeutic-cloning-patients#:~:text=Therapeutic%20cloning%20could%20allow%20an,lab%20into%20the%20doctor's%20office. Last accessed on 21 Feb. 22.

[341] Common Position 26 February 1998, *Official Journal EC - C* - 8 April 1998, 110/(17), 30, point 35. Available at https://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=CELEX:51998AG0408(02):EN:HTML. Last accessed on 21 Feb. 22.

[342] Ibid

[343] National Research Council, *Scientific and medical aspects of human reproductive cloning*. National Academies Press, 2002. Available at https://www.ncbi.nlm.nih.gov/books/NBK223962/pdf/Bookshelf_NBK223962.pdf. Last accessed on 5 June 2022.

[344] John Harris, "Clones, genes, and reproductive autonomy: The ethics of human cloning." *Annals of the New York Academy of Sciences* 913, no. 1 (2000): 209-217.. Available at https://www.research.manchester.ac.uk/portal/files/32298212/FULL_TEXT.PDF. Last accessed on 3 June 2022.

[345] Anthony Grayling, 'We should not let baby Eve tempt us away from progress', *The Independent on Sunday*, 29 December 2002. Available at https://www.independent.co.uk/voices/commentators/a-c-grayling-we-should-not-let-baby-eve-tempt-us-away-from-progress-137578.html. Last accessed on 3 June 2022.

concluded that by excluding the term 'reproductive' from Article 6(2)(a), the Council has somewhat adopted the second position that reproductive cloning might still prove to be patent eligible subject matter.

### iii. Patenting embryonic stem cells

In the Opinion of the Advocate General of the Court of Justice for the European Union of 10 March 2011, certain inventions related to human embryonic stem cells were found not be patentable. In the case of *Brüstle v. Greenpeace Case C-34/10,*[346] several questions were referred to the CJEU concerning patenting of human embryonic stem cells (hESC). Two of those attracted the most attention: 'whether a stem cell obtained from a human embryo at the blastocyst stage constitutes a "human embryo" within the meaning of that provision'[347] and whether technical teaching is 'to be considered unpatentable even if the use of human embryos does not form part of the technical teaching claimed with the patent, but is a necessary precondition for the application of that teaching.'[348] In answering the first question, the Advocate General stated that 'any human ovum after fertilisation, any non-fertilised human ovum into which the cell nucleus from a mature human cell has been transplanted and any non-fertilised human ovum whose division and further development have been stimulated by parthenogenesis constitute a "human embryo" within the meaning of Article 6(2)(c) of the Directive.'[349] Concerning the second question posed here, the CJEU found that '[i]t is apparent from the observations presented to the Court that the removal of a stem cell from a human embryo at the blastocyst stage entails the destruction of that embryo'[350] and thus 'must be regarded as unpatentable'[351] finding the fact that 'destruction may occur at a stage long before the implementation of the invention' irrelevant.[352]

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[346] *Brustle v Greenpeace* concerns a referral from the Bundesgerichtshof (the Federal Court of Justice of Germany) to the European Court of Justice (ECJ) for an interpretation of three issues under the Biotechnology Directive. The patent was challenged by Greenpeace on the grounds of morality. The Bundespatentgericht (Federal Patent Court) ruled that the patent was invalid because it covered precursor cells obtained from human embryonic stem cells, processed for the production of those precursor cells. The defendant appealed against that judgment to the Bundesgerichtshof (Federal Court of Justice)

[347] Case C-34/10 Oliver Brüstle v Greenpeace eV, para 2

[348] C-34/10, para 23(3)

[349] C-34/10, para 38

[350] C-34/10, para 48

[351] C-34/10, para 49

[352] Ibid

b. Scope of Patent Protection

Chapter II of the Biotech Directive provides for the scope of biotechnological patents.

Article 8 gives protection to secondary products of an already patented biological material or process. That is, assuming there is a patent on a biological material, and this material has got specific characteristics due to an invention, patent protection is provided to biological material which is derived from the said patented biological material by means of propagation or multiplication in identical or divergent form provided it possesses the same specific characteristics.[353] Furthermore, not only do products of biological materials enjoy patent protection, but also do products of biological processes[354] if the said products are directly obtained through the process. Similarly, products of the material obtained from the process also fall under the scope of the patent if they are obtained by means of propagation or multiplication in identical or divergent form if they also possess the same specific characteristics.

As per Article 9, all material incorporating a product which contains or is consisted of patented genetic information, provided it is contained in and performs its function, falls within the patent scope. Some commentators have found that the Biotech Directive seems to introduce the 'function' as an additional condition to patentability of biotechnological inventions.[355] Moreover, while Article 5 in its provision employs the term 'genetic sequences,' Article 9 makes use of the term 'genetic information' to refer to the protected subject matter. Furthermore, difference in the wording of these two articles extends to 'industrial applicability' and function, respectively.[356] This provision raised the debate concerning purpose-bound patents since the Biotech

[353] Article 8(1)
[354] Article 8(2)
[355] Peter Heinrich, *PatG/EPÜ-Schweizerisches Patentgesetz/Europäisches Patentübereinkommen: Kommentar in synoptischer Darstellung*. Stämpfli Verlag, 2010. 'regardless of whether a sequence is completely technically produced or derived from a naturally occurring sequence, a function of the sequence must be specifically disclosed, or else there would be no "invention" and no industrial application.' in Jessica C. Lai, "Gene-related inventions in Europe: purpose-vs function-bound protection." *Queen Mary Journal of Intellectual Property* 5, no. 4 (2015): 449-473, Available at SSRN: https://ssrn.com/abstract=3053067
[356] Jessica C. Lai, "Myriad GENETICS and the BRCA patents in Europe: the implications of the US Supreme Court decision." *UC Irvine L. Rev.* 5 (2015): 1041. Available at https://www.law.uci.edu/lawreview/vol5/no5/Lai.pdf. Last accessed on 8 March 2022.

Directive stipulates that a certain function must be performed, that is, a purpose must be fulfilled in order for patent protection to be granted.[357]

Interpreting the 'function' of patented nucleotide sequences in accordance with Article 9, several questions need to be considered. Firstly, if product claims for nucleotide sequences are purpose-bound,[358] it would mean that one structure, which is a subject to a certain production process, is patentable as such only if it performs a certain purpose, that is, it has got a certain function, where it is incorporated. If so, therefrom arises the question of what if the process for production of the same sequence differs from the patented process but the same sequence performing the same function is obtained as a result of the new process.[359] Further questions which follow are how many separate patents could the patenting of a sequence involve and whether or not the patent covers the process, the result and the product in which the said sequence performs its function. The latter can be answered by means of Article 8(2) which allows for secondary patents but the ownership of the obtained sequence, that is the product, could be a subject to dispute. When a sequence is modified, it is modified to have a purpose but without its function it doesn't seem to have purpose.

If a certain DNA sequence is transcribed into RNA and further translated into a protein it performs a function, however, the purpose of the said translation does not necessarily have to be known. This means that according to the Directive, if a sequence codes a protein, then it performs a function without it having a specific purpose and as such it is patentable in Europe.

Furthermore, the wording of Article 9 also suggests that patent is granted to products of information, albeit genetic information. Information as such does not enjoy patent protection and Article 9 suggests that genetic information is to be treated differently from information in general. On the other hand, the purpose of the patent, among else,

[357] Ibid

[358] An example of such claims is the use of an existing medicament for the treatment of a new disease. See *Hospira UK Ltd vs Genetech Inc* [2014] EWHC 1094 (Pat).

[359] Lai (2015), 'Gene-related inventions in Europe..." *supra* note 355, p. 460 'DNA sequences that code for a protein, one must disclose which protein is produced from the sequences and what function the protein has.' This would suggest that it is the protein that is being patented since the function of the protein is the one which should be disclosed. If the only function of a DNA sequence is to code for proteins, then the relation between the sequence and the function is indirect. The questions that arises is whether the same sequence could be used for coding of a different protein.

is to share information so that it can be used by the public in return granting a monopoly right over the invention subject to such information. However, if the invention itself is nothing more than a mere information, genetic or otherwise, it would mean that monopoly is granted to the information itself thus effectively leaving it outside of public reach for the effective duration of the patent protection.

c. Exclusions from and Exceptions to Patentability

Patent scope is also determined in light of exclusions and exceptions provided by law. **Exclusions** to patentability include the subject matter that is considered not patentable subject matter regardless of whether the invention meets the criteria of novelty and inventive step. **Exceptions** to patent rights, on the other hand, involve uses of patented inventions which do not require permission or licence from the patent holder. That is, exceptions represent the limits to which patent protection is provided. Examples of exclusions include discoveries or methods of treatment whereas examples of exceptions could be compulsory licences, non-voluntary licences or statutory licences.[360]

A study commission by WIPO in 2010 and published in 2015 was conducted by the WIPO Standing Committee on the Law of Patents. It discusses exclusions and exceptions historically and finds that 'pharmaceutical compositions or medicines of all kind,' and 'schemes and combinations relating to credit and finance' were excluded from patentability in accordance with the French law of 1844. According to the Austrian law of August 1852, 'preparations of food, beverages, and medicines,' were excluded from patentability while discoveries, scientific principles, or purely scientific theorems, inventions or improvements which cannot be worked for reasons of public health, morals or safety, or as being contrary to the general interest of the state are excluded according to existing regulations. Article 6 of the Italian Patent Law of January 1864 specified that 'inventions or discoveries relating to trade which are contrary to law, morals, public safety', 'inventions or discoveries not relating to the manufacture of material objects', 'inventions or discoveries of a mere theoretical nature' and 'all kinds of medicines' were unpatentable.[361]

[360] WIPO Standing Committee on the Law of Patents SCP/15/3, Annex I, 2010, p. 7
[361] *Ibid* p. 13.

In many jurisdictions, genetical material is excluded from patentability.[362] In others, where patenting of genetical sequences is permitted, there are exceptions[363] which allow uses of the patented invention which, were it not for the exception, would constitute infringement of the patent right.

### 3.5. Patenting Biotechnology under the EPC

Biotechnology became explicitly patentable subject matter under the EPC upon the introduction of the Biotech Directive and the subsequent incorporation of its substantive provisions in the EPC. This part looks into the general patentability provisions of the EPC and the provisions governing biotechnological patents.

Article 52 of the EPC outlines the conditions of patentability. While it does not specifically define what an invention is, it provides for what a patentable invention is under the Convention. As per the article 52(1) EPC, 'European patents shall be granted for any inventions, in all fields of technology, provided that they are new, involve an inventive step and are susceptible of industrial application.'[364] Article 52(2) provides for what a patentable invention is by way of exclusion. Relevant is the exclusion of discoveries since they do meet the novelty criterion of Article 52(1), however, discoveries as such have no technical impact and therefore are not inventions. If put into practical use, on the other hand, newly discovered features of a known material or article, could represent a patentable subject matter.[365]

Article 52(2) reads:

> (2) The following in particular shall not be regarded as inventions within the meaning of paragraph 1:

[362] Latin America, Türkiye, India
[363] Developed countries.
[364] EPC
[365] For example, the discovery that a known material can withstand mechanical impacts cannot be patented, but a rail threshold made of that material can be patented. Finding a previously unrecognized substance in nature is also a mere discovery and therefore unpatentable. However, if it can be shown that the substance found in nature has a technical effect, it can be patented. An example of such a situation is a substance found in nature and found to have an antibiotic effect. Also, if a microorganism is found to exist in nature and produces an antibiotic, the microorganism itself may be patented as an aspect of the invention. Similarly, if a gene found to exist in nature, and a technical effect is detected, for example, its use in the manufacture of a particular polypeptide or in gene therapy, such application represents a patentable subject matter. *Guidelines for substantive examination of the European Patent Office*, Part C, Chapter 2,3 available at https://www.epo.org/law-practice/legal-texts/html/guidelines/e/c_iv.htm.

(a) discoveries, scientific theories and mathematical methods;
(b) aesthetic creations;
(c) schemes, rules and methods for performing mental acts, playing games or doing business, and programs for computers;
(d) presentations of information.

Article 52(3) complements Article 52(2) to emphasise that the exclusion of the subject matter or activities under Article 52(2) 'only to the extent to which a European patent application or European patent relates to such subject-matter or activities as such.'[366]

The exclusionary articles 53(a) and 53(b) also delineate the limits of patentability. Article 53(a) stipulates that patent shall not be granted in respect of invention the commercial exploitation of which would be contrary to *ordre public* or morality while article 53(b) excludes plant or animal varieties or essentially biological processes for the production of plants or animals from patentability, however, specifies that 'microbiological processes or the products thereof' shall not be subject to this exclusion.

Article 53(a) and article 53(b) read as follows:

European patents shall not be granted in respect of:
(a) inventions the commercial exploitation of which would be contrary to "*ordre public*" or morality; such exploitation shall not be deemed to be so contrary merely because it is prohibited by law or regulation in some or all of the Contracting States;
(b) plant or animal varieties or essentially biological processes for the production of plants or animals; this provision shall not apply to microbiological processes or the products thereof;

[366] Article 52(3) EPC

### 3.5.1. '*Ordre public*' and morality

The morality of patenting biological inventions, especially inventions relating to human body, is a subject to a never-ending philosophical debate that does not get old. '*Ordre public*' or morality clauses are present in article 53(a) EPC and some of its member states had already such clauses in their national laws[367] while others[368] introduced them upon adoption of the EPC. The said debate is ongoing since the notion of '*ordre public*' and morality is rather vague. However, the Boards of Appeal of the EPO offers guidance through its several rulings on the matter. Case T 356/93 from 21 February 1995 is the leading EPO Board of Appeal case on the '*ordre public*' and morality issue. This case relates to a dispute between Plant Genetic Systems (PGS) and Greenpeace on a patent related to plant cells resistant to glutamine synthetase inhibitors, made by genetic engineering.[369] According to Point 8 of the decision, the Board finds that 'the concept of patentability in the European patent law must be as wide as possible' and this is the predominant view and that accordingly, exceptions to patentability are narrowly construed. Furthermore, the Board joined the view that this approach applies equally in respect of the provisions of Article 53(a) EPC.[370] Point 11 emphasises that 'under Article 53(a) EPC, the relevant question is not whether living organisms are excluded as such, but rather whether or not the publication or exploitation of an invention related to a particular living organism is to be considered contrary to "*ordre public*" or morality.'[371]

The Board further finds that the second half of Article 53(a) EPC[372] clarifies that the assessment of whether or not a particular subject-matter is to be considered contrary to either '*ordre public*' or morality is not dependent upon any national laws or

[367] Article 5 of the Dutch Patent Act already provided for '*ordre public*' and morality (Geen octrooi wordt verleend voor voortbrengselen of werkwijzen, waarvan het openbaar worden strijdig zou zijn met de openbare orde of de goede zeden.) while a similar clause was laid down in Article 1 (2) (1) of the 1877 German Patent Act.
[368] The Belgian Patent Act of 1854 implemented the '*ordre public*' and morality clauses only after it was adopted by the EPC.
[369] Board of Appeal EPO, Decision 21 February 1995, Case T 356/93, Official Journal EPO, 1995, 545. Available at https://www.epo.org/law-practice/case-law-appeals/recent/t930356ex1.html . Last accessed on 17 February 2022.
[370] *Ibid*.
[371] See Point 11 of Case T 356/93, Official Journal EPO, 1995, (545), 559.
[372] Article 53(a) EPC 'that the exploitation shall not be deemed to be so contrary merely because it is prohibited by law or regulation in some or all of the Contracting States'

regulations.[373] Therefore, particular subject-matter shall not automatically be regarded as complying with the requirements of Article 53(a) EPC merely because its exploitation is permitted in some or all of the Member States.[374]

Protection of public security and the physical integrity of individuals as part of society covered by the '*ordre public*' concept also includes the protection of environment.[375] The Board finds that the concept of morality is related to the belief that some behaviour is right and acceptable, whereas other behaviour is wrong, this belief being founded on the totality of the accepted norms which are deeply rooted in a particular culture. The culture inherent in the European society and civilisation is the culture in question and accordingly, inventions the exploitation of which is not in conformity with the conventionally accepted standards of conduct pertaining to this culture, are to be excluded from patentability as being contrary to morality.[376] This provision is unlikely to be invoked frequently and whether or not an invention meets the conditions of Article 53(a) can be examined by applying a fair test if it is probable that the public in general would regard the invention as so abhorrent that the grant of patent rights would be inconceivable.[377] However, if the invention can be exploited in a manner that does not infringe "*ordre public*" or morality, then such invention should not be denied patent protection pursuant to Article 53(a).[378]

The previously discussed patents on CRISPR technology found themselves to be subject to an exact such inquiry as soon as they were granted in Europe. However, decisions of the EPO Board of Appeal seem to be taking a different turn lately, especially in light of the CRISPR technology. As discussed in the previous chapter, the Nobel prize winning technology found itself not only before the USPTO Board of Appeal but also before the EPO Board of Appeal. In addition to being challenged by the Broad Institute on the same 'inventive step' grounds as in the US, CRISPR in

[373] See Point 7 of Case T 356/93, Official Journal EPO, 1995, (545), 559.
[374] Ibid.
[375] See Point 5 of Case T 356/93, Official Journal EPO, 1995, (545), 557. Cf. point 14, Official Journal EPO, 1995, (545), 560.
[376] See Point 6 of Case T 356/93, Official Journal EPO, 1995, (545), 557.
[377] G-II, 4.1 Matter contrary to "*ordre public*" or morality - Guidelines for Examination. Available at https://www.epo.org/law-practice/legal-texts/html/guidelines/e/g_ii_4_1.htm#:~:text=A%20fair%20test%20to%20apply,patent%20rights%20would%20be%20inconceivable.&text=The%20mere%20possibility%20of%20abuse,patent%20protection%20pursuant%20to%20Art. Last accessed on 18 February 2022.
[378] Ibid

Europe was challenged on grounds of morality and '*ordre public*.' As editing the genome of human embryos can modify the germline identity of human beings, it can also be used to eradicate hereditary diseases in new-born babies and create resistance to life-threatening conditions for future generations.

The first European patent granted to the Regents of the University of California, the University of Vienna and Emmanuelle Charpentier (EP2800811), concerning the basic CRISPR method, was granted on 7 April 2017.[379] Opposition Proceedings at the EPO were filed subsequently by seven parties, with oral proceedings taking place on 5–7 February 2020.[380] The foundational patent on CRISPR-based genome editing was upheld in amended form[381] in EPO opposition proceedings, where the patent and the invention to which it relates were found to meet the requirements of the EPC, that is, the invention was found to be in line with Art. 53(c) and Rule 28, according to which objection raised by only one of several opponents against EP2800811. The Opposition Division's provisional opinion was fairly dismissive of the Article 53(c) and Rule 28 objections.

The second European patent, claiming compositions and uses of a chimeric version of the Cas9 protein, most often associated with use in regulation of gene expression as opposed to direct editing of the genetic code itself, was granted on 26 January 2018.[382] Opposition proceedings against the grant of the second European patent were initiated by four parties, while the most recent European patent for a CRISPR-related invention claiming methods and compositions of using CRISPR-Cas9 to modify DNA and regulate gene activity in eukaryotic cells, including kits to carry out such work, was granted on 1 March 2019. The first opponent filed an EPO Opposition almost immediately on 1 April 2019. On 29 June 2021 the Opposition Division adopted a decision to revoke the European patent 3 241 902 with the title 'methods and

[379] EP2800811: https://register.epo.org/application?number=EP13793997&tab=main. Last accessed on 25 May 2023.
[380] Duncan Matthews, "Access to CRISPR Genome Editing Technologies: Patents, human rights and the public interest." In *Access to Medicines and Vaccines: Implementing Flexibilities Under Intellectual Property Law*, pp. 105-133. Springer International Publishing, 2022. Available at https://link.springer.com/chapter/10.1007/978-3-030-83114-1_4#Fn6. Last accessed on 25 May 2023.
[381] EP3401400, auxiliary request 10 of 5.8.2020; available at https://register.epo.org/application?documentId=E432G1NE8139DSU&number=EP18152360. Last accessed on 25 May 2023.
[382] EP3241902: https://register.epo.org/application?number=EP17163434&tab=main. Last accessed on 25 May 2023.

compositions for RNA-directed target DNA modification and for RNA-directed modulation of transcription,' against which an appeal to the Technical Board of Appeal was lodged, however, it was rejected as inadmissible.[383] As of the time of writing, the Decision of the Opposition has not yet been published.

### 3.5.2. Biotechnological Inventions under EPC

Biotechnological inventions are provided for by Chapter V of the Implementing Regulations to Part II of the EPC.[384] Rule 26(2) governs the general provisions and definitions and defines biotechnological inventions as 'inventions which concern a product consisting of or containing biological material or a process by means of which biological material is produced, processed or used.' The same definition is found in Article 3 of the Biotech Directive,[385] which also includes the patentability requirements of novelty, inventive step, and susceptibility of industrial application. Rule 26 further defines biological material,[386] plant variety,[387] biological process[388] and microbiological process.[389] These definitions incorporate the same definitions found in Article 2 of the Biotech Directive. Rule 27(a) providing for the protection of biotechnological inventions incorporates Article 3(1) of the Biotech Directive as well as Article 4(2) and (3), which govern the exclusions from patentability. Exclusions to patentability of biotechnological inventions are governed by Rule 28 and its first paragraph refers to Article 53(a) pertaining to '*ordre public*' or morality and accordingly particularly leaves out of patentability of processes for cloning human beings,[390] processes for modifying the germ line genetic identity of human beings,[391]

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[383] D E C I S I O N of Technical Board of Appeal 3.3.08 of 1 March 2022. Available at https://www.epo.org/law-practice/case-law-appeals/pdf/t210950eu1.pdf. Last accessed on 25 May 2023.
[384] Chapter V, EPC. Available at https://www.epo.org/law-practice/legal-texts/html/epc/2020/e/rcii_v.html. Last accessed on 13 May 2022.
[385] See *supra* Part 3.4 on the Biotech Directive patentability provisions
[386] Rule 26(3) 'Biological material' means any material containing genetic information and capable of reproducing itself or being reproduced in a biological system.
[387] Rule 26(4) 'Plant variety' means any plant grouping within a single botanical taxon of the lowest known rank, which grouping, irrespective of whether the conditions for the grant of a plant variety right are fully met.
[388] Rule 26(5) A process for the production of plants or animals is essentially biological if it consists entirely of natural phenomena such as crossing or selection.
[389] Rule 26(6) 'Microbiological process' means any process involving or performed upon or resulting in microbiological material.
[390] Rule 28(1)(a) EPC
[391] Rule 28(1)(b) EPC

uses of human embryos for industrial or commercial purposes[392] and processes for modifying the genetic identity of animals which are likely to cause them suffering without any substantial medical benefit to man or animal, and also animals resulting from such processes.[393] The same subject matter is excluded from patentability under Article 6 of the Biotech Directive. Rule 29 mirrors Article 5 of the Directive in its entirety and precludes patenting of the human body at its various stages of its formation and development[394] while allowing for patent protection of elements isolated from the human body or otherwise produced by means of a technical process, including gene sequences and partial gene sequences.[395] Essentially, Rules 26 to 29 incorporate patentability provision of the Biotech Directive entirely.

The interpretation of *ordre public* or morality was restrictively interpreted before 2009.[396] The grounds for establishing this an approach was a 1994 case of Howard Florey Institute /Relaxin[397] involving a DNA sequence application for a European patent which sequence was isolated from the human body by means of recombinant techniques.[398] On the ground that DNA represents 'life' the application was opposed as immoral under European law, immorality being found in the isolation of the DNA relaxin gene from tissue of a pregnant woman which would constitute an abuse of the woman whose mRNA had been isolated thus effectively representing return to slavery.[399] The argument was rejected on the grounds that, among other, the woman had consented to donate their tissue 'within the framework of necessary gynaecological operations' and that 'DNA is not 'life' but a chemical substance which carries genetical information and can be used as an intermediate in the production of proteins which may be medically useful.'[400] As to the morality issues, the EPO

[392] Rule 28(1)(c) EPC
[393] Rule 28(1)(d) EPC
[394] Rule 29(1) EPC and Article 6(1) of the Biotech Directive
[395] Rule 29(2) EPC and Article 6(2) of the Biotech Directive
[396] Justine Pila, "Intellectual property rights and detached human body parts." *Journal of medical ethics* 40, no. 1 (2014): 27-32, p. 28. Available at https://citeseerx.ist.psu.edu/viewdoc/download?doi=10.1.1.895.7580&rep=rep1&type=pdf. Last accessed on 5 June 2022.
[397] T0272/95 *Relaxin/Howard Florey Institute* (Unreported, Boards of Appeal, European Patent Office), 23 October 2002), [4], [6]–[7]; cf. Howard Florey/Relaxin [1995] EPOR 541.
[398] Even before the incorporation of the Biotech directive in the EPC, isolated DNA sequences had been confirmed by earlier EPO case law.
[399] *Ibid*
[400] *Ibid*

concluded that among the EPC Contracting States existed no 'overwhelming consensus' that the patenting of human genes was 'abhorrent.'

When it comes to embryonic stem cell, the EPO took a similar approach to the CJEU in the *Brüstle* case[401] when deciding on case G 0002/06, Use of embryos/WARF.[402] European Patent No. 0770125 was filed in 1996 with James Thomson describing a method by which primate (including human) stem cells derived from an embryo can be maintained *in vitro* without losing their potential to differentiate into any cell of the body. The question at hand primarily concerned the application of Rule 28(c) EPC, formally Rule 23d(c) EPC, which the Enlarge Board answered positively further finding that the said rule forbids patenting of a method 'which necessarily involved the destruction of the human embryos' for preparation of the claimed product 'even if the said method is not part of the claims.'[403] This decision shoed the divergence of the EPO from the practices of the USPTO, which granted three human stem cell patent to WARF.[404]

Rules 30 to 34 of the Chapter V pertaining to biotechnological inventions concern procedural European patent application requirements and fall outside the limits of this work.

### 3.6. Conclusion

Rather than discussing the morality of patenting embryonic stem cells deriving from a fertilised or unfertilised ova, access to the potential therapeutic inventions deems deeper attention. The courts find patenting of such invention to be contrary to '*ordre public*' or morality as prescribed by patent legislation in many national jurisdictions, however, it seems that ethically, the human life in its embryonic form is more valuable than the life of an actual human being whose life might be saved if such technologies

[401] See *supra* Part 1.a.iii
[402] G 0002/06, Use of embryos/WARF, Decision of the Enlarged Board of Appeal dated 25 November 2008, OJ EPO, 2009, 306.
[403] Ibid
[404] U.S. Patents Nos. 5,843,780 (1st December 1998), 6,200,806 (13th March 2001) and 7,029,913 (18th April 2006). The patents were challenged by Consumer Watchdog (CW) and claims of 780 and 806 were narrowed to include only stem cells deriving from 'pre-implantation embryos' in 2008. For more details see Sarah E. Fendrick and Donald L. Zuhn. "Patentability of Stem Cells in the United States." *Cold Spring Harbor Perspectives in Medicine* 5, no. 12 (2015): a020958. Available at https://www.ncbi.nlm.nih.gov/pmc/articles/PMC4665039/. Last accessed on 14 May 2022.

are accessible. Battles fought against patents for the purposes of access seem to be lost on every front, however, legislator and courts alike do care for embryos which have the potential to be developed in human being more than they care about the actual human beings. It could be argued that the court decisions are made in consideration of the access restrictive patents, however, in light of the argument that patents incentivise research and development, courts seem to favour human embryonic cells not to be used at all rather than patented, again, favouring embryonic life to actual human life.

The discussion on '*ordre public*' and morality is a vast one and with many implications at that. It is hugely dependent on cultural context of different countries and human values differ drastically throughout jurisdictions. Such considerations are not included in the US patent law, for example. In Europe, the topic bears a lot of weight. Notwithstanding, the access to affordable medicine does not seem to be considered as a question of '*ordre public*' or morality compared to commercialisation of patented medical inventions. Practice shows that the latter is a matter of fact as it is, and different alleys should be sought for in order to ensure such access. This is further discussed in Chapter 6 below.

## 4. PATENT LAW IN TURKEY – THE PATH THUS FAR

The patent rights are monopolist right as are all intellectual property rights. The purpose of these monopolies is, of course, to provide right holders competitive advantage and enable them to dispose of their patented product exclusively and at a price of their choosing without the constrains of the competitive market.

Monopolies are not as new of a concept in Türkiye, and neither are patents. As discussed later, the Turkish legal regulation of patent rights is almost as lasting and as similar regulation to those in the western world. In order to provide a cleared picture of the patent protection in Türkiye today, it is important to briefly discuss the historical trade customs in the Ottoman Empire and see how monopolies developed and still, today, thrive in the form of intellectual property rights.

### 4.1 Monopolies in the Ottoman Empires

According to the website[405] of the Turkish Industrial Property Office (Türk Patent), innovation was a driving force within the Ottoman society centuries ago, in the 13 and 14th century, when trade unions or guilds were established based on separate inventions developed by inventors. The same source attributes these activities to a specific guild known as "ahilik müessesesi" or “ahi community”. Whereas many sources exist for the guild system in the Ottoman Empire as early as the 17th century, however, no specific written documents can testify for the developments in trade before that.[406]

The guilds, indeed, were monopolies in their own right, and the number of members of a certain guild was limited as was the territory where they were able to sell their goods or practice their craft.[407] In order for a certain guild to function, they were in possession of a written permission called *gedik*, which literally translates to ‘breach,’ granting access to practice within a given guild. The number of *gediks* was limited to no more than 50[408] and these could be obtained only after a *gedik* was vacant, which

[405] A brief history of the practices serving as the foundation for the patent system in Türkiye can be found at https://www.turkpatent.gov.tr/TURKPATENT/commonContent/History. Last accessed on 24/06/2020

[406] Gabriel Baer, "Monopolies and restrictive practices of Turkish guilds." *Journal of the Economic and Social History of the Orient* 13, no. 1 (1970): 145-165.

[407] *Ibid* p. 148

[408] Charles White, *Three years in Constantinople: Or, domestic manners of the Turks in 1844. In 3 vol*. Vol. 1. Colburn, 1846, p. 148. Available at https://catalog.hathitrust.org/Record/011537312. Last

usually happened when a *gedik* owner would die.[409] Then the *gedik* could be transferred to another person, which was usually the son of the passed owner since a given craft or trade was commonly a family business. Occasionally, the *gedik* could be passed on to an apprentice (çırak) or a journeyman (*kalfa*), the latter being a veteran or a skilled person.[410] However, almost never were these *gediks* transferred outside of the guild community, and even more so, they were restricted to a given religious or ethnical group. Namely, certain crafts were reserved only for the Muslim community whereas others were practiced exclusively by non-Muslim members.[411] The *gediks* were issued by a judge (*kadı*) and they had the power to cut or increase the number of *gediks* in a guild depending on the societal needs. Hence, the guild system was endorsed and maintained by the central government, that is, the sultan, and served the purposes of the empire.[412] The sultan would issue a *firman*, which is a decree or royal mandate dictating the terms of a *gedik*. For example, a *firman* was issued prohibiting the transfer of a physician *gedik* to foreigners.[413]

It was not until the industrial revolution in Europe that the Ottoman system began to change when European forces became more powerful with the mass production of goods and thus, more competitive compared to the manual labour still in high regard within the Ottoman society.[414]

accessed on 23 April 2023. The 'goodwill' is White's translation of *gedik*. Also, Baer, *supra* note 406, p. 162

[409] Osman Nuri Ergin, "Mecelle-I Umur-u Belediyye, vol. 1." *Istanbul: Matbaa-i Osmaniye* (1922). pp. 559, 656, 658 in Baer, *supra* note 406, p. 162

[410] Baer, *supra* note 406, p. 163

[411] *Ibid*; Baer gives specific details on the separate guilds and crafts practiced by the different ethnicities within the Ottoman Empire.

[412] *Ibid*, p. 164

[413] Ergin, pp. 657-8 in Baer, *supra* note 406, p. 154

[414] Mehmet Seyitdanlioğlu, "Tanzimat dönemi Osmanlı sanayii (1839-1876)." *Tarih Araştırmaları Dergisi* 28, no. 46 (2009): 53-69, p. 54. Available at https://dergipark.org.tr/en/download/article-file/782064. Last accessed on 4 June 2022.

## 4.2 Treaty of Balta Limani in the Tanzimat Period

With the adoption of the Treaty of Balta Limani,[415] or the Anglo-Ottoman Treaty, the Ottoman Empire had to abolish all its monopolies and give British merchants and their collaborators full access to all Ottoman markets while taxing them equally to local merchants.[416] The treaty coincides with the beginning of the Ottoman reformation period, Tanzimat,[417] which aimed at modernization and reorganization of the Ottoman Empire.

The centuries long competitive advantage, and even superiority in trade, the Ottoman Empire had before the treaty was lost to countries such as France and Austria, especially England upon the Anglo-Ottoman Treaty of 1838 enabling abandonment of the protectionist approach of the Ottoman Empire, and lifting of restrictions on foreigners' commercial activities.[418] This led to the disadvantage the small scale producers faced when the cheap and abundant European products entered the Ottoman market.[419] The decline seen by the weaving sector continued throughout the 19th century and in the last quarter of the century, the Ottoman trade was crippled under the financial clamps of Europe.

The Ottoman Empire put a lot of effort to gain competitive advantage over the west. Exhibitions were seen as events worthy of participation since local products could be

[415] M. Şükrü Hanioğlu, (1992) 'Batılılaşma' in: Kate Fleet, Gudrun Krämer, Denis Matringe, John Abdallah Nawas, Everett K. Rowson, and Roger Allen, eds. *The Encyclopaedia of Islam Three*. Brill, 2019. *The Encyclopaedia of Islam Three*. Brill.

[416] V. Necla Geyikdağı, "Foreign investment in the Ottoman Empire, international trade and relations." *Osmanlı Araştırmaları* 40, no. 40 (2011): 453-457, p. 453. Available at < https://dergipark.org.tr/en/pub/oa/issue/10938/130741>. Also, Serkan Demirbaş, "The Treaty of Balta Limani's Role in Anglo-Ottoman Relations During the Mehmet Ali Problem." *Tarih Okulu Dergisi* (2015): 233-251. Available at https://johschool.com/Makaleler/421846186_9.%20SERKAN%20DEM%C4%B0RBA%C5%9E.233-251.pdf. Last accessed on 12 April 2023.

[417] Tamzimat is a period of reform which began in 1839 and ended in 1976, which is considered the year when the Ottoman Constitutional Era began.

[418] Tolga Akay, "Osmanlı Devleti'nde Fikri Mülkiyet (1850-1914)." *Unpublished PhD Thesis* 68 (2015), p. 145

[419] The weaving sector felt the first blow as the Ottoman local weaving was rapidly dropping. The number of silk looms, one of the advanced weaving centers in Shkodra, had a production of 6000 silk looms in 1812 compared to decreased to 400 in ten years time. The number of looms in Tarnova was 2000 in 1812 and decreased to only 200 in the beginning of the 1830s. For further details, Rifat Önsoy, "Tanzimat Dönemi Sanayileşme Politikası 1839-1876." *Hacettepe Üniversitesi Edebiyat Fakültesi Dergisi* 2, no. 2 (1984), p. 1841. Available at https://dergipark.org.tr/en/download/article-file/612188. Last accessed on 23 April 2023.

displayed and subsequently traded with other countries. These exhibitions[420] provided the incentive for the local rise of inventions. Given the at-the-time interests of the Ottoman Empire, military and medical inventions were the priority, the Ottoman Empire granted concessions and licences to increase investment in the manufacturing industry. Licences were narrower than concessions and the monopoly right granted by concessions was not seen in the licences.[421] It could be argued that these are comparable to current non-exclusive and exclusive licences, respectively, granted for exploitation of patented inventions, only the granting party being the state rather than the patent holder. Due to the concessions granted by the state, many factories in industries such as the industry for manufacture of metal products were founded.[422]

It is known that the Ottoman State gave awards to inventors who invented something useful, according to the nature of the invention. However, at a time when the patent system was not yet implemented, the inventors made concession requests to obtain income from their inventions and to protect themselves from competition in legal terms. The state started to give concessions under certain conditions by evaluating such concession requests. Inventions were granted legal protection by the concession procedure until the İhtira Beratı Kanunu entered into force.[423]

The struggle for competitive advantage over Europe as well as the ongoing practice of concessions for inventions led to the adoption of the *İhtira Beratı* law on 23 March 1879.[424] The French Law was taken as an example after which *İhtira Beratı* law was drafted. Similar to the French Law, the Ottoman law excluded medicines from patentability since this enabled market grabs and rise of medication prices that the local population could not afford. As discussed further on, even with the adoption of the Decree Law 551 on the Protection of Patent Rights[425] (hereinafter Decree Law 551) in 1995, Türkiye was not inclined to grant protection of pharmaceutical product straight

[420] Vedit İnal, "The eighteenth and nineteenth century Ottoman attempts to catch up with Europe." *Middle Eastern Studies* 47, no. 5 (2011): 725-756, p. 742.
[421] A. Gündüz Ökçün, "XIX. Yüzyılın ikinci yarısında imalat sanayii alanında verilen ruhsat ve imtiyazların ana çizgileri." (1972), p. 136. Available at https://kitaplar.ankara.edu.tr/xmlui/handle/20.500.12575/51882. Last accessed on 29 March 2023.
[422] Baer, *supra* note 406, p. 161; Also Ökçün, *supra* note 421, p. 136.
[423] Akay, *supra* note 418, pp. 186-187, referencing BOA, ŞD, Dossier No: 1173, Folio No: 19, 1.S.1286
[424] Law of the 20th Day of the Month of Rabia Z, A, H. 1297 (February 18, 1879)
[425] Decree-Law No. 551 of 24.06.1995 on the Protection of Patent Rights, OG No: 22326, 27.06.1995 (551 Sayılı Patent Haklarının Korunması Hakkında Kanun Hükmünde Kararname)

away. It was only in 1999 with the Decree Law 566 amending the Decree Law 551 that the pharmaceutical products were granted patent protection.[426]

### 4.3 Privileges granted before the İhtira Berat Law

The Turkish term 'İmtiyaz' or 'concession' basically expresses privilege or distinction. It is a gratitude, that is, a versatile concept that changes its frame and meaning depending on the reason for the grant. Concessions could be granted in many political, religious, and commercial ways. Special permits deriving from the concession were granted to a congregation while judicial, financial, administrative, and diplomatic privileges were also granted to foreigners in the country and the concession also covered private entities who were allowed to monopolize public goods or a public service for profit at their own expense.[427]

Consequently, beginning in the 19th century, the privilege procedure became widespread due to reasons such as the expansion of the service sector and the attempts to eliminate the backwardness of the Ottoman Empire against European states. Almost all kinds of services were subject to privilege from the second half of the XIX century. Secondary sources indicate that concessions were made for long periods in many areas such as railway, river transport, agricultural irrigation projects, mine operation, drinking water transportation, and lighting of cities.[428]

The Ottoman State also gave privileges to the capital owners, regardless of the indigenous-foreign discrimination, especially in large projects.[429]

The main policy pursued in the concessions given by the Ottoman State for inventions was in harmony with the modernization process that was felt in almost the entire 19th

[426] Decree Law 566 amending the Decree Law 551
[427] Seda Örsten Esirgen. "Osmanlı Devleti'nde yabancılara verilen kamu hizmeti imtiyazları." *(No Title)* (2012). p. 6. Available at https://dergiler.ankara.edu.tr/xmlui;/handle/20.500.12575/33983. Last accessed on 23 April 2023.
[428] Konya Plain Irrigation Project was tendered to Anadolu Railway Company for five years, BOA, İ. DUİT, Dossier No: 84, Folio No: 53, 04.L.1331 also the privilege of transporting potable water from Istanbul to Buyukada with a steam machine, BOA, İ.MMS, Dossier No: 82, Folio No: 3564, 22.C.1303 in Akay, p. 160
[429] Esirgen, *supra* note 427, p. 10 – 11.

century starting from the end of the 18th century with the reforms introduced by Sultan Selim III, known as Nizam-i Djedid, which were primarily military reforms.[430]

The need for transfer of technologies was also recognized and efforts were made to acquire the necessary technological knowledge by utilizing qualified foreign labour force in addition to the privileges granted to inventors directly in order to attract new inventions to the country.[431] In this regard, the technology transfer needed was the primary reason for concessions for inventions and the fact that more than half of such concessions were granted to foreigners goes in line with it.[432]

It is important to mention that the rules established for granting invention concessions resembled today's most basic patent concepts. Namely, the invention to which concession was to be granted had to be useful and had to be feasible. This corresponds to the current patent requirement for industrial applicability. However, inventions which could turn agricultural products into monopolies were excluded from protection.[433] Example of this is the request for 25 years of concession over a method for production of a plant species, which was denied, and instead a 5-year license was granted, and the licensee was exempt from tax during this five-year period.[434]

Tolga Akay[435] in his doctoral dissertation provides details on the period of concessions requested and granted and identifies the grants to coincide with the periods of protection granted for inventions in France at the time. The Ottoman ambitions to compete with European trends justifies the similarities between conditions for granting concessions and patents for inventions. Accordingly, during the concession period, the holder had the right to manufacture and sell their invention within the borders of the

[430] M. Şükrü Hanioğlu, "*A Brief History of the Late Ottoman Empire" Princeton University Press,* 2008, pp. 55–71.
[431] *Ibid*
[432] Rahmi Deniz Özbay and Yaşar Bülbül. "Osmanlı Devleti'nde Bir Teknoloji Transferi Yöntemi Olarak Yabancı İşgücü İstihdamı." *Tülin Aren Armağanı. İstanbul: Pamuk Yayınları* (2009): 189-218, p. 190. Available at https://mimoza.marmara.edu.tr/~rahmideniz/eserler/teknoloji.pdf. Last accessed on 29 March 2023.
[433] The current international legal framework also provides for protection of plant and seed varieties separate from the patent protection. See International Convention for the Protection of New Varieties of Plants (UPOV Convention 1991 Act) of December 2, 1961, revised in 1972, 1978 and 1991. Available at https://www.upov.int/edocs/pubdocs/en/upov_pub_221.pdf. Last accessed on 4 April 2022.
[434] BOA, İ. ŞD, Dossier No: 9, Folio No: 480, 05. Ca.1285.
[435] Akay, *supra* note 418, p. 146.

Ottoman State. Not unlike the current patent rights, nobody other than holder would be able to produce and sell the invention, and in case of infringement, the holder had the right to take away the infringing product or seek its destruction. As previously mentioned, foreigners also had the right to seek concession within the Ottoman Empire, but these were required to provide proof of privileges granted in their respective countries.[436]

Similar condition for making inventions public were available to Ottoman denizens, too. Namely, they used exhibitions to promote their new inventions but there were also fears of theft upon making the inventions know due to the rise of industrial espionage throughout Europe.[437]

Furthermore, privilege of the Ottoman State to the inventions also involved rights for it to be transferred or sold. In order for this right to be exercised, the state's permission had to be obtained.[438] Fees were charged for the privilege of concession, and they varied from one to another grant. The fees were paid in *Mecidiye* Liras, or golden liras, and they could amount to ten for the first year and reduced to five for the subsequent years.[439]

Public opinion differed regarding the fees due for the concessions. Rather than seeing them as encouragement for inventing, some considered them to be harmful practice making their work difficult. The fees seem to have overweighed the benefits of decreased taxes.[440]

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[436] The concession period for a French citizen who invented industrial stone for use in buildings was determined by taking into account the concession he received in France. The inventor was asked to deliver a copy of the license he received in France to Ticarethane-i Âmire within three months. In BOA, A. MKT. NZD, Dossier No: 276, Folio No: 70, 4.B.1275 in Akay, *supra* note 418, p. 164.
[437] Özbay, *supra* note 432, p. 194. Also, Ha-Joon Chang, "Regulation of foreign investment in historical perspective." *The European Journal of Development Research* 16, no. 3 (2004): 687-715, p. 695. Available at https://media.law.wisc.edu/m/myftc/foreign_investment1.pdf accessed on 29 March 2023
[438] *BOA*, A. MKT. NZD, Dossier No: 276, Folio No: 70, 4.B.1275 in Akay, *supra* note 418, p. 165.
[439] *Ibid*. Examples of the differences between the fees paid include a concession issued in 1864, which involved fifteen liras fee for the first year followed by five liras fee for the following years. A concession given to a British citizen who lived in İzmir involved a five liras fee whereas the concession fee for the cotton washing machine invented in 1867 increased to twenty liras for the first year and ten years for the subsequent years. On the other hand, another concession of 1869, again involved a fee of ten followed by five liras fee.
[440] BOA, ŞD, Dossier No: 1173, Folio No: 19, 1.S.1286 in Akay, *supra* note 418, p. 165.

The beginnings of the İhtira Beratı Law can be seen with the introduction of "bröve" or badge system which closely resembled the European practice of granting badges as a means of distinction or honour of an inventor. Originating from military practices, they were seen as quality that will contribute to development. The enactment of the İhtira Beratı Law had the same purpose of rewarding inventions from which the country's industry could benefit, that is, would contribute to the domestic technology development.[441]

Having in mind that the level of development of the Ottoman State at the time did not seem to have the conditions for domestic technology development, legal infrastructure was necessary for foreign technology transfer to take place. Scientists, engineers, or industrialists of the time refused to work in countries where the technology they create was not provided legal protection. Consequently, entrepreneurs willing to produce their new technologies in the Ottoman State would examine the legal protection provided by the state, which proved to be a driving factor that accelerated the creation of legal infrastructure for inventions.[442] This is not much dissimilar to the current conditions since companies still refuse to invest in countries where effective intellectual protection system is not set in place.[443] It is one of the very reasons why countries are encouraged to implement intellectual rights protection and rip the benefits from foreign investments.

### 4.4 The İhtira Beratı Law

Succeeding the practice of granting privileges for invention by concessions, the İhtira Beratı Law is the first Turkish law granting so called 'Certificate for Invention.' The term '*İhtira'* means 'invention' and '*berat'*, 'certificate' or 'licence.' As previously mentioned, the law was introduced in 1879 in order to allow new

[441] BOA, İ. DUİT, Dossier No: 99, Folio No: 8, 08.R.1340 in Akay, *supra* note 418, p. 188.
[442] The incentive for the introduction of stronger intellectual property protection in countries which are considered to be less developed than the western countries, and proportionally provide rather loose protection of the said rights, is the same as today as it was a century and a half in the Ottoman Empire. New products are introduced on markets which provide suitable enough intellectual property legal protection whereas the lack of it dissuades them from entering these markets.
[443] Mitchel B. Wallerstein, Mary Ellen Mogee, and Roberta A. Schoen, eds. *Global dimensions of intellectual property rights in science and technology*. Washington, DC: National Academy Press, 1993, p. 111. Available at https://nap.nationalacademies.org/read/2054/chapter/9#111. Last accessed on 12 April 2023.

technologies to be imported in the Ottoman Empire and thus enable the society to catch up with the western development.

Not unlike in the Ottoman Empire, the Venetian Patent Statute of 1474, which is the law recognised as the first law on patents in the world,[444] was preceded by granting concessions for innovative works. The law provided grant of patents for 'any new and ingenious device, not previously made' requiring them also to be useful. In this sense, contemporary patent laws echo these patentability conditions just as the İhtira Beratı Law took the French Patent Law of 5 July 1844 as its example.[445] For the sake of acquiring a wider picture of patent protection development in Türkiye, the substantive provisions as well as some procedural provisions are briefly outlined below. Secondary sources[446] provide insight into the wording of the original law, however, the translation of the same law as recorded in 1886 by Benjamin Vaughan Abbott[447] is used for the following discussion.

### 4.4.1 Substantive provisions of the İhtira Beratı Law

Article 1 provided that the right to benefit from *hiref*, which referred to professions or arts in the Ottoman Empire, and any kind of discovery, invention or improvement in industry belongs to the inventors, explorers and *muslihler*. Such right was to be enjoyed only under the conditions provided by the law and the period determined by the state. Article 1 states:

> 'Every new discovery, invention, or improvement in any branch of industry, confers on its author, under the conditions and for the time hereinafter mentioned, the right to work the said discovery, invention, or improvement for his own benefit. This right is confirmed by a *berat* (patent) delivered by the government.'

[444] Stephen Pericles Ladas, *Patents, trademarks, and related rights: national and international protection*. Vol. 1. Harvard University Press, 1975, p. 7.
[445] Ayşegül Sezgin Huysal, *İlaç patenti*. Marmara Universitesi (Türkiye), 2009.
[446] İhtira Beratı Kanunu, 1. Madde. Düstur, Zeyl 1, s. 74, 11 Rebiülahir 1297, in Akay, *supra* note 418, pp. 171-179
[447] Benjamin Vaughan Abbott, "The Patent Laws of All Nations: Algeria− Türkiye" Washington: C. R. Brodix, 2009, pp. 571-580. Available at https://catalog.hathitrust.org/Record/007685028. Last accessed on 6 April 2022.

*İhtira* is understood to involve a new result and improvement to the industrial corpus and to develop a new way or a known way with new methods to exploit them. The law did not only accept *İhtira* by revealing a new *İhtira*, but also included new ways and methods for new application.[448]

Pursuant to Article 3, 'Pharmaceutical compounds and medicines of all kinds' were excluded from protection. Secondary Turkish sources[449] list 'treatment methods' as also excluded from protection, which might have been lost in translation. The exclusions were introduced considering that the İhtira Beratı created monopolies, and in consideration of the public interests. Article 3 also excludes form protection simple innovations which involve 'Devices or combinations relating to banking or finance.'[450]

The period of protection provided by Article 4 was five, ten or fifteen years for innovations that the law defined as *ihtira*. According to Article 19, this term could also be extended. Article 4 also provided for patent fees, or taxes, which were determined in accordance with the duration of such protection and amounted to ten Ottoman gold coins for five years protection, twenty for ten years and thirty for fifteen years of protection.[451] The fee determined was for the whole period of protection and it was to be paid in instalments amounting to two gold coins per year of protection, the first one being when the application was filed and all subsequent instalments were paid at the beginning of each year.

### 4.4.2 Procedural Provisions of the İhtira Beratı Law

The procedure for obtaining protection included four steps and was provided for by Article 5. The first involved filing an application or a request for such protection followed by a description of the invention and explanation of its applicability. This was to be completed with drawings and samples corresponding to the description provided, which would then be submitted in a sealed envelope to the Ministry of

[448] Article 2 of İhtira Beratı Kanunu
[449] Akay, *supra* note 418, p. 171 also Huysal, *supra* note 445, p. 52.
[450] *Ibid*
[451] When the Venetian Patent Statute was introduced, grant of patents was free of tax and 'explains their relatively high number' in Carlo Poni, Giorgio Mori, M. Teich, and R. Porter. "Italy in the longue duree: the return of an old first comer." *The industrial revolution in national context: Europe and the USA* (1996): 149, p. 160

Commerce and the governor of the province where they were located or provide details of their residence if different from the one where protection was sought.

The specifics on how the description and the explanation were to be drafted were governed by Article 6. It required the applicant to submit detailed and error free documentation and state the period of protection they sought. All measurements were to be accurate, and drawing were to be made in ink. It also required for the application to be signed by the applicant or their attorney. The validity of the application would be established with the submission of a letter to the regional ruler when two Ottoman gold coins were paid as the first instalment of the fee provided for in Article 7. A memorandum accompanying the patent application was to be submitted so as to 'authenticate each deposit, showing the date of remission of the application papers' and bear the signature of the applicant. Upon submission, the acceptance would be verified by an official stamp of the Ministry of Commerce and Agriculture or under the supervision of the governorships in the provinces.[452] The delivery date of the documents coincides with the beginning of the protection period.[453]

According to Article 9, a badge, or *berat*, was granted by the Ministry of Commerce and Agriculture without conducting preliminary research of the invention for which protection was sought. Validity, authenticity, and novelty[454] of the invention were determined by identifying the benefits of the invention, for which the state did not provide any guarantees. Profit and loss stemming from the invention belonged to the owner of the invention. Thus, the state had no responsibility concerning the inventions. The sole role of the state was regulatory, and it was played only for the purpose of granting the *berat*.

Conditions on altering, correcting, supplementing and completing protected inventions were governed by Article 20. Accordingly, such actions could be taken only within the protection period and the new certificate, or acknowledgement, issued for the improvements would be combined with the previously issued *berat*. The protection period for both the original invention and the improvements to it would expire at the

[452] Article 7
[453] Article 8.
[454] Akay, *supra* note 418, p. 173.

same time, that is, with the expiration period of the original invention. Pursuant to Article 22, invention whose protection had been transferred could not be amended.

Anyone other than those who possessed a *berat* could file for a new *berat* for an amended version of the same invention a year after the date of issue of the original *berat*. If such a filing took place within the first year, it had to be submitted in a sealed envelope which was to be open only after one year has passed from the grant of the original *berat*. However, within one year, the original owner of the *berat* could also request a certificate of approval or a new statement to amend or improve their invention. In this case, the owner of the principal invention was entitled to priority.[455] The period of protection could also be increased by submitting an appropriate request to do so.[456] They were entitled to choose any of the three periods provided for by Article 4. Pursuant to Article 24, in case of an invention being granted a *berat* for building on an original invention, the rights in the latter would remain with the original inventor and, in turn, the original inventor would have no rights over the amended invention.

### 4.4.3 Military inventions under the İhtira Beratı Law

The approach to military inventions was different. Article 12 governed this type of inventions specifically. It provided that for military-related inventions with the potential to increase the strength and power of the country and its naval forces, a *berat* could be granted upon successful completion of an examination conducted to confirm the claimed properties of the invention. However, the *berat* granted for such an invention, and therefore, the invention itself, would subsequently be bought by the government whilst the inventor would be awarded a medal according to the degree of benefit of the invention. The monetary value of the invention was to be determined by experts representing both the state and the inventor. In case of dispute, the first instance would be appointment of arbitrators. If no decision were reached, the Chief of the Court of Appeal would have the right to determine the price.

The Ottoman State considered it appropriate to reward inventions that were useful in military terms and beneficial for the defence of the country, as well as establishing a system to reward inventions that would contribute to the development of the country

[455] Article 23
[456] Article 21

and to encourage the invention of new ones. The incentive and reward system would mainly be given to inventions that would contribute to the technological development of the country and provide significant benefits in terms of use. In other words, it included inventions that could be widely used. Rewarding would be done with gold, silver, and bronze medals, depending on the degree of benefit of the invention. The medals awarded were not only for the inventions themselves, but also the originality and value of a given invention after it entered commercial life. The medals had added value since they were to be placed next to the brand of the product which was to be placed on the market. Thus, the public would be informed of the award by the state for the product's superior qualities. Such a product will have been insured to have a significant advantage over similar products.[457] The rewarding system was applicable to both domestic and foreign inventors. The state had created a general incentive mechanism, regardless of the nationality of the inventor that created the invention, taking into account its utility to the country.

#### 4.4.4 Transfer of Rights under the İhtira Beratı Law

The right to transfer the invention to a third party was govern by Article 25. This could be done in whole or in part, for a fee or free of charge, provided the transfer was registered by the governors in the provinces and forwarded to the Trade and Agriculture Supervision within five days. The transfer could also be done for a certain period of time. Within this period, the transferee was obliged to take all measures required for the safe production of the protected product. The transfer of responsibility is regulated by Article 26, which specifically governs the handling of dangerous inventions which require certain control.

Not unlike the current deal the patent right holders have with the public, the documentation including the description, explanation and drawings of the invention were kept by the Ministry of Trade and Agriculture, where they were filed at the time when protection was sought, and kept there during the legal protection period to be displayed free of charge to those who want to see them while samples were given to those who want to buy them at a certain fee. Article 29 governs this contract between the right holder and the public. Article 30 governs the publishing of the said

[457] Article 14

documentation to the public. Upon expiry of the protection period, the original documentation was kept in the Istanbul Industrial School sampling office.

### 4.4.5 Foreign Inventions under the İhtira Beratı Law

Articles 33 and 34 governed the protection of foreign inventions provided they would meet the same conditions as the domestic invention. Furthermore, the protection granted to foreigners was based on a previous grant in a foreign state and the duration of the protection was also based on the duration of the protection in the said foreign state. In other word, when the protection in the foreign state would expire, so would the protection in the Ottoman State.

### 4.4.6 Cancellation and Exclusions under the İhtira Beratı Law

The Law also provided for cancellation of protection under specific circumstances exhaustively provided for by Article 36. Namely, lack of novelty would be the first ground for cancellation. Medicines and treatment methods were also excluded from protection as were non-industrial products such as pearls, beads, hardware. Products of the imagination without industrial applicability, inventions in breach of public safety, order of the country or general moral rules were not subject to protection either. Inventions found to have obtained the *baret* based on a fraudulent name of the original invention were cancelled as well as inventions whose performance and benefits were not sufficiently explained. Inventions which had undergone development and amendment during the one-year period and thus incurred inaccuracies related to the *berat* as well as *berats* granted for development and amendment of an original invention which were found to lack the connection to the said original invention were also subject to cancellation.

Moreover, Article 38 provides for the reasons to cut the *baret* duration short and these include: failure to pay *baret* fees at the beginning of each year, failure to implement and use the protected invention on the territory of the Ottoman Empire within two years from the date of the granted protection or inoperability of the invention for two years continuously as well as importation of the same product from a foreign country.

Legal remedies available to individuals who would claim a certain invention to be invalid are governed by Article 40. They had the right to complain to the competent courts, which were the *Bidayet* Courts. In addition to the legal remedies, Articles 39 to 50 provide for the penalties prescribed for counterfeiting a protected invention. These range from fines to imprisonment, depending on the gravity of the committed infringement.

## 4.5 Conclusion

This Chapter shows the difference in the approach to patenting inventions related to human health in the developed versus developing countries. The background of Turkish monopolist society proves that conditions for introduction of intellectual property monopolies in Türkiye were just as ripe as they were in today's developed countries, however, unlike the developed countries, Türkiye first introduced pharmaceutical patents to fulfil its obligation under the TRIPS Agreement.

This Chapter should duly include analysis of the latest Industrial Property Law of Turkiye, however, due to the author's language barrier, contemporary scientific literature could not be advised so as to provide proper representation of Turkish biotechnology patent protection.

As discussed in the following part, the issue of access to medicine does not require only national efforts but intense international efforts, too, as such issues span globally and should be addressed globally.

PART II INTERNATIONAL PERSPECTIVE OF PATENTS

## 5. TRIPS AND DOHA AGREEMENT ON ACCESS TO ESSENTIAL MEDICINE: COVID-19 PANDEMIC PERSPECTIVE

Intellectual property right are the last remaining monopolist rights which are still legal and have been found, due to their intangible and unique nature, to stimulate rather than impede competition. This competition is among inventors and thus, they seem to stimulate progress, too. However, their roots and development lay in today's developed countries,[458] whereas developing and least developed countries still do not seem to be very keen on them, mainly because developing countries are not yet large producers of intellectual property, hence, arguably, have no incentive to protect them but rather prefer to have maximum access to western technology for their own development.[459] The initiative for international regulation of intellectual property right was first met by disagreement of which international organisation was to administer such regulation. Developing countries preferred the World Intellectual Property Organisation (WIPO) which the developed countries insisted on General Agreement on Trade and Tariffs (GATT), later the World Trade Organisation (WTO).[460] Pharmaceuticals proved to be the main cause of the strife between the two.

This chapter provides a brief overview of the TRIPS Agreement and its subsequent amendments as well as the circumstances under which it was adopted and amended. It further looks at the application of TRIPS and its flexibility in the COVID pandemic, which is taken as a case study.

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[458] 'Developed countries uniformly view intellectual property as embodying pure property rights, entitled to comprehensive international protection in order to assure a full economic return to creators and owners. Reducing the potential for uncompensated, infringing uses by enacting and enforcing international protection norms is perceived as beneficial for both developed and developing countries' cited in Duane Nash, "South Africa's Medicines and Related Substances Control Amendment Act of 1997." *Berkeley Technology Law Journal* (2000): 485-502, p. 485. Available at https://www.btlj.org/data/articles2015/vol15/15_1_AR/15-berkeley-tech-l-j-0485-0504.pdf. Last accessed on 5 June 2022.

[459] Tara Kalagher Giunta and Lily H. Shang. "Ownership of information in a global economy." *Geo. Wash. J. Int'l L. & Econ.* 27 (1993): 327.

[460] Nash, *supra* note 458, at p.486.

## 5.1 Overview of the TRIPS Agreement

The Agreement of Trade-Related Aspects of Intellectual Property Rights (hereinafter TRIPS Agreement)[461] was concluded when the WTO Agreement replacing GATT was formally signed at Marrakesh on 15th April 1994, in order to reduce distortions and impediments to international trade as well as promote effective and adequate protection of IPRs while ensuring that measures and procedures to enforce intellectual property rights do not themselves become barriers to legitimate trade.[462] It is strategically annexed to the WTO agreements thus becoming binding for all WTO member states, which count 164 full members and 25 observer government.[463] Accordingly, the TRIPS agreement did not leave much room for developing and underdeveloped countries to decide whether to provide intellectual property protection or not. It was an obligation they had to take up on and fulfil sooner or later.[464] That did not make IP rights less controversial or unacceptable, nor culturally less understandable. Be they obliged to enforce IP rights, awareness among populations round the globe has failed to follow the western 'awareness' so fervently advocated, or better, raised by rather strict enforcement laws literally obscuring any other form of awareness to be acquired, like sharing.

Sharing has been largely associated with copyright since it has been introduced by the internet culture and gained its fame through this rather novel phenomenon, compared to the industrial property rights, which are like restrictive elders relentless to yield before a gigantic culture.

The TRIPS Agreement provides minimum standards for IP rights protection. As one of the most comprehensive multilateral agreements on intellectual property rights, it is characterized by its main features providing for standards, enforcement and dispute resolution. It takes the substantive provisions of the Berne Convention[465] and the Paris

[461] Marrakesh Agreement Establishing the World Trade Organization, Annex 1C, 1869 U.N.T.S. 3; 33 I.L.M. 1197 (1994)
[462] TRIPS Agreement, Preamble – Available at https://www.wto.org/english/docs_e/legal_e/27-trips_02_e.htm. Last accessed on 16 Mar. 22
[463] WTO – Members and Observers. Available at https://www.wto.org/english/thewto_e/whatis_e/tif_e/org6_e.htm. Last accessed on 16 Mar. 22
[464] Deadlines when provisions of TRIPS should have been adopted in national laws. 2016
[465] Berne Convention for the Protection of Literary and Artistic Works, September 9, 1886, as revised at Stockholm on July 14, 1967

Convention for the Protection of Industrial Property[466] in their most recent versions as its cornerstones, with the exception of Berne Convention's provision on moral rights[467] and incorporates them by reference. TRIPS takes IP protection a step ahead of the existing intellectual property legislation since it addresses the question on enforcement (Part III) more thoroughly. Furthermore, it addresses civil and administrative procedures and remedies (Part III, Section 2), provisional measures (Part III, Section 3), special requirements related to border measures (Part III, Section 4) and criminal procedures (Part III, Section 5).

The TRIPS Agreement is the first international agreement which in addition to governing intellectual property rights, introduces IPRs enforcement provisions. These are contained in Part III of the Agreement, which is further divided into five sections. General obligations that must be met by enforcement procedures are governed by section one and are contained in Article 41 requiring members to introduce such enforcement procedures in their respective national laws 'so as to permit effective action against any act of infringement of intellectual property rights' as well as 'expeditious remedies to prevent infringements and remedies which constitute a deterrent to further infringements.' Thus, the agreement ensures that right holders can rely on effective means to enforce their IPRs. Furthermore, the provisions are to be applied in 'such a manner as to avoid the creation of barriers to legitimate trade and to provide for safeguards against their abuse.'[468] Articles 42-49 contain provisions on civil and administrative procedures and remedies, provisional measures, special requirements related to border measures and criminal procedures.

TRIPS is particularly interesting not only because it takes IPRs protection a step further but also because the most disputed part of that protection are pharmaceutical patents both before and after the adoption of the agreement. Between 1987 and 1989, developing countries were successful in stalling discussion on norms and standards of

[466] Paris Convention, *supra* note 276
[467] Moral rights were excluded from TRIPS due to United States' political and economic pressure on other signatories during the Uruguay Round of the General Agreement on Tariffs and Trade ('GATT') in 1994. The General Agreement on Tariffs and Trade, opened for signature 30 Oct. 1947, 61 Stat. A3, 55 U.N.T.S. 187
[468] Article 41, para 1, TRIPS

intellectual property protection only to agree to discuss these norms in April 1989.[469] Namely, the level of patent protection advocated by developed countries was not acceptable for developing countries, both then and now, ultimately resulting in adoption of the Doha Declaration concerning access to essential medicine.[470] Before the introduction of the TRIPS Agreement, the major patent authority was the Paris Convention, which does not provide for the patent protection of pharmaceutical subject matter, nor does it prevent it, thus leaving space for individual countries to decide whether or not they will provide protection for such products. Article 1 (3) of the Paris Convention states,

> 'Industrial property shall be understood in the broadest sense and shall apply not only to industry and commerce property, but likewise to agricultural and extractive industries and to all manufactured or natural products, for example, wines, grain, tobacco leaf, fruit, cattle, minerals, mineral waters, beer, flowers, and flour.'

At the time, living organisms, save plants, were not considered patentable subject matter out of ethical reasons among all else. Accordingly, many developing countries opted not to provide patent protection for subject matter relating to medications. Consequently, the adopting the TRIPS agreement proved to be a thorny endeavour. A committee of experts on biotechnological inventions and industrial property was set up by the World Intellectual Property organisation (hereinafter WIPO) in 1984 and met four time between 1984 and 1988 without completing its work. Reaching a consensus, despite the work done and the clarification of many problems, was not achieved either.[471]

Article 27(3)(b) proved to be the most controversial and difficult to agree upon. The initial draft proposed by developed countries got through and the amendments proposed by developing countries were not accepted.[472] Article 27(1) states that 'patents shall be available for any inventions, whether products or processes, in all

[469] C. Niranjan Rao, "Patents for biotechnology inventions in TRIPs." *Economic and Political weekly* (2002): 2126-2129, p. 2126. Available at http://www.jstor.org/stable/4412187. Last accessed on 18 March 2022.
[470] See *infra* discussion on Access to Medicine, Part 5.2
[471] BioT/CE/IV/4. October 1988. Report of the Committee of Experts on Biotechnological. Inventions and Industrial Property, fourth session, Geneva, 24-28 October 1988.
[472] Daniel J. Gervais, "The TRIPS agreement: drafting history and analysis." *(No Title)* (1998).

fields of technology'[473] which also includes pharmaceutical and biotechnology patents. Article 27(2) and (3) provide for the exclusions of patentability. Article 27(3)(b) specifically allows for countries to exclude 'plants and animals other than micro-organisms, and essentially biological processes for the production of plants or animals other than non-biological and microbiological processes,' however, everything else outside of this provision is considered patentable subject matter. Also, under TRIPS, protection of human, animal or plant life or health warrants exclusions from patentability as well as inventions which seriously prejudice the environment.[474] Furthermore, paragraph 3 lists specific subject matter which member states may exclude from patent protection.

Members may also exclude from patentability:

(a) diagnostic, therapeutic and surgical methods for the treatment of humans or animals;
(b) plants and animals other than micro-organisms, and essentially biological processes for the production of plants or animals other than non-biological and microbiological processes. However, Members shall provide for the protection of plant varieties either by patents or by an effective *sui generis* system or by any combination thereof. The provisions of this subparagraph shall be reviewed four years after the date of entry into force of the WTO Agreement.

Same exclusions from patentability are also stipulated by the EPC which are rooted in the Strasbourg Convention on the 'Unification of certain points of substantive law on patents for inventions' of 1963 of the Council of Europe. Article 2 (b) of the Strasbourg Convention states:

(c) 'The contracting states shall not be bound to provide the grant of patents in respect of… plant or animal varieties or for essentially biological processes for the production of plants or animals; this provision does not apply to microbiological processes or the products thereof.'

It is arguable that the distinction between biology and microbiology this provision is trying to make was applicable to the scientific knowledge at the time, however, later and current scientific developments blur the distinction between the two.

[473] Provided they meet the substantive conditions, that is, novelty, inventive step and industrial applicability.
[474] TRIPS Agreement Article 27.2

The purpose of TRIPS was to create a 'level playing field' of mutually recognised IPRs among all member states, encouraging trade and, in turn, economic growth.[475] However, the controversies stemmed from the impact of TRIPS on the ability of the world's poor to access affordable medicines.[476] Low-to-middle income countries (LMICs) had a thriving trade in generic and recently marketed drugs produced in countries where patent rights were not recognised before 1995, when the TRIPS agreement came in power. Such trade was a source of cheap medicine for the importing countries, especially those with severe resource constraints facing major public health problems such as HIV/AIDS.[477] TRIPS cut such practices short for all member states of the WTO and imposed granting patent holders exclusive rights to produce and sell protected drugs.[478] This effectively enabled pharmaceutical companies of developed countries to enlarge their potential markets at the expense of access to affordable medicine in these countries.

In 2001, in order to settle concerns regarding public health protection, the Doha Declaration was adopted, which was followed by the Implementation of the Paragraph 6 Decision in 2003.[479] However, Doha did not produce the desired results since it was and is easily circumvented by bilateral trade agreements between developed countries, mainly the US,[480] and developing or underdeveloped countries. By triggering Doha mechanism, these countries would find themselves in breach of bilateral trade agreements which are also essential for their economic development.

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[475] Vanessa Bradford Kerry and Kelley Lee. "TRIPS, the Doha declaration and paragraph 6 decision: what are the remaining steps for protecting access to medicines?." *Globalization and health* 3 (2007): 1-12, p. 2. Available at https://link.springer.com/article/10.1186/1744-8603-3-3. Last accessed on 3 June 2022.

[476] Christopher P. Adams and Van V. Brantner. "Estimating the cost of new drug development: is it really $802 million?." *Health affairs* 25, no. 2 (2006): 420-428. Available at http://moglen.law.columbia.edu/twiki/pub/LawNetSoc/BahradSokhansanjFirstPaper/25HealthAff420_Estimating_cost_new_drug_development_2006.pdf. Last accessed on 2 June 2022 and Joseph A. DiMasi, Ronald W. Hansen, and Henry G. Grabowski. "The price of innovation: new estimates of drug development costs." *Journal of health economics* 22, no. 2 (2003): 151-185.

[477] Kerry & Lee, *supra* note 475

[478] Monique F. Mrazek, "Pharmaceutical pricing in the developing world: issues of access to medicines." *Expert Review of Pharmacoeconomics & Outcomes Research* 2, no. 1 (2002): 43-50. Also, Frederic M. Scherer and Jayashree Watal, "Post-TRIPS options for access to patented medicines in developing nations." *Journal of International Economic Law* 5, no. 4 (2002): 913-939.

[479] WTO: Implementation of Paragraph 6 of the Doha Declaration on the TRIPS Agreement and Public Health, Decision of 30. 2003, WT/L/540, 2 September 2003., http://www.who.int/medicines/areas/policy/WT_L_540_e.pdf. Last accessed on 18 March 2022.

[480] Also known as FTAs or Federal Trade Agreements

## 5.2 Access to Medicine and TRIPS Flexibilities

The most relevant aspect of the TRIPS agreement for the current work is its provisions on pharmaceutical patents and how they affect public health. Given that biotech patents, indeed, affect public health and are owned by pharmaceutical companies as well, these provisions have strong bearing for this work.

Some commentators observe that the aim of TRIPS is to achieve 'a series of equilibriums: between intellectual property protection and free trade … between highly industrialised and developing nations; between the private rights of intellectual property owners and cases where the public interest may trump some aspects of the protection of intellectual property.'[481] The objective of TRIPS is governed by Article 7, providing that IP protection and enforcement 'should contribute to the promotion of technological innovation and to the transfer and dissemination of technology' thus benefiting both right holders and users 'in a manner conducive to social and economic welfare, and to a balance of rights and obligations.'[482] It is based on the principles of protecting 'public health and nutrition' and promoting 'the public interest in sectors of vital importance to their socio-economic and technological development' through allowing members to adopt measures for these purposes as long as they are consistent with the Agreement.[483] However, these articles do not impose any actionable obligations, nor do they construe exceptions to the mandatory IP protection standards established by TRIPS.[484]

In line with its objective, the TRIPS allowed developing countries five years to comply with its provisions, while developed countries were required to do so within a year.[485] Moreover, developing countries were allowed five more years to implement product patents, which included pharmaceutical inventions.[486] Least developed countries were

[481] Ezinne Miriam Igbokwe and Andrea Tosato. "Access To Medicines and Pharmaceutical Patents: Fulfilling The Promise of TRIPS Article 31bis." *U of Penn, Inst for Law & Econ Research Paper* 22-08 (2022). Available at https://scholarship.law.upenn.edu/cgi/viewcontent.cgi?article=3805&context=faculty_scholarship. Last accessed on 11 Apr. 22.
[482] TRIPS, *supra* note 279, art. 7
[483] TRIPS, *supra* note 279, art. 8
[484] Igbokwe and Tosato, *supra* note 481.
[485] TRIPS, *supra* note 279, art. 65(1)
[486] TRIPS, *supra* note 279, art. 65(2)-(4)

afforded ten years to comply with TRIPS,[487] with this deadline being repeatedly extended[488] with the current extension being until 2034.[489] Least-developed countries are afforded greater flexibility regarding pharmaceutical patents as they can adapt their domestic legislation in accordance with their socio-economic needs and provide partial protection to pharmaceutical inventions as Article 66(1) does not forbid member states to provided lower protection levels.[490]

Not unlike regional and national legislations, as a principle, the TRIPS agreement allows for exclusions from patentability when it comes to protecting public health and nutrition as well as promoting public interest in sectors of vital importance for their socio-economic and technological development.[491] Furthermore, the TRIPS Agreement provides for the so called 'TRIPS Flexibilities' under Article 30 (Exceptions) and Article 31 (Licences).

Exceptions to patentability are governed by Article 30 allowing Members to curb patent protection as they deem appropriate as long as they are 'limited', and neither 'unreasonably conflict with a normal exploitation of the patent,' nor 'unreasonably prejudice the legitimate interests of the patent owner, taking account of the legitimate interests of third parties.'[492] It is at the Members' discretion to introduce exception without further restrictions insofar as they meet the said three requirements. These may include use for private purposes, parallel importation, preparation of medicine for personal use, experimental use etc.[493] . Such exceptions also include compulsory licenses and non-voluntary licenses or statutory licenses.[494]

[487] TRIPS, *supra* note 279, art. 66(1)
[488] The transition period has been extended three times.
[489] WTO, *WTO members agree to extend TRIPS transition period for LDCs until 1 July 2034*. Available at https://www.wto.org/english/news_e/news21_e/trip_30jun21_e.htm. Last accessed on 11 Apr. 22.
[490] Igbokwe and Tosato, *supra* note 481, at p. 26
[491] Article 8
[492] TRIPS, *supra* note 279, art. 30.
[493] Andrew Law, "Patents and public health: legalising the policy thoughts in the Doha TRIPS Declaration of 14 November 2001." (2009) at p. 93-95 Available at http://www.jstor.org/stable/j.ctv941vg7. Last accessed on 11 April 2022.
[494] Brad Sherman and Lionel AF Bently. "Limiting Patents' in R Hilty and L Kung-Chung (Ed), Compulsory Licensing: Practical Experiences and Ways Forward." *Compulsory Licensing: Practical Experiences and Ways Forward (Springer, Berlin 2015)* (2015): 313-332.

Compulsory licences are provided for by Article 31, granting governments freedom to do so without any restrictions as to their nature, composition or function and authorisation is to be given 'on its individual merits.'[495] The grant of compulsory licence is conditioned on previous efforts made by the proposed user 'to obtain authorisation from the right holder on reasonable commercial terms and conditions and that such efforts have not been successful within a reasonable period of time.'[496] However, such authorisation is not required in 'circumstances of extreme urgency' or for 'public non-commercial use' only requiring the issuing Member to notify the patent holder of the issued compulsory licence.[497] Notification by the government is to be given concerning scope and duration of the issued licence,[498] which should be non-exclusive, non-assignable and authorized predominantly for the supply of the domestic market.[499] Though 'predominantly' is not specifically quantified, it is not boundless and it is unequivocal in its restrictive meaning.[500] Furthermore, 'adequate renumeration' is due to the patent holder depending on the relevant circumstances and the economic value of the protected invention.[501] The right to judicial review conferred on the patent holder is guaranteed by Article 31(i) to 31(j).

Article 31 has been a subject to fervent criticism ever since its adoption. Its perceived hindrance of the Members' sovereign prerogatives to issue compulsory licences and entrenching impregnable safeguards for patentees[502] attracted the support of scholars, activists and NGOs,[503] which resulted in the proposal from a large group of developing

[495] TRIPS, *supra* note 279, art. 31(a).
[496] TRIPS, *supra* note 279, art. 31(b).
[497] *Ibid*
[498] TRIPS, *supra* note 279, art. 31(c).
[499] TRIPS, *supra* note 279, art. 31(d)-(f).
[500] Andrew D. Mitchell and Tania Voon, "Patents and Public Health in the WTO, FTAs and Beyond: Tension and Conflict in International Law." *FTAs and Beyond: Tension and Conflict in International Law (June 5, 2015)* 43, no. 3 (2009): 571-601 (suggesting that 'this requirement means that only a relatively small portion of pharmaceuticals manufactured pursuant to compulsory licenses worldwide may be legitimately exported to countries in need and lacking manufacturing capacity') at p. 576. Available at https://papers.ssrn.com/sol3/papers.cfm?abstract_id=2614891. Last accessed on 11 Apr. 22.
[501] TRIPS, *supra* note 279, art. 31(h).
[502] Igbokwe and Tosato (2022), *supra* note 481 at p. 27-28
[503] Brook K. Baker, "Access to medicines activism: collaboration, conflicts, and complementarities." *Intellectual Property Law and the Right to Health: A History of TRIPs and Access to Medicine (Srividhya Ragavan & Amaka Vanni eds., 2020 Forthcoming), Northeastern University School of Law Research Paper* 369-2020 (2020). Available at https://papers.ssrn.com/sol3/papers.cfm?abstract_id=3538270. Last accessed on 11 Apr. 22. Also see Ellen t Hoen, "Private patents and public health." *Changing Intellectual Property Rules For Access to Medicines* (2016), pp. 31-73 Available at https://haiweb.org/wp-content/uploads/2016/07/Private-

countries to fundamentally recast Articles 27 and 31 at the 2001 Doha Ministerial Conference.[504] Despite the resistance of developed members,[505] the Doha Declaration on the TRIPS Agreement and Public Health was unanimously supported and adopted in 2001.[506]

## 5.3 Doha Declaration

### 5.3.1 Background

In December 1997, South Africa adopted the Act to Medicines and Related Substances Control Amendment Act.[507] The purpose was to address the AIDS pandemic and provide mechanism for making antiretroviral drugs more accessible and cheaper. It was immediately accused of being in breach of the TRIPS agreement provisions as it granted power to the South African Minister of Health to grant compulsory licences and allow parallel import of pharmaceuticals. As it did not specify which pharmaceutical specifically it referred to, the Minister was granted the power to issue compulsory licences for any medicines. The only criterion the medications subject to compulsory licences were to meet was stipulated under Section 10 providing that:

> The Minister may prescribe conditions for the supply of more affordable medicines in certain circumstances so as to protect the health of the public, and in particular may (a) determine that the rights with regard to any medicine under a patent granted in the Republic shall not extend to acts in respect of such medicine which has been put onto the market by the owner of the medicine, or with his or her consent.[508]

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Patents-Public-Health.pdf. Last accessed on 11 Apr. 22.; Kapczynski, Amy. "The access to knowledge mobilization and the new politics of intellectual property." *Yale LJ* 117 (2007): 804, at pp. 828-830. Available at https://openyls.law.yale.edu/bitstream/handle/20.500.13051/2696/The_Access_to_Knowledge_Mobilization_and_the_New_Politics_of_Intellectual_Property.pdf?sequence=2. Last accessed on 11 April 2022.

[504] Council for Trade-Related Aspects of Intellectual Property Rights, Proposal by the African Group, et al., IP/C/W/312, WT/GC/W/450, 4 October 2001 (01-4803). Available at https://www.wto.org/english/tratop_e/trips_e/mindecdraft_w312_e.htm. Last accessed on 11 April 2022.

[505] 'The Proposal by the African Group was met with stark opposition from the United States and the European Union' in Igbokwe and Tosato (2022), *supra* note 481 at p. 35.

[506] Doha Declaration, Paragraph 1 Declaration on the TRIPS Agreement and Public Health No. WT/MIN(0)/DEC/2, 14 November 2001. Available at https://www.wto.org/english/thewto_e/minist_e/min01_e/mindecl_trips_e.pdf. Last accessed on 11 Apr. 22

[507] Medicines and Related Substances Control Amendment Act, No. 90 (1997) (S.Aft.)

[508] Medicines and Related Substances Control Amendment Act, No. 90, § 10(a) (1997) (S. Afr.)

This was followed by mass protests in 2000, after more than 40 pharmaceutical companies challenged the legislation and sued South Africa in 1998[509]. The issue was finally brought before the WTO on 20 June 2001. It received wide international support and is considered to be the origin of the discussions leading to the Doha Declaration.

As one of the most numerous international organizations, the WTO also includes least developed countries where patent protection of pharmaceuticals only further prevents, rather than facilitates, access to medications, which are essential for people's health. For this reason, and due to the almost unsurmountable differences between developed and developing countries, the Doha Development Agenda[510] was introduced, represented mainly by India, Brazil, China, and South Africa. Before the introduction of the TRIPS Agreement, in order to ensure affordable drug prices, India and Brazil allowed only pharmaceutical process patents, excluding product patens from patentability.[511] Given that the process is much easier to reverse-engineer, these countries used the advantage to develop and build up their pharmaceutical industry.[512] The TRIPS Agreement is well drafted to serve the interests of pharmaceutical patent holders in developed countries consequently depriving developing countries from medications necessary for protection of public health. After TRIPS, pharmaceutical companies extended their markets while setting up high prices for their patented products, which helped them recoup their R&D costs but deprived the poor of access to such medicines. Thus, in August 2003, after two years of contentious negotiations,[513] the TRIPS Council adopted the Decision on Implementation of Paragraph 6 of the Doha Declaration on the TRIPS Agreement and Public Health, an interim waiver, allowing members to export pharmaceutical products made under

[509] Pat Sidley, "Drug companies sue South African government over generics." (2001): 447. doi:10.1136/bmj.322.7284.447. Available at https://www.ncbi.nlm.nih.gov/pmc/articles/PMC1119675/. Last accessed on 10 April 2022.
[510] Implementation of Paragraph 6, *supra* note 479.
[511] Rudolf V. Van Puymbroeck, "Basic survival needs and access to medicines—coming to grips with TRIPS: Conversion+ calculation." *Journal of Law, Medicine & Ethics* 38, no. 3 (2010): 520-549, p. 525.
[512] *Ibid*
[513] Frederick M. Abbott, "The WTO medicines decision: world pharmaceutical trade and the protection of public health." *American Journal of International Law* 99, no. 2 (2005): 317-358, pp. 326-360

compulsory licenses to least developed and certain other members,[514] free from the obligations imposed by Articles 31(f) and (h).[515]

The need for access to generic medications is addressed and provided for by the two declarations. The waiver of Article 31(f) of the TRIPS agreement, stating that a compulsory license can only be issued for primarily domestic use, is one of the most important results of these declarations.[516] The provision allowed for government intervention only for domestic market use of patented products, thus effectively leaving the countries without domestic production without access to affordable medication. With the waiver, countries are allowed to 'grant… a compulsory licence to the extent necessary for the purposes of production of a pharmaceutical product(s) and its export to an eligible importing Member(s).'[517] This development was initially praised as triumph by advocates of public health since it appeared that medicines were distinguished from other products and WTO members were imparted flexibilities allowing them to protect public health.[518] Furthermore, the Doha Declaration extended the deadline for least developed countries (LDCs) to comply with the TRIPS agreement, however, this did not apply to LMICs, for whom the transition period ended in 2005. The distinction between LDCs and LMICs is made by the United Nation so as to distinguish the countries that are in greatest need of aid.[519]

In 2005, the WTO General Council adopted the "Protocol Amending the TRIPS Agreement" (the Amendment Protocol) which incorporated the substance of the

[514] Charles E. Hanrahan, "Agriculture in the WTO Doha Round: The Framework Agreement and Next Steps." In *Congressional Research Service Report for Congress*. 2005, p .4 Available at http://nationalaglawcenter.org/wp-content/uploads/assets/crs/RS21905.pdf. Last accessed on 3 June 2022

[515] General Council Decision, Implementation of Paragraph 6 of the Doha Declaration on the TRIPS Agreement and Public Health (Aug. 30, 2003), WT/L/540/Corr. 1 (1 September 2003) [hereinafter the Waiver Decision]. Available at https://docs.wto.org/dol2fe/Pages/FE_Search/FE_S_S009-DP.aspx?language=E&CatalogueIdList=51809,2548,53071,70701&CurrentCatalogueIdIndex=0&FullTextHash=&HasEnglishRecord=True&HasFrenchRecord=True&HasSpanishRecord=True. Last accessed on 11 April 2022. This Waiver is permissible because any requirement of a WTO agreement, including TRIPS, may be waived.

[516] Kerry and Lee, *supra* note 475, p. 3.

[517] Abbott, *supra* note 513.

[518] Jorge A. Zepeda Bermúdez, Maria Auxiliadora Oliveira, and Gabriela Costa Chaves. "Intellectual property in the context of the WTO TRIPS Agreement: what is at stake." *Intellectual property in the context of the WTO TRIPS Agreement: challenges for public health. Rio de Janeiro: Escola Nacional de Saúde Pública, Fundação Oswaldo Cruz* (2004): 23-61.

[519] UN Office of the High Representative for the Least Developed Countries, Landlocked Developing Countries and Small Island Developing States (n.d.) The Criteria for the Identification of the LDCs available at https://www.un.org/ohrlls/content/ldc-category. Last accessed on 19 March 2022.

Waiver Decision into TRIPS via the addition therein of Article 31bis, its Annex and the Appendix to the Annex (henceforth the Article 31bis System).[520] The Amendment Protocol entered into force in 2017, after ratification by two-thirds of Members.[521] Members who have still not accepted the amendment, currently have until 31 December 2023 to do so.[522]

### 5.3.2 Compulsory Licensing under TRIPS as Amended

Compulsory licences are involuntary contracts 'between a willing buyer and an unwilling seller imposed and enforced by the state.'[523] Though allowed by the TRIPS agreement, compulsory licences as provided for still could not match the needs of developing and least developed countries for access to affordable medicines. To remedy this, the TRIPS Agreement was amended and now includes Article 31*bis*, which most notably, derogates the provisions of Article 31(f) and Article 31(h) to allow an exporting Member to grant a compulsory licence necessary for production of a pharmaceutical product[524] for an importing Members and exempts the latter from payment if a compulsory licence for the same product has already been granted and remuneration has already been paid by the exporting Member.[525]

The issuance of compulsory licences is subject to the obligation stipulated in the Annex. A notice to the TRIPS Council must be sent by the exporting Member. The notice must include the prescribed details as are 'name and address of the licensee, the product(s) for which the licence has been granted, the quantity(ies) for which it has been granted, the country(ies) to which the product(s) is(are) to be supplied and the

[520] WTO General Council Decision of 6 December 2005, Amendment of the TRIPS Agreement, WT/L/641, 8 Dec. 2005. Available at https://docs.wto.org/dol2fe/Pages/FE_Search/FE_S_S009-DP.aspx?language=E&CatalogueIdList=225408,121046,96083,96293,69009,58276&CurrentCatalogueIdIndex=5&FullTextHash=&HasEnglishRecord=True&HasFrenchRecord=True&HasSpanishRecord=True. Last accessed on 11 April 2022.
[521] At the time of writing, 108 Members have ratified the Protocol Amending the TRIPS Agreement, while Members yet to do so have until 31 December 2021; see https://www.wto.org/english/tratop_e/trips_e/amendment_e.htm. Last accessed on 22 April 2023.
[522] WTO, Amendment of the Trips Agreement – Eighth Extension of the Period for the Acceptance by Members of the Protocol Amending the Trips Agreement, Decision of 22 November 2021, WT/L/1122. Available at https://docs.wto.org/dol2fe/Pages/SS/directdoc.aspx?filename=q:/WT/L/1122.pdf&Open=True. Last accessed on 11 April 2022.
[523] Nash, *supra* note 460, at p. 489
[524] Paragraph 1 of Article 31bis, TRIPS Agreement
[525] Paragraph 2 of Article 31bis, TRIPS Agreement

duration of the licence.[526] Similarly, the importing Member must also send a notice to the TRIPS Council, though not a subject to approval, specifying the names and expected quantities of the product(s) needed.[527] In addition, the importing Member must declare its lack of capacities to produce the medicine subject to the compulsory licence,[528] unless the Member in question is an LDC,[529] and confirm 'it has granted or intends to grant a compulsory licence' for the pharmaceutical product if it has been patented on its territory.[530]

The compulsory licence can be issued by the exporting Member upon TRIPS Council's receipt of the notification. Such licence must still abide by the provisions of Article 31 save the exemption from Article 31(1) 'to the extent necessary for the purposes of production of a pharmaceutical product(s) and its export to an eligible importing Member(s)'.[531] Subject to the terms in the notice to TRIPS Council, the issued compulsory licence must bind the licensee to manufacture only the notified quantities and export them only to 'the Member(s) which has notified its needs' to the TRIPS Council.[532] Furthermore, the exported products are subject to 'specific labelling or marking' so that they can be clearly identifiable and distinguishable through special 'packaging and/or colouring/shaping of the products themselves' which does not impact the price of the products.[533] Before shipping the licenced products, the licensee is obliged to post on their website information on the quantities and distinguishing features of the product.[534]

The exporting Member is required to pay the patentee 'adequate remuneration pursuant to Article 31(h)… taking into account the economic value to the importing

[526] Annex to the TRIPS Agreement, 2(c).
[527] Annex to the TRIPS Agreement, 2(a)(i).
[528] Annex to the TRIPS Agreement, 2(a)(ii). The Appendix to the Annex to the TRIPS Agreement ("insufficient or no manufacturing capacities for the product(s) in question may be established in either of the following ways: (i) the Member in question has established that it has no manufacturing capacity in the pharmaceutical sector; or) ii) where the Member has some manufacturing capacity in this sector, it has examined this capacity and found that, excluding any capacity owned or controlled by the patent owner, it is currently insufficient for the purposes of meeting its needs").
[529] Appendix to the Annex to the TRIPS Agreement ("Least developed country Members are deemed to have insufficient or no manufacturing capacities in the pharmaceutical sector).
[530] Annex to the TRIPS Agreement, 2(a)(iii).
[531] TRIPS Art. 31bis(1).
[532] Annex to the TRIPS Agreement, 2(b)(i).
[533] Annex to the TRIPS Agreement, 2(b)(ii).
[534] Annex to the TRIPS Agreement, 2(b)(iii) and 2(c).

Member of the use that has been authorized in the exporting Member.'[535] However, the exporting Member is exempt from this obligation in respect of products for which remuneration has already been paid under the System.[536]

### 5.3.3 Results of the TRIPS Agreement Amendment

The Decision to implement Article 6 of August 2003 was hailed as a 'historic agreement for the WTO.'[537] The creation of compulsory licences system was praised by government representatives, activists, and scholars as it was seen as a promise of easier access to medications for WTO Members with deficient manufacturing capabilities for pharmaceutical products. The prospect of furthering the cooperation between the developed and developing Members was also seen with excitement.[538] However, this enthusiasm diminished as the system proved to be difficult to use, on the one hand, and almost all attempts to do so were unsuccessful, on the other.[539]

In its 2020 publication titled 'Promoting access to medical technologies and innovation: intersections between public health, intellectual property and trade,' WIPO includes some instances when the Article31*bis* System was used, or attempt was made to use it.[540] As an example Ghana's consideration of using the System in 2005 is given, when it declared an emergency situation with regard to HIV/AIDS. Consequently, it issued a government use authorization order to import generic HIV/AIDS medicines. Initially, these patented medicines were to be imported from Canada, however, importation from an Indian generic manufacturer was chosen as the better option since

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[535] TRIPS Art. 31bis(2)
[536] *Ibid*
[537] Not all were happy with the Decision, for example, the representative from Djibouti stated that he was not satisfied although was pleased by the decision. The representative from the Barbados 'felt obliged to register
[their] disappointment and concern' as the decision would now prevent regional approach for implementation and the Jamaican representative was not satisfied with some elements of the text. However, opposing the decision was found to be harmful than its adoption. See more details in the WTO General Council Minutes (13.11.2003) WT/GC/M/82, pp. 9, 11, 13, available at https://docs.wto.org/dol2fe/Pages/SS/directdoc.aspx?filename=q:/WT/GC/M82.pdf, accessed on 13 Apr. 22
[538] Carlos M. Correa, *Research handbook on the protection of intellectual property under WTO rules*. Edward Elgar Publishing, 2010, p.623 citing citing Verma, S. K. (2010). The Doha Declaration and access to medicines by countries without manufacturing capacity. *Chapters*, p. 38
[539] World Health Organization, *Promoting access to medical technologies and innovation: intersections between public health, intellectual property and trade*, (2020). pp.178-179. Available at https://www.wipo.int/publications/en/details.jsp?id=305. Last accessed on 13 Apr. 22.
[540] *Ibid*

the patent did not apply in India.[541] India was also the chosen exporting country for Nepal in 2007, when Nepal requested several patented anti-cancer medications patented in India.[542] This application was later withdrawn since, as a LDC, Nepal was required to notify WTO of its intention to use these medication but it did not do so,[543] while the Indian manufacturer, Nadco, was sued for patent infringement.[544]

Another notable attempt to use the System was made by the Thai government when in November 2006, it authorised the Government Pharmaceutical Organisation to manufacture generic versions of efavirenz[545] until 2011.[546,547] As the manufacturer of the medicine in question, Merck did not dispute compliance with TRIPS, but claimed the government did not engage in sufficient consultation. The validity of the licence was brought into question by both the US government and the European Commission and put political pressure on Thailand to withdraw the decision and negotiate with Merck.[548] Nonetheless, in January 2007, Thailand issuing yet another two compulsory licences for Kaletra[549] and Plavix,[550] patented by Abbott and Sanofi-Aventis, respectively. In response, Abbott withheld a number of new medications from the Thai

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[541] *Ibid*
[542] On Nepal's attempt to use the Article 31bis see generally *Ibid*.; also Donald Harris, "TRIPS after fifteen years: Success or failure, as measured by compulsory licensing." *J. Intell. Prop. L.* 18 (2010): 367 at https://digitalcommons.law.uga.edu/cgi/viewcontent.cgi?referer=&httpsredir=1&article=1184&context=jipl, accessed on 13 Apr. 22
[543] *Ibid*
[544] *Ibid*
[545] An antiretroviral medication used to treat and prevent HIV/AIDS
[546] Department of Disease Control – Thailand. *Announcement of the Department of Disease Control, Ministry of Public Health, Thailand on the Public use of patent for Pharmaceutical Products.* Ministry of Health Bangkok;;
2006. http://www.cptech.org/ip/health/c/thailand/efavirenz.html
[547] Consumer Project on Technology. *Imatinib Mesylate (Gleevec/Glivec/STI571)* Geneva/Washington, CPTech;
2007. http://www.cptech.org/ip/health/gleevec/
[548] Suwit Wibulpolprasert, Vichai Chokevivat, Cecilia Oh, and Inthira Yamabhai. "Government use licenses in Thailand: The power of evidence, civil movement and political leadership." *Globalization and Health* 7 (2011): 1-8. Available at https://doi.org/10.1186/1744-8603-7-32. Last accessed on 13 April 2022.
[549] Decree of Department of Disease Control, Ministry of Public Health, Regarding Exploitagion of Patent on Drugs & Medical Supplies by the Government on Combination Drug Between Lopinavir & Ritonavir. Available at http://www.cptech.org/ip/health/c/thailand/thai-cl-kaletra_en.pdf. Last accessed on 13 April 2022.
[550] Ministry of Public Health Announcement Regarding Exploitation of Patents on Drugs and Medical Supplies for Clopidogrel. Available at http://www.cptech.org/ip/health/c/thailand/thai-cl-clopidogrel_en.pdf. Last accessed on 3 June 2022.

market, which later served as a warning to other countries who would try to use the mechanism provided for by Article 31bis.

As a case study, the WIPO publication refers to the one successful attempt to use the Article31bis System when in 2007, Rwanda expressed its intention to import a combination of three antiretrovirals against HIV/AIDS from Canada.[551] The requested medicines were exported to Rwanda at the end of 2008, after several delays. The extremely limited use of the Article 31bis System as well as its insignificant success rate bring its effectiveness into question.

As previously indicated, in order for the Members to be able to use the Article31bis System, they would need to notify the TRIPS Council of such intention so as to be eligible as an importing Member.[552] Thus far, only 37 developed Members have sent such notification, either to use it or use it in circumstances of extreme urgency.[553] The opt-outs were expressed at the time of the adoption of the Amendment Protocol.[554] However, with the COVID-19 pandemic and the inadequate mRNA vaccine production capabilities of some developed countries, the opt-outs are likely to be in

[551] Nicholas G. Vincent, "TRIP-ing Up: The Failure of TRIPS Article 31bis." *Gonzaga Journal of International Law* 24, no. 1 (2021): 1-38, pp. 19-21. Available at https://papers.ssrn.com/sol3/papers.cfm?abstract_id=3778945. Last accessed on 13 Apr. 22.; see generally Christina Cotter, "The implications of Rwanda's Paragraph 6 Agreement with Canada for other developing countries." *Loy. U. Chi. Int'l L. Rev.* 5 (2007): 177. Available at https://lawecommons.luc.edu/cgi/viewcontent.cgi?article=1067&context=lucilr. Last accessed on 13 Apr. 22.; Tolulope Anthony Adekola, "Has the Doha Paragraph 6 system reached its limits?." *Journal of Intellectual Property Law & Practice* 15, no. 7 (2020): 525-529., p. 528, at https://www.researchgate.net/profile/Tolulope-Adekola/publication/340918095_Has_the_Doha_Paragraph_6_system_reached_its_limits/links/5ea4739f45851553faaed25e/Has-the-Doha-Paragraph-6-system-reached-its-limits.pdf, accessed on 13 Apr. 22.

[552] Annex to the TRIPS Agreement, 1(b)

[553] 'This group of Members indicated through the Chairperson's Statement that they would not use the system other than in cases of emergency or extreme urgency. ('As we have heard today, and as the Secretariat has been informed in certain communications, some other Members have agreed that they would only use the system as importers in situations of national emergency or other circumstances of extreme urgency. These are the following: Hong Kong, China; Israel; Korea; Kuwait; Macao China; Mexico; Qatar; Singapore; the Separate Customs Territory of Taiwan, Penghu, Kinmen and Matsu; Türkiye and the United Arab Emirates'.)' in Frederick M. Abbott and Jerome H. Reichman. "Facilitating access to Cross-border supplies of patented pharmaceuticals: the case of the COVID-19 pandemic." *Journal of International Economic Law* 23, no. 3 (2020): 535-561. Available at https://academic.oup.com/jiel/article/23/3/535/5909036?login=true. Last accessed on 13 April 2022.

[554] *Ibid*

need of recourse.[555] Section 5.4 below considers compulsory licence in light of the Covid-19 pandemic in more detail.

As pointed out by Jerome Reichman and Rochelle Dreyfuss, '[t]he domestic patent laws as… practiced were largely formulated for the inventions of the Industrial Revolution, and these laws still reflect the technological premises and concepts of the creative sectors as they were then structured.'[556] The provisions of the foundational IP law treaties[557] are largely absorbed by TRIPS[558] even though they predate the pharmaceutical and biotech industries, with TRIPS barely addressing the specifics of the innovative processes in these industries, on one hand, and the characteristics of the consumers of their emerging goods, on the other.[559] In implementing the provisions of TRIPS, some countries like India,[560] which took the advantage of the full length of the transition period,[561] managed to at least find a way to restrict secondary patents in their national legislation.[562] Despite the national legislative efforts to limit the impact of patents on access to affordable medicines, contemporary IP regimes render different types of drugs and biotech products unavailable to populations in need around the globe.[563]

## 5.4 The Covid Pandemic and the TRIPS Agreement

On 30 January 2020, the World Health Organization declared the COVID-19 outbreak a Public Health Emergency of International Concern, and a pandemic on 11 March

[555] *Ibid* (pointing out the 'ill-considered decision' and considering legal avenues for 'opting back in'), pp. 558-560
[556] Jerome H. Reichman and Rochelle Cooper Dreyfuss. "Harmonization without consensus: critical reflections on drafting a substantive patent law treaty." *DUke lJ* 57 (2007): 85. Available at https://scholarship.law.duke.edu/cgi/viewcontent.cgi?referer=&httpsredir=1&article=2854&context=faculty_scholarship. Last accessed on 26 March 2022.
[557] Paris Convention, supra note 276
[558] TRIPS Agreement, Articles 2 and 9.
[559] Ana Santos Rutschman, "Intellectual property as a determinant of health." *Vand. J. Transnat'l L.* 54 (2021): 413., p. 422
[560] Janice M. Mueller, "The tiger awakens: the tumultuous transformation of India's patent system and the rise of Indian pharmaceutical innovation." *U. Pitt. l. reV.* 68 (2006): 491. Available at https://pdfs.semanticscholar.org/6511/eb383636245c43eccac6d0b31a5b6355075e.pdf?_ga=2.34142689.1731860671.1648227935-1088711028.1647619893. Last accessed on 26 March 2022.
[561] The transition period for implementing the TRIPS provision concerning pharmaceutical products was 1 January 2016
[562] Bhaven N. Sampat and Kenneth C. Shadlen. "Secondary pharmaceutical patenting: A global perspective." *Research Policy* 46, no. 3 (2017): 693-707. Available at https://www.nber.org/system/files/working_papers/w23114/w23114.pdf. Last accessed on 26 March 2022.
[563] *Ibid* at p. 10

2020.[564] COVID-19 disease is a sister clade to the prototype human and bat severe acute respiratory syndrome coronaviruses (SARS-CoVs) of the species *Severe acute respiratory syndrome-related coronavirus*, and is designated as SARS-CoV-2.[565] The name is derived from the crown-like appearance of the spike protein, which plays a crucial role in viral infection as it bind to a receptor on the host cell surface and then fuses viral and host membranes.[566]

The COVID-19 pandemic is not the first of its kind. The first SARS outbreak was in 2002 to 2004 when 29 counties and territories were affected and over 8.000 people were infected. Then came the Middle East respiratory syndrome (MERS) disease caused by the Middle East Respiratory Syndrome Coronavirus (MERS-CoV), which was first identified in Jeddah, Saudi Arabia, in 2012. During the SARS outbreak, the scientific community saw the patent race of the coronavirus,[567] which later contributed to the engineering a new way to stabilise the coronavirus spike proteins in the prefusion shape. This resulted in a patent application and a grant of patent on 31 March 2021[568] for a technology which employs protein engineering to stabilize the spike protein in its prefusion conformation, thus preventing structural rearrangement, and exposing antigenically preferable surfaces.[569] This technology, developed as a response to the MERS outbreak, was determined to be also applicable to the SARS virus resulting in

[564] WHO Director-General's opening remarks at the media briefing on COVID-19 - 11 March 2020, https://www.who.int/director-general/speeches/detail/who-director-general-s-opening-remarks-at-the-media-briefing-on-covid-19---11-march-2020. Last accessed on 25 Mar. 22

[565] Coronaviridae Study Group of the International Committee on Taxonomy of Viruses, "The species Severe acute respiratory syndrome-related coronavirus: classifying 2019-nCoV and naming it SARS-CoV-2." *Nature microbiology* 5, no. 4 (2020): 536-544.. *Nature microbiology, 5(4),* 536–544. Available at https://www.ncbi.nlm.nih.gov/pmc/articles/PMC7095448/. Last accessed on 25 Mar. 22

[566] Fang Li, "Structure, function, and evolution of coronavirus spike proteins." *Annual review of virology* 3 (2016): 237-261. Available at https://www.annualreviews.org/doi/abs/10.1146/annurev-virology-110615-042301. Last accessed on 25 Mar. 22.

[567] Matthew Rimmer, "The race to patent the SARS virus: the TRIPS Agreement and access to essential medicines." *Melbourne Journal of International Law* 5, no. 2 (2004): 335-374. Available at https://papers.ssrn.com/sol3/papers.cfm?abstract_id=603234. Last accessed on 14 April 2022.

[568] U.S. Patent No. 10,960,070 B2 available at https://patentimages.storage.googleapis.com/a7/b3/70/666f8c5c2ab026/US10960070.pdf and International Patent Application No. WO/2018/081318 entitled 'Prefusion Coronavirus Spike Proteins and Their Use' available at https://patentimages.storage.googleapis.com/68/47/0c/2b5bc4f43c9f74/WO2018081318A1.pdf. Last accessed on 25 Mar. 22.

[569] Prefusion Coronavirus Spike Proteins and Their Use, PCT/US2017/058370. Available at https://www.ott.nih.gov/bundle/tab-3261. Last accessed on 22 April 2023.

another patent application in 2019.[570] Currently, the majority of the first-generation COVID-19 vaccines, which include those by Pfizer/BioNTech, J&J, Novavax, CureVac and Moderna, are using the publicly developed 2P approach.[571]

Table 5.3.3.1 Covid-19 Vaccine Using 2p Approach[572]

| **Corporation** | **Vaccine Description** |
|---|---|
| Pfizer/BioNTech | **'**BNT162b2, encodes the SARS-CoV-2 full-length spike, **modified by two proline mutations** to lock it in the prefusion conformation.'[573] |
| Johnson and Johnson | **'**We produced seven Ad26 vectors that expressed SARS-CoV-2 S variants that reflected different leader sequences, antigen forms and stabilization mutations**…** wild-type leader sequence with full-length S and mutation of the furin cleavage site and **proline-stabilizing mutations**.'[574] |
| Novavax | **'**rSARS-CoV-2 is generated with 682-QQAQ-685 mutations at the S1/S2 cleavage sites to confer protease resistance and **two proline substitutions** at residues K986P and V987P at the top of the heptad repeat 1/central helix in the S2 subunit to stabilize the construct in a prefusion conformation.**'**[575] |

[570] US Patent Application No. 62/972886 entitled '2019-nCoV Vaccine' in Kizzmekia S. Corbett, Darin K. Edwards, Sarah R. Leist, Olubukola M. Abiona, Seyhan Boyoglu-Barnum, Rebecca A. Gillespie, Sunny Himansu et al. "SARS-CoV-2 mRNA vaccine design enabled by prototype pathogen preparedness." *Nature* 586, no. 7830 (2020): 567-571. Available at https://www.ncbi.nlm.nih.gov/pmc/articles/PMC7301911/. Last accessed on 25 Mar. 22.

[571] Zain Rizvi ,"Leading COVID-19 vaccine candidates depend on NIH technology." *Public Citizen* (2020). Available at https://www.citizen.org/article/leading-covid-19-vaccines-depend-on-nih-technology/. Last accessed on 25 Mar. 22

[572] *Ibid*

[573] Edward E. Walsh, Robert W. Frenck Jr, Ann R. Falsey, Nicholas Kitchin, Judith Absalon, Alejandra Gurtman, Stephen Lockhart et al. "Safety and immunogenicity of two RNA-based Covid-19 vaccine candidates." *New England Journal of Medicine* 383, no. 25 (2020): 2439-2450. Available at https://www.nejm.org/doi/full/10.1056/NEJMoa2027906. Last accessed on 25 Mar. 22.

[574] Noe B. Mercado, Roland Zahn, Frank Wegmann, Carolin Loos, Abishek Chandrashekar, Jingyou Yu, Jinyan Liu et al. "Single-shot Ad26 vaccine protects against SARS-CoV-2 in rhesus macaques." *Nature* 586, no. 7830 (2020): 583-588. Available at https://www.nature.com/articles/s41586-020-2607-z#citeas. Last accessed on 25 Mar. 22.

[575] Cheryl Keech, Gary Albert, Iksung Cho, Andreana Robertson, Patricia Reed, Susan Neal, Joyce S. Plested et al. "Phase 1–2 trial of a SARS-CoV-2 recombinant spike protein nanoparticle vaccine." *New England Journal of Medicine* 383, no. 24 (2020): 2320-2332. Available at https://www.nejm.org/doi/full/10.1056/NEJMoa2026920#article_citing_articles. Last accessed on 25 Mar. 22.

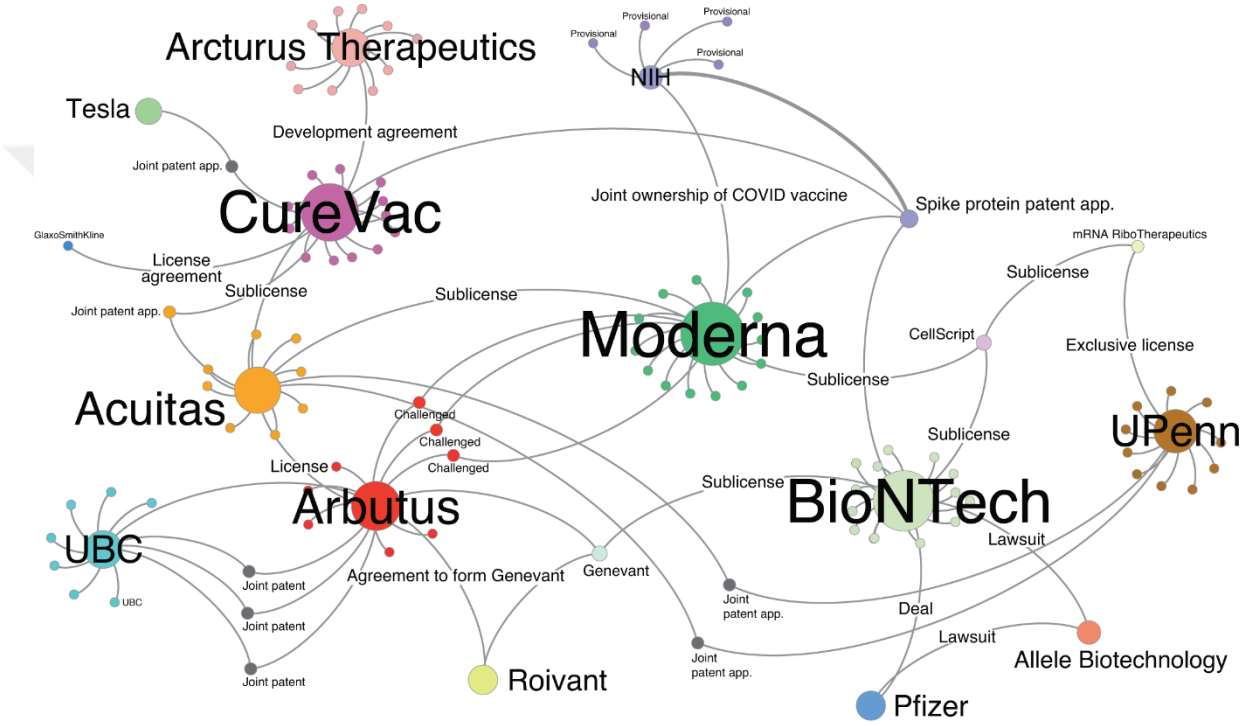
| | |
|---|---|
| CureVac | 'CVnCoV is comprised of lipid nanoparticle (LNP)-formulated, non-chemically modified, sequence engineered mRNA encoding full length S protein **with two proline mutations** (S-2P).'[576] |
| Moderna | 'The mRNA-1273 vaccine candidate, manufactured by Moderna, encodes the S-2P antigen . . . S-2P is stabilized in its prefusion conformation **by two consecutive proline substitutions** at amino acid positions 986 and 987, at the top of the central helix in the S2 subunit.'[577] |

The technology is ground-breaking and is certain to save millions if not billions of lives, however, as it is innovative, it is also a subject to patent protection, which inevitably restricts access. To demonstrate this, in May 2021, Mario Gaviria and Burcu Kilic published a paper providing and overview of the current technologies used to develop COVID-19 vaccines, but more importantly, made a network analysis of the patents these technologies are subject to.[578] They identify that the most promising vaccines are viral vector–based and protein-based technologies as well as mRNA and lipid nanoparticle technology.[579] Regardless of who or where the technology was invented, be that universities or small biotechnology start-up companies, the patent rights usually end up being owned by corporations, which are better prepared to commercialise the innovative technology and even develop it further. Gaviria and Kilic pay special attention to the mRNA and lipid nanoparticle technology, whose development they traced to the early 1990s,[580] but attribute the

[576] Susanne Rauch, Nicole Roth, Kim Schwendt, Mariola Fotin-Mleczek, Stefan O. Mueller, and Benjamin Petsch. "mRNA-based SARS-CoV-2 vaccine candidate CVnCoV induces high levels of virus-neutralising antibodies and mediates protection in rodents." *npj Vaccines* 6, no. 1 (2021): 57. Available at https://www.nature.com/articles/s41541-021-00311-w. Last accessed on 25 Mar. 22.
[577] Lisa A. Jackson, Evan J. Anderson, Nadine G. Rouphael, Paul C. Roberts, Mamodikoe Makhene, Rhea N. Coler, Michele P. McCullough et al. "An mRNA vaccine against SARS-CoV-2—preliminary report." *New England journal of medicine* 383, no. 20 (2020): 1920-1931. Available at https://www.nejm.org/doi/full/10.1056/NEJMoa2022483. Last accessed on 25 Mar. 22.
[578] Mario Gaviria and Burcu Kilic. "A network analysis of COVID-19 mRNA vaccine patents." *Nature Biotechnology* 39, no. 5 (2021): 546-548. Available at https://www.nature.com/articles/s41587-021-00912-9. Last accessed 12 May 2023.
[579] *Ibid* at p. 546
[580] *Ibid* at p. 547 citing Jon A. Wolff, Robert W. Malone, Phillip Williams, Wang Chong, Gyula Acsadi, Agnes Jani, and Philip L. Felgner. "Direct gene transfer into mouse muscle in

importance of the findings on mRNA to researchers at the University of Pennsylvania in 2005.[581] In order to identify the potential patents in play, they used Gephi, an open-source software for exploring and manipulating networks,[582] which resulted in Figure 1 below.

Figure 5.1. Patent network analysis of mRNA-based vaccine candidates for COVID-19. Large nodes represent the relevant entities while the edges represent agreements or patents between two entities. Smaller nodes around the entities represent patents that were identified as being relevant to the underlying vaccine technology[583]




Their work is illustrative of the patent landscape, which under normal circumstances should be crossed in order to get access to innovative vaccines, medications and diagnostics. Under the current circumstance, the World Health Organisation together

vivo." *Science* 247, no. 4949 (1990): 1465-1468. Available at https://media.ellinikahoaxes.gr/uploads/2021/07/science.1690918.pdf. Last accessed on 12 May 2023.

[581] *Ibid* at p. 547 citing Katalin Karikó, Michael Buckstein, Houping Ni, and Drew Weissman. "Suppression of RNA recognition by Toll-like receptors: the impact of nucleoside modification and the evolutionary origin of RNA." *Immunity* 23, no. 2 (2005): 165-175. Available at https://www.sciencedirect.com/science/article/pii/S1074761305002116. Last accessed on 3 June 2022.

[582] Mathieu Bastian, Sebastien Heymann, and Mathieu Jacomy. "Gephi: an open source software for exploring and manipulating networks." In *Proceedings of the international AAAI conference on web and social media*, vol. 3, no. 1, pp. 361-362. 2009. Available at https://sci2s.ugr.es/sites/default/files/files/Teaching/GraduatesCourses/RedesSistemasCompejos/gephi-bastian-feb09.pdf. Last accessed on 2 June 2022.

[583] Gaviria & Kilic, *supra* note 578, at p. 546

with Gavi, the Vaccine Alliance and the Coalition for Epidemic Preparedness Innovations (CEPI) have taken it upon themselves to lend a hand.

### 5.4.1 Funding of COVID-19 Vaccines

As a response to the Covid-19 pandemic, The Access to COVID-19 Tools (ACT) Accelerator was launched at the end of April 2020 in order to accelerate development, production, and equitable access to COVID-19 tests, treatments, and vaccines.[584] It was set up in response to a call from G20 Leaders in March 2020 and launched by the WHO, European Commission, France and The Bill & Melinda Gates Foundation in April 2020.[585] It is comprised of four pillars, each responsible for different aspects of addressing the needs to stop the pandemic. These are the Diagnostics Pillar, Therapeutics Pillar, Vaccines Pillar (COVAX)[586], and the Health Systems Connector Pillar, which works across the other three.[587]

Tests and equitable access to them is in the purview of the Diagnostics Pillar. It aims at development of more accurate and affordable test which are easy to use.[588] The Therapeutics Pillar aims at delivering treatment to everyone in the world while the Vaccine Pillar, the largest of them all, focuses on vaccines, of which it owns the largest and most varied portfolio.[589] The purpose of the Health System connector is to identify barriers and gaps in capacity so as to map systems requirements for COVID-19 tool delivery.[590] Fair allocation of Covid-19 vaccines is conducted through the COVAX Facility, which aims at providing investments and incentives to manufacturers so as to ensure the production of necessary vaccine doses as soon as they are approved.

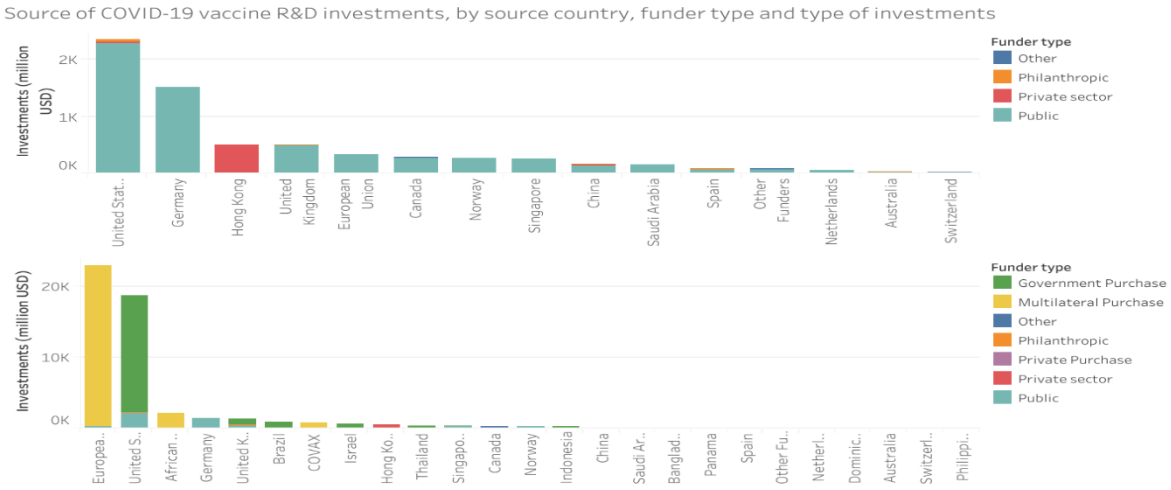
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[584] WHO, 'What is the ACT-Accelerator?', at https://www.who.int/initiatives/act-accelerator/about. Last accessed on 14 April 2022.
[585] Access to COVID-19 Tools (ACT) Accelerator high-level meeting for finance ministries on 29 January 2021 Chairs' Summary, at https://www.regjeringen.no/contentassets/4191f6edc90647dd997c1b737f3f6bc5/2021-01-29-chairs-summary.pdf. Last accessed on 14 Apr. 22
[586] COVAX is coordinated by Gavi, the Vaccine Alliance, the Coalition for Epidemic Preparedness Innovations (CEPI) and the WHO
[587] WHO, 'The ACT-Accelerator frequently asked questions', at https://www.who.int/initiatives/act-accelerator/faq. Last accessed on 14 April 2022.
[588] *Ibid*
[589] *Ibid*
[590] *Ibid*

Gavi is a unique private-public global health partnership founded in January 2000 with the aim of improving 'childhood immunisation coverage in poor countries and to accelerate access to new vaccines.'[591] It rebranded in 2014 and is now known as Gavi, the Vaccines Alliance.[592]

The development of the coronavirus vaccines is heavily funded by governments, health organizations, scientists, businesses, civil society, and philanthropists. As of March 2021, the US and Germany alone have invested approximately $2 billion and $1.5 billion into the effort, respectively, in vaccine R&D.[593] Further data on funding per country is given in Figure 5.2.

Figure 5.2 Source of COVID-19 vaccine R&D investments, by source country and funder type[594]




[591] Devax, 'Global Alliance for Vaccines and Immunisation (Gavi) (GAVI)', available at https://www.devex.com/organizations/global-alliance-for-vaccines-and-immunisation-gavi-44118. Last accessed on 14 April 2022.
[592] Seth Berkley, "COVAX explained." *Gavi The Vaccine Alliance* 3 (2020). Available at https://www.gavi.org/vaccineswork/covax-explained?gclid=Cj0KCQjwjN-SBhCkARIsACsrBz5mvs2YXxce2jzLP2dYJXwPfiWWcoBSrGXvlvTnkVPCJNwzZPhxQqAaAhHgEALw_wcB. Last accessed on 12 May 2023.
[593] Niall McCarthy, "Which Companies Received the Most Covid-19 Vaccine R&D Funding? [Infographic]." (2021). Available at, https://www.forbes.com/sites/niallmccarthy/2021/05/06/which-companies-received-the-most-covid-19-vaccine-rd-funding-infographic/?sh=6dcbba9b4333. Last accessed on 25 Mar. 22
[594] COVID-19 Vaccine R&D Investments, Available at https://www.knowledgeportalia.org/covid19-r-d-funding. Last accessed on 25 Mar. 22.

On 1 March 2022, the WTO announced that Germany will invest further US$ 1.22 billion towards the partnership's vital work on access to COVID-19 treatments, tests, vaccines, and personal protective equipment, becoming the first country to pledge to meet its 'fair share' of the ACT-Accelerator's 2021/22 budget.[595] The Access to COVID-19 Tools (ACT) Accelerator was launched by the WTO in April 2020 to develop tools to fight the COVID-19 disease. It is the fastest, most coordinated, and successful global effort in history.[596] In February 2022, the WHO called for fair share-based financing of US$ 23 billion to end pandemic as global emergency in 2022.[597] This initiative proved necessary to overcome the access inequity between developed and low-income countries. Namely, of all administered tests, only 0.4% are administered in the low-income countries and only 10% of people in low-income countries have received at least one vaccine dose. For this reason, a new financing framework has been agreed by the ACT-Accelerator Facilitation Council's Finance and Resource Mobilization Working Group, comprised of countries across income groups and chaired by Norway.[598] The aim is for the richer countries to contribute their 'fair-share' in helping the ACT-Accelerator's global response to the pandemic.[599]

However, the cost of COVID-19 treatment has not only been a struggle for the low-income countries, but also to many patients in the developed countries, particularly those who suffered from severe COVID-19 and subsequent complications.[600] This is even more true for COVID-19 patients in developing and low-income countries which have under-resourced healthcare systems, and many suffer from weak lungs or

[595] WHO, ACT-Accelerator welcomes Germany's generous 'fair share' commitment. Available at https://www.who.int/news/item/01-03-2022-act-accelerator-welcomes-germany-s-generous-fair-share-commitment. Last accessed on 25 Mar. 22.
[596] WHO, Access to COVID-19 Tools (ACT) Accelerator, available at https://www.who.int/initiatives/act-accelerator. Last accessed om 25 Mar. 22.
[597] WHO, ACT-Accelerator calls for fair share-based financing of US$ 23 billion to end pandemic as global emergency in 2022, available at https://www.who.int/news/item/09-02-2022-act-accelerator-calls-for-fair-share-based-financing-of-usdollar-23-billion-to-end-pandemic-as-global-emergency-in-2022. Last accessed on 25 Mar. 22.
[598] *Ibid*
[599] *Ibid*
[600] Kim Rodgers, Brief: The Projected Economic Impact of the COVID-19 Pandemic on the US Healthcare System (2020). Available at https://www.naccho.org/blog/articles/brief-the-projected-economic-impact-of-the-covid-19-pandemic-on-the-us-healthcare-system. Last accessed on 2 June 2022.

compromised immune systems from chronic malnutrition, tuberculosis, or HIV.[601] Compulsory licences provided for under the TRIPS Agreement can help overcome these struggles as governments would be able to secure generic versions of patented treatments, either through domestic production or foreign import. However, due to the complexity of the TRIPS flexibilities, even though available, countries opted to request a waiver rather than making use of the compulsory licences provided by TRIPS.[602]

### 5.4.2 COVID-19 Patent Waiver

With the breaking of the COVID-19 pandemic, the issue of life science patents reached its highest peak drawing the global public attention. Pressure from both international, namely WHO, and national organisations alike prompted governments worldwide to consider a general patent waiver to medications relating to COVID-19.

A proposal for patent waiver came from South Africa and India in October 2020.[603] They requested that the Council for TRIPS recommends to the General Council a waiver from the implementation, application, and enforcement of Sections 1, 4, 5, and 7 of Part II of the TRIPS Agreement in relation to prevention, containment or treatment of COVID-19 as early as possible.[604] The adoption of the annexed decision text is incorporated in the Communication as a Draft Decision Text.[605] This proposal was generally accepted by the US,[606] however, it was met by a sturdy opposition by the

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[601] Hilary Wong, "The case for compulsory licensing during COVID-19." *Journal of global health* 10, no. 1 (2020). Available at https://www.ncbi.nlm.nih.gov/pmc/articles/PMC7242884/. Last accessed on 25 Mar. 22.

[602] Susy Frankel, "COVID-19, vaccines and international knowledge governance on trial." *Queen Mary Journal of Intellectual Property* 12, no. 4 (2023): 441-469, p. 453. Available at https://www.elgaronline.com/view/journals/qmjip/12/4/article-p441.xml. Last accessed on 26 May 2023.

[603] Communication from India and South Africa, Waiver from Certain Provisions of the Trips Agreement for The Prevention, Containment and Treatment of COVID-19, WTO Doc. IP/C/W/669, 2 October 2020. Available at https://docs.wto.org/dol2fe/Pages/SS/directdoc.aspx?filename=q:/IP/C/W669.pdf&Open=True. Last accessed on 22 March 2022.

[604] *Ibid* para 12

[605] *Ibid*, pp 3-4

[606] Statement by President Joe Biden on the Omicron COVID-19 Variant, 26 Nov. 202. Available at 1 at https://www.whitehouse.gov/briefing-room/statements-releases/2021/11/26/statement-by-president-joe-biden-on-the-omicron-covid-19-variant/: 'I call on the nations […] to meet the U.S. challenge to waive intellectual property protections for COVID vaccines, so these vaccines can be manufactured globally. I endorsed this position in April; this news today reiterates the importance of moving on this quickly.' Last accessed on 22 March 2022.

EU, together with Canada, Australia, Norway, Switzerland and the UK.[607] Although the EU opposed the waiver, it advocated for use of flexibility provided by TRIPS for such circumstances, namely, compulsory licenses facilitating the manufacturing and export of vaccines in favour of LMICs.[608]

In its Communication from 4 June 2021, it proposed that:

> 'WTO Members agree as soon as possible on a global trade initiative for equitable access to COVID-19 vaccines and therapeutics encompassing the following three components: 1) trade facilitation and disciplines on export restrictions; 2) expansion of production, including through pledges by vaccine producers and developers and; 3) clarification and facilitation of TRIPS Agreement flexibilities relating to compulsory licenses.'[609]

The Communication goes on to affirm that the TRIPS Agreement does not and should not prevent Members from taking measures to protect public health with the Doha Declaration clarifying the links between the TRIPS Agreement, its flexibilities and public health.[610] The Doha Declaration states that each Members have the right to grant compulsory licenses and the freedom to determine the grounds upon which such licenses are granted. The provision under paragraph 1 of Article 66 of the TRIPS Agreement concerning the extension period for least developed country Members as well as the exemption from the obligations under the TRIPS Agreement, save Articles 3, 4 and 5 until July 2021 is also communicated as part of the flexibilities provided by the TRIPS agreement in cases of national emergencies.[611] It is worth noting that prior to the TRIPS Agreement, notions such as 'national emergency and other circumstances of extreme urgency' had not been defined, nor properly addressed on international level. Paragraph 5(c) of Declaration allows for member states 'to determine what constitutes a national emergency or other circumstances of extreme urgency, it being

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[607] Alain Strowel, *ALLEA Statement on vaccination and bottlenecks in the Global South and patent waiver for COVID-19 vaccines*. No. UCL-Université Catholique de Louvain. 2021. Available at https://www.wto.org/english/tratop_e/covid19_e/allea_letter_e.pdf. Last accessed on 22 March 2022.
[608] WTO, Communication from the European Union to the Council for TRIPS, Urgent Trade Policy Responses to the COVID-19 Crisis: Intellectual Property, WTO doc. IP/C/W/680 (4 June 2021). Available at https://docs.wto.org/dol2fe/Pages/SS/directdoc.aspx?filename=q:/IP/C/W680.pdf&Open=True. Last accessed on 22 March 2022.
[609] *Ibid* para 4
[610] *Ibid* para 8
[611] *Ibid*.

understood that public health crises, including those relating to HIV/AIDS, tuberculosis, malaria, and other epidemics…'[612]

In order to address certain aspects related to compulsory licenses, 'the EU considers that all WTO Members should be ready to agree on

> a. The pandemic is a circumstance of national emergency and therefore the requirement to negotiate with the right holder may be waived;
> b. To support manufacturers ready to produce vaccines or therapeutics at affordable prices, especially for low- and middle-income countries, on the basis of a compulsory licence, the remuneration for patent holders should reflect such affordable prices; and
> c. The compulsory licence could cover any exports destined to countries that lack manufacturing capacity, including via the COVAX facility.'[613]

In order to achieve these goals, the Communication refers to Article 31(b) of the TRIPS Agreement providing for the conditions under which compulsory licenses can be granted. Such conditions include grant of compulsory licenses after 'the proposed user has made efforts to obtain authorisation from the right holder on reasonable commercial terms and conditions and that such efforts have been unsuccessful for a reasonable period of time.' Article 31(b) further provides that '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.' Given the national emergency that the COVID-19 pandemic represents for any and all countries in the world, the EU proposes that the efforts to negotiate for a certain period of time can be waived.[614] Furthermore, the provisions of paragraph 5 of Article 31*bis* are also proposed to be subject to the waiver, that is, negotiations with the patent holders would not be required under the waiver. In addressing the adequate renumeration of the patent holder, regulated by Article 31(h), the EU clarifies that paragraph 2 of Article 31*bis* would apply thus allowing the price to reflect the one 'charged by the manufacturer of the vaccine or therapeutic under a compulsory licence'[615] As to the notification[616] to the Council, which had proven to be the reason why the Doha Declaration has been burdensome and very difficult to use as it requires exporting Member to include

[612] Ministerial Declaration on the TRIPS Agreement and Public Health, *supra* note 506, para 5(c)
[613] *Ibid* para 9
[614] *Ibid* para 10
[615] *Ibid* para 11
[616] Article 31*bis*

information on the licence, the product and the quantities needed as well as the duration of the licence, the EU proposes a single notification including a list of all countries for which compulsory licences are issued and which would be supplied directly or through the COVAX mechanism.[617]

The WTO Draft Declaration[618] recognised the COVID-19 pandemic to be a global health and economic crises requiring urgent multilateral action[619] and consequently accepted all EU proposals found in its Communication. However, as the Draft Declaration did not answer the request made with the Communication[620] proposing the patent waiver, the negotiations went on under the leadership of World Trade Organization director-general Ngozi Okonjo-Iweala who said her team members were 'ready to roll up their sleeves to reach an agreement on waiving intellectual property for COVID-19 vaccines.'[621] Consequently, on 6th May 2022, WTO members discussed an outcome document,[622] which was leaked mid-March 2022,[623] that was conducted with the Quad (the European Union, India, South Africa and the United States) for an intellectual property response to COVID-19.[624]

The Communication from the Chairperson allows eligible Members to limit the rights provided for under Article 28.1 of the TRIPS Agreement 'by authorizing the use of patented subject matter 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-

[617] Communication from the European Union to the Council for TRIPS, *supra* note 608, para 12
[618] WTO, Draft General Council Declaration on the TRIPS Agreement and Public Health in the Circumstances of a Pandemic, WTO Doc. IP/C/W/681, 18 June 2021. Available at https://docs.wto.org/dol2fe/Pages/SS/directdoc.aspx?filename=Q:/IP/C/W681.pdf. Last accessed on 22 March 2022.
[619] *Ibid*
[620] Communication from India and South Africa, *supra* note 603
[621] Editorial, "Time is running out for COVID vaccine patent waivers." (2022) *Nature 603*, 764, (2022). Available at https://www.nature.com/articles/d41586-022-00878-x. Last accessed on 15 May 2022
[622] WTO, Communication from the Chairperson, WTO Doc. IP/C/W/688, 3 May 2022. Available at https://docs.wto.org/dol2fe/Pages/SS/directdoc.aspx?filename=q:/IP/C/W688.pdf&Open=True. Last accessed on 15 May 2022.
[623] MSF urges governments to reject the draft COVID-19 text tabled at WTO today, that would set a negative precedent (3 May 2022), available at https://reliefweb.int/report/world/msf-urges-governments-reject-draft-covid-19-text-tabled-wto-today-would-set-negative. Last accessed on 15 May 2022.
[624] WTO News, TRIPS Council hears initial reactions to Quad's outcome document on IP COVID-19 response (2022). Available at https://www.wto.org/english/news_e/news22_e/trip_06may22_e.htm. Last accessed on 15 May 2022.

19 pandemic.'[625] Such authorisation is to be permitted without the patent holder's consent by means of 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.'[626] Eligible Members are free to 'issue a single authorization to use the subject matter of multiple patents necessary for the production or supply of a COVID-19 vaccine.'[627] This is conditioned on listing all patents covered for which purpose the assistance of WIPO is afforded in regards to determining the relevant patents.[628] Similar to the Communication of the EU above,[629] the requirements of Article 31(f) TRIPS are also waived but a further allowance is made for 'any proportion of the authorized use to be exported to eligible Members.'[630]

The waiver proposed is much better compared to the 2021 proposal by the EU, however, it only applies to vaccines, which is just a fraction of the requested waiver for 'prevention, containment or treatment of COVID-19,' that is, covers just the 'prevention' part. Médecins Sans Frontières responded with their Technical Note[631] stating that some TRIPS-plus requirements (e.g., listing of all patents) are still imposed, which goes against the objectives of flexibilities contained in Article 31(a).[632] They require substantive revision and improvement of the text to address, among other, IP barriers to access to therapeutics and diagnostics, not vaccines only.

Regardless of the opposition and the further demand for a more comprehensive patent waiver for COVID-19, the final decision, indeed, remained to incorporate the COVID-19 patent waiver to only vaccines excluding all other requested medications. It appears that no further compromise could be made to allow low and middle-income countries access to the much needed therapeutic and diagnostic tools to fight off the COVID-19 pandemic.

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[625] WTO, IP/C/W/688, *supra* note 622, para 1.
[626] *Ibid* para 2
[627] *Ibid* para 3(a)
[628] *Ibid*
[629] Communication from the European Union to the Council for TRIPS, *supra* note 608
[630] Communication from the Chairperson, *supra* note 622, para 3(c)
[631] MSF, Comments on the Patent Listing Requirements in the Draft Text of the TRIPS Waiver Negotiation, March 2022. Available at https://msfaccess.org/sites/default/files/2022-03/COVID19_TechNote_Patent-listing_ENG_March2022.pdf. Last accessed on 15 May 2022.
[632] *Ibid*, p. 1

### 5.4.3 Instead of Conclusion

As patent protection originates in developed economies, it is arguable that it even makes sense in such economies and provides incentives for their further development. Intellectual property protection is considered as one of the most important factors for a country's status on the scale of development. Accession to the European Union is conditioned on harmonisation of the EU legislation divided into 35 chapters, among which Intellectual Property protection is almost at the top of the list.[633] In this regard, even the TRIPS agreement lists essentially biological process invention as subject to exclusion from patentability at the discretion of member states.[634] A society that can afford to provide such protection successfully is considered higher on this scale since it would mean that its population is capable of maintaining the balance between the knowledge it obtains in return for exclusivity on the market it grants. Fair balance achieved in a world developed enough to afford itself such transactions.

The majority of biotechnology patents held in the world are granted in the United States, European Union and Japan.[635] A polarisation concerning this specific field exists in the legislation of the industrialised countries versus developing countries which for various reasons, among which protection of public health and historical ethical reasons, refuse to provide patent protection to genetic material.[636]

However, in a global society where the pursuit of larger markets for placement of innovative products is ever so greater, intellectual property protection is imposed in largely less developed economies than those from which such innovative products

[633] 'In the field of industrial property rights, the acquis sets out harmonised rules for the legal protection of trademarks and designs. Other specific provisions apply for biotechnological inventions, pharmaceuticals and plant protection products.' 'Chapters of the Acquis' At https://ec.europa.eu/neighbourhood-enlargement/enlargement-policy/conditions-membership/chapters-acquis_en. Last accessed on 2 June 2022

[634] Article 27 (3) (b) 'Members may also exclude from patentability: (b) plants and animals other than micro-organisms, and essentially biological processes for the production of plants or animals other than non-biological and microbiological processes.'

[635] Distribution of biotechnology patents filed in 2019, by major country. Statista.com. Available at https://www.statista.com/statistics/379996/share-of-select-countries-in-biotechnology-patents/. Last accessed on 22 Apr. 23.

[636] Salvador Darío Bergel, "Patentability of human genes: The conceptual differences between the industrialised and Latin American countries." *Journal of community genetics* 6, no. 3 (2015): 321-327. Available at https://www.ncbi.nlm.nih.gov/pmc/articles/PMC4524826/. Last accessed on 20 December 2020.

originate.[637] More often than not, majority of the population in the less developed countries is unable to afford such innovative products and yet, it is forced to grant the same exclusive rights which seem to be more balanced in countries where the innovative products are considered more affordable for advancement of their domestic trade.[638] Social inequality has always been reality and it is nothing new, nor introduced by intellectual property protection, albeit reinforced by it. However, the human pursuit of life and health is a human right[639] with an ambition just as strong as the ambition of intellectual property to take global proportions. Biotechnological patents do not favour the former and only work in the interest of strengthening the effects of the latter.[640]

This is ever so evident with the global COVID pandemic. The race for COVID vaccines[641] is incentivised both by the need to stop the spread of the virus, which at the time of writing crippled healthcare systems and economies worldwide,[642] and by the benefits to be ripped by the fastest and most successful companies which can manage to obtain patents for their innovative vaccines despite the fact that the majority of them are being publicly funded.[643] However, the COVID-19 pandemic is not the first, one example being the 2003 and 2004 SARS pandemic, which rushed in a global patent race putting immense pressure on scientists to discover the genetic structure of the then current coronavirus spreading throughout Southeast Asia.[644] Surprisingly, the virus disappeared on its own and research in the coronavirus was all but stopped since

[637] European Union aspiring countries must create conditions for IPRs protection and enforcement in order for the market to be considered safe for potential companies to accept trading there.
[638] Usually through bilateral trade agreements concluded with the US.
[639] Article 21 (1) of The International Covenant on Economic, Social and Cultural Rights, provides that 'The States Parties to the present Covenant recognize the right of everyone to the enjoyment of the highest attainable standard of physical and mental health.' Available at https://www.ohchr.org/en/professionalinterest/pages/cescr.aspx. Last accessed on 20 December 2020.
[640] See Anupam Chander and Madhavi Sunder. "The romance of the public domain." *Calif. L. Rev.* 92 (2004): 1331 arguing further that there is a unidirectional transfer of ownership from less developed to developed countries which reap the biodiversity resources from the former. Available at https://static1.squarespace.com/static/5c899ec09b7d151febd5660e/t/5d1bc87a84af9d000170e76c/1562101883315/romance.pdf. Last accessed on 27 May 2022
[641] As of the time of writing, 641 therapies and 189 vaccines related to COVID-19 are under development. See BioWorld, Biopharma products in development for COVID-19. Available at https://www.bioworld.com/COVID19products. Last accessed on 20 December 2020.
[642] 'COVID-19 to Plunge Global Economy into Worst Recession since World War II,' World Bank website, available at https://www.worldbank.org/en/news/press-release/2020/06/08/covid-19-to-plunge-global-economy-into-worst-recession-since-world-war-ii. Last accessed on 20 December 2020.
[643] See *infra* Part 6.5.3 on University patents
[644] Matthew Rimmer, "The race to patent the SARS virus: the TRIPS Agreement and access to essential medicines." *Melbourne Journal of International Law* 5, no. 2 (2004): 335-374. Available at https://ssrn.com/abstract=603234 Last accessed on 21 Dec. 20.

any invention stemming from such research would unlikely generate profits. As a result, it is safe to conclude that profit-based investments lead to COVID-19-like pandemics. The similarities[645] between the two viruses are still being determined since so little knowledge about SARS-CoV was gathered in 2003 and SARS-Covid-2 has got all the attention of the scientific community now that studies of the former might receive due consideration, that is funding, well after the latter is resolved. This would raise, or answer, the question of whether profitless studies could prevent future crises like the current one.

As patent rights are envisaged to be national rights, each country establishes its minimum standards to provide patent protection to inventions which are to be marketed on the territory where patent protection is provided. Depending on each country's patent laws, when patent application is filed, patent databases can be searched nationally or internationally so as to examine the novelty of invention subject to the filed patent application. Strongest patents must prove novelty on international level, that is, examiners conduct international database search thus guaranteeing the novelty worldwide, which serves the purpose of establishing priority date difficult to oppose in subsequent filing in other countries.[646] This, in turn, prevents any competition from inventions with similar characteristics, not only nationally but internationally, too. Once a product is compiled, all products encompassing the same bases would be in breach of a patent even if an attempt for production is made, let alone marketed.[647]

When this is translated into pharmaceutical and biotechnological patents, the issue shifts from trade to access to health and healthcare. Attempts have been made to tackle the problem with access to essential medicine on international level with the Doha

[645] For discussion on similarities and differences between SARS and Covid 19, see Caldaria Antonio, Claudio Conforti, D. M. Nicola, D. Caterina, Mohammad Jafferany, Torello Lotti, Iris Zalaudek, and Roberta Giuffrida. "COVID-19 and SARS: Differences and similarities." *Dermatologic therapy* 33, no. 4 (2020). Available at https://www.ncbi.nlm.nih.gov/pmc/articles/PMC7235519/#dth13395-bib-0008. Last accessed on 2 June 2022. For comparison of Coronaviruses SARS-CoV-2 and SARS-CoV, see Jiabao Xu, Shizhe Zhao, Tieshan Teng, Abualgasim Elgaili Abdalla, Wan Zhu, Longxiang Xie, Yunlong Wang, and Xiangqian Guo. "Systematic comparison of two animal-to-human transmitted human coronaviruses: SARS-CoV-2 and SARS-CoV." *Viruses* 12, no. 2 (2020): 244. Available https://www.ncbi.nlm.nih.gov/pmc/articles/PMC7077191/ Last accessed on 6 June 2022.
[646] Article 87 'Priority Right' EPC. Available at https://www.epo.org/law-practice/legal-texts/html/epc/2016/e/ar87.html. Last accessed on 20 December 2020.
[647] Patent scope, Article 36, TRIPS Agreement.

agreement amending TRIPS but so far there are not many examples where the instrument provided by Doha has been used by less developed countries to use compulsory licences so as to import essential medicine from developed countries at cost.[648] With the raving pandemic at hand, weaknesses of society pertaining to access to innovative medication, as are the new COVID-19 vaccines and the necessary diagnostic and therapeutic products discussed above, float to surface.

Pharmaceutical companies developing the vaccines can patent their inventions wherever they would see potentially strong market for them. The Doha instrument could be used to supply less developed countries with the much-needed vaccine, but they might opt not to activate the instrument due to bilateral free-trade agreements[649] they would be in breach of if such instrument is triggered. Stopping the virus selectively is not an option in a global society. WHO created international bodies[650] to meet the virus head on and make the vaccines available globally, and this is indeed a temporary solution, but the obstacles posed by the patent system to provide the global population with medication are almost insurmountable in the long-run. As the TRIPS Agreement and its current flexibilities have proven ineffective, some considerations for its further amendment ought to be made.

The fallowing Chapter seeks to address the above by turning back to the balance of rights by utilising some of the philosophical approaches to intellectual property rights in the pursuit to find new means for balancing the private and public interests.

[648] https://www.who.int/medicines/areas/policy/doha_declaration/en/
[649] Hitoshi Nasu, "Public law challenges to the regulation of pharmaceutical patents in the US bilateral free trade agreement." (2010): 10-53. cited in Thomas Pogge, Matthew Rimmer, and Kim Rubenstein, eds. *Incentives for global public health: patent law and access to essential medicines*. Cambridge university press, 2010. p.77-101. Available at https://papers.ssrn.com/sol3/papers.cfm?abstract_id=1652501. Last accessed on 5 June 2022.
[650] See *supra*, Part 5.4.1.

## 6. IN SEARCH OF THE PATENT TRADE-OFF

After reviewing the biotechnology patenting practices in Europe, the US and Türkiye as well as the effects of their overlord, the TRIPS agreement, on access to medicine worldwide, it seems that despite the humanitarian injustice caused by the rights granted for life-saving products, the patent system remains as fortified and as untouchable as ever. However, the patent system, in its essence, is designed to serve companies and generate profits and does not involve any social goals, like providing affordable healthcare or medical technologies to those in need.[651] This designed was developed by centuries of patent practice, even though its historical roots suggest its purpose was to enable talented and inventive individuals to profit from their work.[652] At the time, the prevailing inventions were mechanical since the problems to be solved required such solutions considering the technological development of society. Nowadays, the problems which need solving require significant technological knowledge, first, to identify the problem and then, to find a solution for it. The patent system serves its purpose now just like it did then. The difference is the level of education required, for to solve contemporary problems, simple observation of the world around would not suffice. Inventions discussed thus far can only be made by scientists in very well-equipped laboratories enabling them to further study a problem and offer a patentable solution for it. Companies invest in equipment and in readymade scientists to achieve their commercial goals. This arrangement has worked for decades, and the patent system has been fulfilling its purpose of providing incentive for technological development impeccably.[653]

Nonetheless, the fact that pharmaceutical and biotechnological patents impede access to medicine stands and the need for balance, so sought after,[654] has not yet been found.

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[651] Contreras (2020), *supra* note 170 p. 45.

[652] For example, under the Statute of Anne, copyright was vested in authors rather than publishers. 'An Act for the Encouragement of Learning, by Vesting the Copies of Printed Books in the Authors or Purchasers of such Copies, during the Times therein mentioned.' 8 Ann. c. 21, 1710

[653] It is arguable though if patents have anything to do with inventiveness itself as research studies have failed to find correlation between patents and inventiveness and economists repeatedly fail to find causal relationship between patents and inventiveness. See more in Ikechi Mgbeoji, *Global biopiracy: patents, plants, and indigenous knowledge*. ubc Press, 2007, p. 21.

[654] See generally James C. De Vellis, "Patenting industry standards: balancing the rights of patent holders with the need for industry-wide standards." *AIPLA QJ* 31 (2003): 301. Also, Dan L. Burk and Brett H. McDonnell, "The Goldilocks hypothesis: Balancing intellectual property rights at the boundary of the firm." *U. Ill. L. Rev.* (2007): 575. Available at https://papers.ssrn.com/sol3/papers.cfm?abstract_id=890944. Last accesses on 17 May 2022. Also,

Perhaps, the patent system might need to be ennobled with the social goal it is missing thus gaining favour from wider society in the process becoming more popular and more acceptable worldwide. This chapter examines this possibility. It first focuses on the balance of rights by looking into intellectual property right and human rights and then turns to the possible solutions for reconciling the patent system with society as whole.

## 6.1. Intellectual Property and Human Rights

When the balance of rights is weight, intellectual property rights are always faced with human rights as morally superior and, in most cases, constitutional rights. This is very much pronounced when it comes to pharmaceutical and biotechnology patent rights since they directly interfere with the human right to health as they impede access to medications developed by these industries, even though this stance is advocated and criticised alike.[655] As the biotechnology industry developed and medical advances were made, the border between pharmaceutical and biotechnological products got blurred and the pharmaceutical strife with human rights became biotechnological, too. This is evident from the public response to patenting genes and embryonic stem cells throughout the world.[656]

Considerations have been given to the questions of whether IPRs are legal rights without human rights dimension, IPRs are human rights in terms of property rights or whether IPRs, in some of their aspects, have potentially adverse implications for human rights.[657] Given that with regard to copyright at least, the solemn declaration by the States members of the Assembly of the Berne Union for the Protection of Literary and Artistic Works, 1986, clearly and unambiguously states that ‘copyright is based on human rights and justice and that authors, as creators of beauty, entertainment

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Greg Martin, Corinna Sorenson, and Thomas Faunce. "Balancing intellectual monopoly privileges and the need for essential medicines." *Globalization and Health* 3, no. 1 (2007): 1-5. Available at https://globalizationandhealth.biomedcentral.com/articles/10.1186/1744-8603-3-4. Last accessed on 17 May 2022. Sara M. Ford, "Compulsory licensing provisions under the TRIPS agreement: balancing pills and patents." *Am. U. Int'l L. Rev.* 15 (1999): 941. Available at https://digitalcommons.wcl.american.edu/cgi/viewcontent.cgi?article=1278&context=auilr. Last accessed on 17 May 2022.

[655] See *supra,* Chapter 1.7

[656] See *supra,* Chapters 2 and 3

[657] Duncan Matthews, "Intellectual property rights, human rights and the right to health." In *Intellectual Property and Human Rights*. Edward Elgar Publishing, 2010, p. 2, Available at https://ssrn.com/abstract=1414900. Last accessed on 19 March 2022.

and learning, deserve that their rights in their creations be recognized and effectively protected both in their country and in all other countries of the world'[658] the first cannot be considered as true. The regard of IPRs as essentially human rights to tangible property has been argued to have enjoyed long recognition[659] drawing on the Constitution of the United States and the American Declaration on the Rights and Duties of Man,[660] and, indeed, international human rights documents which include the right to own intellectual property as the right to own property are the Universal Declaration of Human Rights[661] and the United Nations International Covenant on Economic, Social and Cultural Rights.[662]

Article 17(1) of the Universal Declaration of Human Rights recognises that '[e]veryone has the right to own property alone as well as in association with others' and Article 17(2) that '[no] one shall be arbitrarily deprived of his property.' Article 27 then goes on to state that: '(1) Everyone has the right to freely participate in the cultural life of the community, to enjoy the arts and to share in scientific advancement and its benefits. (2) Everyone has the right to the protection of the moral and material interests resulting from any scientific, literary or artistic production of which he is the author.'

The United Nations International Covenant on Economic, Social and Cultural Rights (ICESCR), 1966, in Article 15(1), similarly to the Universal Declaration of Human Rights provides the '[t]he States Parties to the present Covenant recognise the right of everyone: (a) to take part in cultural life; (b) to enjoy the benefits of scientific progress and its applications; (c) to benefit from the protection of the moral and material

[658] Assembly of the Berne Union "Solemn Declaration" of 9 September 1986.
[659] Tom Giovanetti and Merrill Matthews. "Intellectual property rights and human rights." *IT&T News* (2005), p.1. Available at https://www.ipi.org/docLib/IPandHumanRights.pdf-OpenElement.pdf. Last accessed on 19 March 2022.
[660] 'He likewise has the right to the protection of his moral and material interests as regards his inventions or any literary, scientific or artistic works of which he is the author.' American Declaration of the Rights and Duties of Man, Article 13.
[661] Universal Declaration of Human Rights *Adopted and proclaimed by General Assembly Resolution 217 A (III) of 10 December 1948*, G.A. Res217A (III) 3 U.N. GAOR (Resolutions, part 1) at 71, U.N. Doc. A/810 (1948). Available at: https://www.un.org/en/about-us/universal-declaration-of-human-rights. Last accessed on 19 March 2022.
[662] International Covenant on Economic, Social and Cultural Rights adopted 16 December 1966, 993 U.N.T.S. 3 (entered into force 3 January 1976), G.A. Res. 2200 (XXI), 21 U.N. GAOR Supp. (No. 16) at 49, U.N. Doc.A/6316 (1966). Available at https://treaties.un.org/doc/Treaties/1976/01/19760103%2009-57%20PM/Ch_IV_03.pdf. Last accessed on 19 March 2022.

interests resulting from any scientific, literary or artistic production of which he or she is the author.' To achieve this, rights of authors and creators need to facilitate rather than constrain cultural participation, on the one hand, and scientific progress and access, on the other. Thus, components of Article 15 must be complemented, fully respected, and promoted by intellectual property law providing for intellection property protection.[663] The need for balanced protection of public and private interests stipulated by Article 15 ICESCR was recognised in the report of the High Commissioner on Human Rights on the impact of the Agreement on Trade-Related Aspects of Intellectual Property Rights on human rights.[664] Protection of the right of everyone to take part in cultural life and to enjoy the benefits of scientific progress and its applications, on the one hand, and the right of everyone to benefit from the protection of the moral and material interests resulting from any scientific, literary or artistic production of which he or she is the author, on the other, combines the need to promote general public interests in accessing new knowledge and to protect the interests of authors and inventors in such knowledge. This leads to the conclusion that the traditional intellectual property systems are compatible with Article 15 and raises the question of whether greater emphasis should be given to protecting interests of inventors and authors or to promoting public access to new knowledge.[665] Striking the right balance between the interests of right holders and the access to knowledge is crucial for the conclusions of this work and the proposed changes aiming at achieving such balance.[666]

### 6.1.1. Biotech Patents and the Right to Access to Medicine

In view of Article 27 TRIPS providing for protection of inventions in all fields of technology, thus including pharmaceutical products, the right to health and access to medicine affected by such protection must be taken in account. Article 25 of the

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[663] *Implementation of the International Covenant on Economic, Social and Cultural Rights*. Discussion paper submitted by Audrey R. Chapman, American Association for the Advancement of Science (AAAS), Washington, USA, to the United Nations Committee on Economic, Social and Cultural Rights, E/C.12/2000/12, 3 October 2000, available at https://www.iprsonline.org/tbs/doc-nsf/898586b1dc7b4043c1256a450044f331/951444022ab674cbc1256999005aadb0/_FILE/G0044783.pdf. Last accessed on 3 June 2022.

[664] United Nations Commission on Human Rights, "Economic, Social and Cultural Rights: The impact of the Agreement on Trade-Related Aspects of Intellectual Property Rights on human Rights." Report of the High Commissioner, 27 June 2001, E/CN.4/Sub.2/2001/13, page 5.

[665] *Ibid* at p. 5

[666] See *infra* Part 6.2 on Balance of Rights

Universal Declaration of Human Rights, 1948, states explicitly that '[e]veryone has the right to a standard of living adequate for the health and well-being of himself and his family, including food, clothing, housing and medical care…' Furthermore, Article 12 of the United Nations International Covenant on Economic, Social and Cultural Rights, 1966, states that '[t]he States Parties to the present Covenant recognize the right of everyone to the enjoyment of the highest attainable standard of physical and mental health.'[667]

UN Committee on Economic, Social and Cultural Rights has also elaborated, in General Comment 14, adopted on 11 May 2000, that health is a fundamental human right and indispensable for the exercise of other human rights.[668] Countries are obliged to undertake actions to fulfil their obligations under Article 12(2)(c) ICESCR for 'the prevention, treatment and control of epidemic, endemic, occupational and other diseases.' They are also required to make individual and joint efforts to make available relevant technologies and promote strategies of infectious disease control.[669] As discussed above, most recently, the COVID pandemic proved just the right occasion for this obligation to be put into practice. This is underlined by the international obligation to 'provide essential drugs, as from time to time defined under the WHO Action Programme on Essential Drugs' and to 'take measures to prevent, treat and control epidemic and endemic diseases.'[670] The General Comment 14 goes further to address the violations of the obligation to protect and includes failure to regulate activities of individuals, groups or corporations which violate the right to health of others as one of the violations to their obligations[671] as well as the failure to take

[667] The 'highest attenable standard' is still sought after and is on the list of the 2030 Agenda for Sustainable Development. See Dainius Puras, "Right of everyone to the enjoyment of the highest attainable standard of physical and mental health: note/by the Secretary-General" in UN, Document A/71/304 - Report of the Special Rapporteur on the right of everyone to the enjoyment of the highest attainable standard of physical and mental health (2016). Available at https://digitallibrary.un.org/record/839996. Last accessed on 5 June 2022.
[668] United Nations Economic and Social Committee General Comment No. 14 on the right to the highest attainable standard of health (Article 12 of the International Covenant on Economic, Social and Cultural Rights). Committee on Economic, Social and Cultural Rights, Twenty-second session, Geneva, 25 April-12 May 2000, E/C.12/2000/4. Available at https://www.refworld.org/pdfid/4538838d0.pdf. Last accessed on 20 March 2022.
[669] *Ibid* at para 19
[670] *Ibid* at paras 43 and 44.
[671] *Ibid* para 51

measures to reduce the inequitable distribution of health facilities, goods and services.[672]

The report of the High Commissioner on the impact of TRIPS on human rights reaffirms that states have a duty to ensure equal access to health care and remove any threat to the availability, accessibility, acceptability and quality of health facilities, goods and services.[673] States are also obliged to provide affordable health facilities, goods and services for all, 'based on the principle of equity, ensuring access to these services, whether privately or publicly provided.'[674]

In its Resolution 2000/7, The United Nations Sub-Commission on the Promotion of Human Rights also declared 'that since the implementation of the TRIPS Agreement does not adequately reflect the fundamental nature and indivisibility of all human rights, including the right everyone to enjoy the benefits of scientific progress and its applications, the right to health, the right to food and the right to self-determination, there are apparent conflicts between the intellectual property rights regime embodied in the TRIPS Agreement, on the one hand, and international human rights law, on the other.'[675] Moreover, it commended the Conference of Parties to the Convention on Biodiversity for its decision to assess the relationship between biodiversity concerns and intellectual property rights in general, and between the Convention on Biodiversity and TRIPS, in particular, and urged it also to consider human rights principles and instruments in undertaking this assessment.[676]

On 21 November 2005, the UNHCR Committee on Economic, Social and Cultural Rights adopted General Comment 17 elaborating on the right of everyone to benefit from the protection of the moral and material interests resulting from any scientific, literary or artistic production of which he is the author, as set out in Article 15, paragraph 1(c), of the Covenant.[677] General Comment 17 states that human rights are

[672] *Ibid* para 39
[673] *Ibid* para 35
[674] *Ibid* para 12(b)
[675] United Nations High Commission for Human Rights Sub-Commission on Human Rights Resolution 2000/7: Intellectual property rights and human rights, para 2. Available at https://www.aaas.org/sites/default/files/SRHRL/PDF/IHRDArticle15/E-CN_4-SUB_2-RES-2000-7_Eng.pdf. Last accessed on 20 March 2022.
[676] *Ibid* at para 13
[677] General Comment No. 17 on the right of everyone to benefit from the protection of the moral and material interests resulting from any scientific, literary or artistic production of which he is the author

fundamental, inalienable and universal entitlements belonging to individuals and, in under certain circumstances, groups of individuals and communities. However, General Comment 17 also notes that human rights are fundamental as they are inherent in the human person as such, whereas intellectual property rights are first and foremost means by which states seek to provide incentives for inventiveness and creativity, encourage the dissemination of creative and innovative productions, as well as the development of cultural identities, and preserve the integrity of scientific, literary and artistic productions for the benefit of society as a whole.[678] Moreover, it states that in contrast to human rights, intellectual property rights are generally of a temporary nature, and 'can be revoked, licensed or assigned to someone else. While under most intellectual property systems, intellectual property rights, with the exception of moral rights, may be allocated, limited in time and scope, traded, amended and even forfeited, human rights are timeless expressions of fundamental entitlements of the human person.'[679]

When considering intellectual property rights as human rights it is important to stress that these rights are nowadays generally held by corporations and as such could not possibly qualify as human rights.[680] As Maria Green points out, 'the drafters [of the ICESCR] do not seem to have been thinking in terms of the corporation-held patent, or the situation where the creator is simply an employee of the entity that holds the patent or the copyright.[681] Similarly, General Comment No. 17 notes that while human rights focus on individuals, groups of individuals, and communities, 'intellectual property regimes primarily protect business and corporate interests and investments.' Since corporations are not imparted human rights protection, 'their entitlements,

(article 15(1)(c) of the Covenant), adopted by the UNHCR Committee on Economic, Social and Cultural Rights on 21 November 2005 (E/C.12/2005/GC/17). The earlier title of the draft document was General Comment No. 18. This draft document, for which Eibe Riedel (CESCR member, Germany) was Rapporteur, was ultimately adopted by the Committee on Economic, Social and Cultural Rights on 21 November 2005 and re-numbered as General Comment No. 17 (a separate General Comment No. 18 now relates to the right to work (Article 6 of the Covenant). Available at https://www.refworld.org/pdfid/474d35ca2.pdf. Last accessed on 20 March 2022.

[678] *Ibid* at para 1

[679] *Ibid* at para 2

[680] Peter K. Yu, "Ten common questions about intellectual property and human rights." *Ga. St. UL Rev.* 23 (2006): 709, p.728. Available at https://papers.ssrn.com/sol3/papers.cfm?abstract_id=1090241. Last accessed on 20 March 2022.

[681] Maria Green, "Drafting History of Article 15 (1)(c) of the International Covenant on Economic, Social and Cultural Rights." (2000). Available at http://www.un.org/en/ga/search/view_doc.asp?symbol=E/C.12/2000/15. Last accessed on 3 June 2022.

because of their different nature, are not protected at the level of human rights.'[682] As human rights are inalienable, they differ from intellectual property rights which authors and creators can assign, licence or release these rights to their employers under work-made-for-hire arrangements. Human rights, on the other hand, are not transferable in such a manner.

Likewise, General Comment No. 17 included a more stringent test than the three-step test laid out in the Berne Convention, the TRIPS Agreement, and the WIPO Internet Treaties, which 'confine limitations or exceptions to exclusive rights to certain special cases which do not conflict with a normal exploitation of the work and do not unreasonably prejudice the legitimate interests of the right holder.'[683] Accordingly, to comply with ICESCR, CESCR stated that the limitations 'must be determined by law in a manner compatible with the nature of these rights, must pursue a legitimate aim, and must be strictly necessary for the promotion of the general welfare in a democratic society, in accordance with article 4 of the Covenant.' Moreover, they must be proportionate and compatible with other provisions and must offer a least restrictive means to achieve the goals. Under certain circumstances, '[t]he imposition of limitations may… require compensatory measures, such as payment of adequate compensation for the use of scientific, literary or artistic productions in the public interest.'

WTO and WIPO explored the relationship between human rights and intellectual property rights on several occasions, one being in November 1998, when WIPO conducted a panel discussion on 'Intellectual Property and Human Rights.'[684] The TRIPS Council also paid closer attention to the lack of access to patented pharmaceuticals in light of HIV/AIDS, tuberculosis, and malaria pandemics in Africa and other less developed countries, which resulted in the adoption of the Doha Declaration on the TRIPS Agreement and Public Health as well as the protocol

[682] General Comment 17, *supra* note 677, para 7.
[683] Article 13, TRIPS Agreement
[684] World Intellectual Prop. Org., *Panel Discussion on Intellectual Property and Human Rights Geneva* (Nov. 9, 1998), Available at https://www.wipo.int/pressroom/en/prdocs/1998/wipo_upd_1998_40.html. Last accessed on 20 March 2022.

amending the TRIPS Agreement by adding a new article 31*bis*. The outcome of this is discussed in Chapter 5 above.

Among others, Peter Yu[685] argues that less developed countries have taken advantage of the human rights regime to 'grow proposals that seek to roll back intellectual property rights or at least eschew further expansions of the monopoly privileges they confer.'[686] Thus, by shifting from one regime to another, these countries were able to alter the status quo or to create tactical advantages by relocating to a more sympathetic forum, such as the public health or human rights regime.[687] Protection of human rights is, indeed, beneficial for less developed countries since this regime has built-in institutional safeguards to protect the poor, the marginalized, and the less powerful. However, it is argued that such protection may limit access to protected materials and frustrate projects that facilitate greater unauthorised recoding or re-use of existing creative works.[688]

### 6.2. The Balance of Private-Public Interests

It can be argued that balance is not anachronic but fluid and synchronized since things rebalance as they change. Alternatively, today's balance might be tomorrow's disarray. This is especially true in the contemporary society driven by constant change and development. However, with societal changes, the already established balances need looking into and making sure that mechanisms placed to keep such balances are still working properly. The balancing of private and public interests in intellectual property rights, especially patent rights, is no different, nor neglected. For example,

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[685] Yu, *supra* note 680, p. 745

[686] Laurence R. Helfer, "Toward a human rights framework for intellectual property." *UC Davis L. Rev.* 40 (2006): 971. Available at https://lawreview.law.ucdavis.edu/issues/40/3/intl-rights-approaches-to-ip/DavisVol40No3_Helfer.pdf. Last accessed on 20 March 2022.

[687] See Laurence R. Helfer, "Regime shifting: the TRIPs agreement and new dynamics of international intellectual property lawmaking." *Yale J. Int'l L.* 29 (2004): 1. Available at https://scholarship.law.duke.edu/faculty_scholarship/2014/. Last accessed on 20 March 2022; Also on forum-shifting see generally John Braithwaite and Peter Drahos. *Global business regulation*. Cambridge university press, 2000; Peter K. Yu, "Currents and crosscurrents in the international intellectual property regime." *Loy. LAL Rev.* 38 (2004): 323. Available at https://digitalcommons.lmu.edu/cgi/viewcontent.cgi?article=2453&context=llr. Last accessed on 20 March 2022.

[688] Yu (2006), *supra* note 680, page 746.

Menell, et al.[689] find that '[t]he key to economic efficiency lies in balancing the social benefits of providing economic incentives for creation and the social costs of limiting the diffusion of knowledge.'

Discussed and researched both by opponents and advocates of patent rights, the balance of rights in patent law is a simple transaction seen through the prism of contractual justice theory. In the words of Robinson:

> A patent is a contract between the inventor and the public, by which the inventor, in consideration that the exclusive use of his invention is secured to him for a limited period of time, confers upon the public the knowledge of the invention during that period and an unrestricted right to use it after that period has expired […]. The specification is the instrument in which the terms of these mutual considerations and promises are declared, and on its completeness and accuracy depends the validity and the value of the contract itself.[690]

In other words, the inventor discloses their invention in detail, and the society grants them an exclusive right to dispose of the disclosed invention as they please. A recent paper by Mario Biagioli concludes that such balance does not really exist outside patents themselves.[691] The more productive the patent is, the more exclusive power it gets.[692] He also argues that an invention which is not provided patent protection falls in the public domain and has got almost no market power since there is nothing to prevent others to produce the products underlined by such invention.[693] This would mean that the market itself is the driver of development, not the inventiveness of products placed on the market.[694] The success of an invention could be estimated by considering its actual production, if it takes place or not, and how many people such

[689] Peter S. Menell, Mark A. Lemley, Robert P. Merges, and Shyamkrishna Balganesh. "Intellectual Property in the New Technological Age: 2022-Chapters 1 and 2." *Available at* https://papers.ssrn.com/sol3/papers.cfm?abstract_id=3884159. Last accessed on 18 May 2022.
[690] William Callyhan Robinson, *The law of patents for useful inventions*. Vol. 2. Little, Brown, 1890, p.70. Available at https://babel.hathitrust.org/cgi/pt?id=uc1.b3124814&view=1up&seq=98&skin=2021. Last accessed on 18 May 2022.
[691] Mario Biagioli, "Weighing intellectual property: Can we balance the social costs and benefits of patenting?." *History of science* 57, no. 1 (2019): 140-163. Available at https://journals.sagepub.com/doi/full/10.1177/0073275318797787. Last accessed on 18 May 2022.
[692] *Ibid*, pp. 160-161
[693] *Ibid*, pp. 150
[694] Mgbeoji (2006), *supra* note 653, argues the missing link between inventiveness and patents.

invention has reached. If the invention is released into the public domain as soon as it is invented, it does not allow anyone to produce it exclusively. If it is successful when placed on the market, it would be copied by competitors and as such it is not a profitable investment. And, yet Biagioli argues that 'progress is ultimately accomplished when inventions and works of authorship are released into the public domain at the expiration of their term or protection, thus becoming free for everybody to use.'[695]

As patented products are sometimes very expensive and time consuming to produce and, yet, very easy and cheap to copy, they are found to have an unusual nature since they require different approach so as to generate profits for the deserving parties.[696] The patent system allows creators or patent holders the deserved gratification, but the cost society pays to access patented products is rather high, especially when it comes to biotechnological inventions which have the potential to save many lives. And these are exactly those requiring time and large investments. Efforts to strike that balance between the needs of the patent holders and the needs of the society are numerous. One recent example to achieve this is the COVID-19 Patent Waiver, which resulted in only a partial waiver of IPRs.[697] From this one example only, it can be argued that the strive to achieving the said balance has so far been a patch work. Competition driven economy further emphasises this as 'limited islands of monopoly'[698] that is patents, are not only tolerated by also encouraged. On the other hand, given the time-limited duration of patents, commentators refuse to refer to them as monopolies but exclusive rights since they argue patents stimulate competition by motivating others to find different solutions for the same problem.[699] However, the fact that patents impede access to medicines is irrefutable as they are brees largely unaffordable products.

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[695] Biagioli, *supra* note 691, p. 142

[696] The tragedy of anticommons as defined in Qianwei Ying, "Anticommons, Tragedy of the." In: Marciano A., Ramello G.B. (eds) Encyclopedia of Law and Economics. Springer, New York, NY, 2019, Available at https://doi.org/10.1007/978-1-4614-7753-2_90. Last accessed on 15 May 2023.

[697] WTO, WT/MIN(22)/30, WT/L/1141, Ministerial Decision on the TRIPS Agreement, adopted On 17 June 2022.

[698] Fritz Machlup, *An economic review of the patent system*. No. 15. US Government Printing Office, 1958. Available at https://cdn.mises.org/An%20Economic%20Review%20of%20the%20Patent%20System_Vol_3_3.pdf . Last accessed on 3 June 2022.

[699] Harold G. Fox, "Patents in relation to monopoly." *Canadian Journal of Economics and Political Science/Revue canadienne de economiques et science politique* 12, no. 3 (1946): 328-342; Jesús Joanós i Timoneda, News 'Patents Are Not Monopolies' C&EN Chemical and Engineering, available

Many alternatives to patents have been proposed and discussed including possible industry-specific length of protection based on the different development costs and incentives in different fields of invention (software, pharmaceuticals, etc.),[700] alternative systems providing the necessary incentive for innovation while enabling access to essential medicine to populations inflicted with poverty, like the Health Impact Fund,[701] or localising the process of patent grant by transferring the granting powers to the society rather than the examiners.[702] Private-public partnership is also one of the alleys to increase public access.[703] It is also argued that exclusive or proprietary rights are used to leverage access, to promote dissemination, and to safeguard downstream use rights through the shaping of license policies.[704] IP license management in an imaginative and solid manner can be a powerful tool for advancing both private and public interest.[705]

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at https://cen.acs.org/articles/85/i34/Patents-Monopolies.html. Last accessed on 22 December 2020. Also Gene Quinn, 'Debunking the Myth that Patents Create a Monopoly,' IPWatchdog.com, available at https://www.ipwatchdog.com/2017/02/25/debunking-myth-patents-create-monopoly/id=78756/ Last accessed on 22 December 2020.

[700] Brian Kahin, "Patent Reform for a Digital Economy." *Computer & Communications Industry Association* (2006). Available at https://www.ccianet.org/wp-content/uploads/2013/09/CCIA_WP_PatReformDigEcon.pdf. Last accessed on 2 June 2022.

[701] Aidan Hollis and Thomas Pogge. *Product-development partnerships and the health impact fund*. Vol. 9, no. 4. IGH Discussion Paper No, 2010. Available at https://healthimpactfund.org/en/publications/. Last accessed on 22 December 2020. Also, Thomas Pogge, "The health impact fund: enhancing justice and efficiency in global health." *Journal of Human Development and Capabilities* 13, no. 4 (2012): 537-559. Available at https://www.tandfonline.com/doi/abs/10.1080/19452829.2012.703172. Last accessed on 15 May 2023.

[702] Biagioli, *supra* note 691, p. 162.

[703] The establishment of public-private partnerships is considered as one of the solutions to maintain or re-establish the balance between IPRs and society. Such partnerships have proven to be beneficial for societies since they prevent complete privatisation of public enterprises and still enable private companies to work profitably within this partnership. However, what public-private partnerships have the private public partnerships seem to have encouraged the rise of nationalism. See more details in Yanqiu Rachel Zhou, "Vaccine nationalism: contested relationships between COVID-19 and globalization." *Globalizations* 19, no. 3 (2022): 450-465. Available at https://www.tandfonline.com/doi/full/10.1080/14747731.2021.1963202. Last accessed on 30 May 2022. Also, Chidi Oguamanam, "Patents and pharmaceutical R&D: consolidating private–public partnership approach to global public health crises." *The Journal of World Intellectual Property* 13, no. 4 (2010): 556-580. Available at https://papers.ssrn.com/sol3/papers.cfm?abstract_id=2283246. Last accessed on 30 May 2022.

[704] Geertrui Van Overwalle, "Individualism, collectivism and openness in patent law: from exclusion to inclusion through licensing." In *Individualism and collectiveness in intellectual property law*. Edward Elgar Publishing, 2012. pp.71-114

[705] Sam Dryden, in his foreword to Anatole Krattiger, Richard T. Mahoney, Lita Nelsen, Jennifer A. Thomson, Alan B. Bennett, Kanikaram Satyanarayana, Gregory D. Graff, Carlos Fernandez, and Stanley Kowalski. "Intellectual Property Management in Health and Agricultural Innovation: A Handbook of Best Practices, Vol. 1." (2007). Available at

The patent system has always been criticised for one or another reason but with the new technologies and with widening the scope of patents to discoveries,[706] while strong arguments for exclusion of discoveries from patentability exist,[707] just because it takes a lot of time and money for those discoveries to take place, it is a small wonder that so many critics advocate against it and try to provide alternative solutions to the patents problem. Incentivising innovation and development of novel solutions to existing problems is the pillar on which the patent system rests, and it is this pillar that should be brought into question.

The balance requiring assessment is the cost (giving up market power) and benefit (overall societal development by means of innovation) of patents. However, since innovative products are priced way above purchasing power of general society,[708] and way beyond the cost of production of such innovative products, the balance should be sought so as to re-establish the equilibrium foreseen by the patent system. Namely, innovation in the 19th century was possible by gifted individuals only. Today, innovation is in the hands of highly educated individuals since genetic issues cannot be solved by naturally gifted individuals only. They would also have to acquire a lot of knowledge in the field in order to solve a problem in an innovative manner and obtain a patent for their trouble.

Consequently, what the society needs to demand in return for the monopolies it confers is return in the form of education. That is, it is the society which actually produces these highly educated individuals, not the companies which rip the benefits of their work. So not only does society grant market monopolies but also enables the individuals who are drivers of such innovation for which patents are granted. In the

https://scholars.unh.edu/cgi/viewcontent.cgi?article=1124&context=law_facpub. Last accessed on 30 May 2022.

[706] The U.S. Patent Act, 35 U.S.C. §§ 1 et seq., was enacted by Congress under its Constitutional grant of authority to secure for limited times to inventors the exclusive right to their discoveries. See Article I, Section 8, Clause 8.

[707] Morton vs N.Y. Eye Infirmary, 17 F Cas 879 (CCSDNY 1862) ("In its naked ordinary sense, a discovery is not patentable. A discovery of a new principle, force, or law operating, or which can be made to operate, on matter, will not entitle the discoverer to a patent.")

[708] Michael Bluhm, "The Role of Monopoly in America's Prescription Drug Crisis." (2019). Available at https://static1.squarespace.com/static/5e449c8c3ef68d752f3e70dc/t/5ea4d29f9bc8f31a1117feec/1587860128096/WhitePaper_DrugPrices_Bluhm.pdf. Last accessed on 23 April 2023. Also, Marta Radelli, "Patent evergreening: technological advancement and abusive commercial practices. Availability of essential medicine in the case of access to insulin." *QMLJ* (2021): 66.

same vein, Oguamanam finds that the society is short-changed twice when considering how gene patents lock up information, thereby denying public access while public funds are poured in university research, which results in patents of inventions exploited by the private sector by way of exclusive licencing of university inventions.[709] Effectively, the public gets almost no reward for its contribution. Oguamanam would see this in a way of fair pricing and access mechanism to the resulting research products or other benefits, which Part 6.5.2 seeks to bring around.[710]

Measuring the value of patents is not a straightforward task since intangibles do not really have a mass which can be weighed on a scale. None-excusive objects become under exclusive control provided for by IP laws.[711] Intellectual properties are non-exclusive as they are abstract objects, information and ideas, with no particular location in time and space.[712] Hence, we could either consider weighing patent features, or profits they generate from the granted monopoly. The specific features of an invention could be great but without commercialisation of that invention, its value from market perspective could be very small and insignificant compared to a widely commercialised and marketed not-so-feature-specific invention which has been widely commercialized and marketed. Hence, the value of the invention, that is of the patent, should be sought in the market power it provides and the plenitude of people who uses it as a solution to the problem it is intended to solve. To achieve this goal, several other aspects are considered below.

[709] Chidi Oguamanam, "Beyond Theories: Intellectual Property Dynamics in the Global Knowledge Economy." *Wake Forest Intell. Prop. LJ* 9 (2008): 104, p. 144. Available at https://www.researchgate.net/profile/Chidi-Oguamanam/publication/336778868_Beyond_Theories_The_Intellectual_Property_Dynamic_in_the_Global_Knowledge_Economy/links/5db23acda6fdccc99d945ea7/Beyond-Theories-The-Intellectual-Property-Dynamic-in-the-Global-Knowledge-Economy.pdf. Last accessed on 25 May 2022.

[710] *Ibid*, also see Higher Education IP Contribution below

[711] Christopher May, "Thinking, buying, selling: Intellectual property rights in political economy." *New Political Economy* 3, no. 1 (1998): 59-78.

[712] The legal term 'intangible' is similar to the philosophical term 'abstract.' An intangible property is a property that lacks a physical or corporeal existence, such as stock options or mechanical designs (Black's Law Dictionary, 1999). In philosophy, an abstract object is an object that does not have physical properties, such as a number or geometric figure. However, although all intangible properties are abstract objects, not all abstract objects are intangible properties: the number 4 is an abstract object, but no one can claim ownership of that number.

## 6.3. Patents and Information

As inventions subject to patent protection are conditioned on the provision of detailed discloser, patents are not only of inventive, but also of informative value to society. Development relies on inventiveness as much as it does on information, however, the latter has also come to enjoy proprietary protection, which contradicts the previously mention quid quo pro. Information derived from patented inventions, beyond those disclosed for marketing authorisation, does not become public upon patent expirations but is afforded unlimited legal protection as it is deemed to provide holders competitive advantage. When this is applied to information pertaining to life science products[713], generic drug manufacturers, which are meant to have access to previously patented products and produce them at affordable prices, might find themselves lacking the information to do so. In a time when competitive means possessing superior information, as argued by Oguamanam,[714] in terms of content and timing, the question of restricting access to life-advancing biotechnological solutions, which could provide further information only if massively used seems to be counterintuitive. Oguamanam also argues that 'the generation, ownership, and management, including the manipulation of information, are considered as pivotal in the 'contemporary global economic order which services, and is in turn, also serviced by the information (or post-industrial) society.'[715]

At the same time, providing patent protection for the purpose of obtaining information is still an argument pro patent protection, counteracting the possibility of not obtaining any information at all. However, the experience with the patented product would be limited to those who can afford to pay for such a product. The limited access is not only detrimental for all the people who will not receive the medicine for their condition, but it is also crippling for the process of obtaining further information of a given product. As biomedical products are improved based on data gathered in post-

[713] Tara Nealey, Ronald M. Daignault, and Yu Cai. "Trade secrets in life science and pharmaceutical companies." *Cold Spring Harbor perspectives in medicine* 5, no. 4 (2015): a020982. Available at https://doi.org/10.1101/cshperspect.a020982. Last accessed on 15 May 2023.
[714] Chidi Oguamanam, "Local knowledge as trapped knowledge: intellectual property, culture, power and politics." *The Journal of World Intellectual Property* 11, no. 1 (2008): 29-57.
[715] Oguamanam (2008), Beyond Theories, *supra* note 709, p. 131

marketing periods from users reporting side effects, the wider the use of the product, the more information on its post-marketing effects can be acquired.

Drahos in his 'Philosophy of Intellectual Property'[716] claims information to be a 'primary good,' which, according to Rawls,[717] can be natural or social and is presumed to something that every rational person wants. Considering the that access to information and data flow to be an invaluable asset to have in possession, the limited information provided by the disclosure of inventions in patent applications not only restrict the access to the invention itself, in terms of unhampered further study and development, but also limit the access to data concerning the said invention due to its restricted use by only a minority who can afford it.[718] The only legal restrictions of individual rights that can be justified are those which are required to protect mutual natural rights from violation by other individuals.[719] John Stuart Mill finds that injustice occurs when one is deprived of his 'personal liberty, his property, or any other thing which belongs to him by law'[720] and that secondly injustice consists in 'taking or withholding from any person that to which he has a moral right.'[721] Access to affordable medicine would definitely fall in the category of not only moral rights, but human rights.

As economic development is crucial aim of governments throughout the world and economic advantages are achieved by countries, or individuals, in possession of more information,[722] the gap between the developed and developing is doomed to widen

[716] See Peter Drahos, *A philosophy of intellectual property*. Routledge, 2016, pp. 199-230. https://press-files.anu.edu.au/downloads/press/n1902/pdf/book.pdf. Last accessed on 12 March 2023.
[717] For more on primary goods, see John Rawls, *A theory of justice: Revised edition*. Harvard university press, 2020, pp. 347-397. Available at https://giuseppecapograssi.files.wordpress.com/2014/08/rawls99.pdf. Last accessed on 13 March 2023.
[718] Drahos (2016), *supra* note 716, 'intellectual property rights, by their very nature, create artificial conditions of scarcity for information, which should not be scarce.' p. 201.
[719] Robert Nozick, *Anarchy, state, and utopia*. Vol. 5038. new york: Basic Books, 1974, p. 141 Available at https://antilogicalism.files.wordpress.com/2018/04/anarchy-state-utopia.pdf. Last accessed on 19 May 2022.
[720] John Stuart Mill, "Utilitarianism" 1863, Kitchener *Canadá: Batoche Books* (reprinted 2001). p. 43. Available at https://socialsciences.mcmaster.ca/econ/ugcm/3ll3/mill/utilitarianism.pdf. Last accessed on 19 May 2022.
[721] *Ibid*, p. 44
[722] 'Social classes are divided by access to education, since without technical and communication skills, people in an information society lack the means for success.' See William Little, Ron McGivern, and Nathan Kerins. *Introduction to sociology-2nd Canadian edition*. BC Campus, 2016, p. 165. Available at https://openlibrary-repo.ecampusontario.ca/jspui/handle/123456789/316. Last

rendering the developing countries underdeveloped and the developed countries overdeveloped in this equation. In addition, in his pluralistic account of intellectual property, Resnik gives succinct description of how property right developed throughout the centuries as well as the underlining causes for such a development.[723] As IP rights received more attention with the scientific and industrial revolutions, corresponding IP laws were adopted at the time to support the contemporary political economy, which had come to depend more on information and ideas.

From a different perspective, Resnik suggests that private information should be treated as intellectual property since every individual possesses such information and is entitled to monetise it in exchange for sharing it. If private information is to be treated as IP, also argued by Samuelson, [724] then the term 'intellectual' would not be appropriate as private information[725] has nothing to do with 'intellectual' abilities as everyone has information which are considered private in the eyes of the law. This is further supported by Resnik's (2020, p. 321) argument that access to private information can be bargained over if confidential information is treated as IP, thus enabling individuals to enforce 'their privacy rights by suing violators for property-related torts, such as theft, trespass and conversion.' Perhaps 'intangible property' would be the more suitable term for such information so as to distinguish it from the actual intellectual property. Perhaps trademarks should also be moved in this category as they are indeed intangible, but it is arguable how 'intellectual' they are. Furthermore, it can also be argued that only patents, copyrights and industrial designs are deserving of the 'intellectual' attribute, while all other currently recognised intellectual property rights as well as rights to private information, albeit intangible, are not intellectual. On the other hand, there have been arguments that the basis for intellectual property are not fundamental metaphysical distinctions but only reflect pragmatic concerns,[726] and the very terminology used in this context suggests the

accessed on 20 May 2022. Also, Drahos draws attention to 'to the fundamental wealth-creating role of information in society' based on commodity-based perspectives of information.

[723] David B. Resnik, "A pluralistic account of intellectual property." *Journal of business ethics* 46 (2003): 319-335, p. 320

[724] Pamela Samuelson, "Privacy as intellectual property." *Stan. L. Rev.* 52 (1999): 1125. Available at https://www.jstor.org/stable/1229511. Last accessed on 19 May 2022.

[725] Resnik, *supra* note 723, p. 321.

[726] Drahos, *supra* note 716.

truthfulness of the argument. John Lock's relation of labour and property supports the argument that not all intellectual property is of same nature:

> 'Whatsoever then he removes out of the state that nature hath provided, and left it in, he hath mixed his labour with, and joined it to something that is his own, and thereby makes it his property.'[727]

This goes in line with Hegel's self-expression[728] in patents, which is disputed as it is considered that it is not required given that the majority of the work is done by machines replacing people, such machines being used in biochemistry, molecular biology, electrical engineering alike.[729] This can be challenged on the fact that the person using these machines directs the process of how and what they do to realise his or her goals, that is to produce the patentable invention deriving from her or his personal imagination, experience and knowledge. Thus, any invention, indeed, would have tight relation with one's own self-expression,[730] albeit this not being the concern of current IP laws.

The world might be better off without any IP rights,[731] however, it might serve a better purpose if those IP right are utilised for more public-oriented goals rather than keep the original form of strictly private and alienating purposes of these rights.

### 6.4. Individualism and Patents

As the Industrial Revolution brought about major industrial changes, so did stronger patent protection for inventions which coincided with the overall social development. Jones & Vollrath[732] find that 'in the last century (or two), the world economy has

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[727] John Locke, *The second treatise of civil government*. Broadview Press, 2015. Available at https://press-pubs.uchicago.edu/founders/documents/v1ch16s3.html#:~:text=The%20Labour%20of%20his%20Body,thereby%20makes%20it%20his%20Property. Last accessed on 19 May 2022.

[728] Georg Wilhelm Friedrich Hegel, translated by S. W. Dyde, Philosophy of right, (2003). Available at https://socialsciences.mcmaster.ca/econ/ugcm/3ll3/hegel/right.pdf. Last accessed on 19 May 2022.

[729] Resnik, *supra* note 723, at p. 327.

[730] 'Learning is not merely the treasuring up of words in the memory; it is through thinking that the thoughts of others are seized, and this after-thinking is real learning. Now that which is learned becomes in turn something which can be disposed of; and the external expression of this material may easily assume a form different from the form into which the original thinker threw his work.' *Ibid*, pp. 74-75.

[731] Brian Martin, "Against intellectual property." *Philosophy and Social Action* 21 (1995): 7-22. Available at https://www.bmartin.cc/pubs/95psa.html. Last accessed on 19 May 2022.

[732] Charles I. Jones, and D. Vollrath. "Introduction to Economic Growth, WW Norton&Company." *Inc. New York, NY* (2013).

witnessed sustained, rapid growth in population, technology and per capita income never seen before in history' justifying patents and copyrights as enablers of 'inventors to earn profits to cover the initial costs of developing new ideas.' However, the phenomenon of individualism began to grow at about the same time, even though traces of individualism can be found in classical antiquity, too ,[733] although emerging as a systematic theory only in the nineteenth century.[734] Swart finds that the term 'individualism' as invented at the time was used to denote at least three different groups of ideas, that is, 'the idealistic doctrine with equalitarian implications of the rights of man' or political liberalism, 'the anti-statist, largely utilitarian doctrine of *laissez faire*, or economic liberalism' and 'the aristocratic cult of individuality, or Romantic individualism.'[735]

Current research shows that this past few decades have shown marked increase in individualism in the world.[736] Santos, Varnum & Grossmann conducted a study examining 51 years of data on individualistic practices and values across 78 countries confirming rise in individualism in most of the tested societies. Previous research in the connection between individualism and intellectual property protection confirms their concomitant rise and interdependency.[737] This is justified on the premise that individualist cultures attach social status rewards to personal achievements, that is, the incentive for innovation is not only monetary but also socially rewarded, which leads to higher rates of innovation and economic growth.[738] The intensity of innovation is measured by patents per million population, as authors find that it is the most suitable available measure for innovation outputs, as well as the innovation performance index

[733] Daniel Lee, "The Origins of Individualism." *Critical Review* 29, no. 3 (2017): 351-361.
[734] Mohd. Akhtar Khan. "Individualism: origin and evolution." *The Indian Journal of Political Science* (1987): 126-132.
[735] Koenraad W. Swart, " Individualism" in the Mid-Nineteenth Century (1826-1860)." *Journal of the History of Ideas* 23, no. 1 (1962): 77-90.
[736] Henri C. Santos, Michael EW Varnum, and Igor Grossmann. "Global increases in individualism." *Psychological science* 28, no. 9 (2017): 1228-1239. Also, Tian Zengrui, Guillermo Andres Buitrago, and Shoirahon Odilova. "Will a Collectivistic Culture protect your Intellectual Property? Effect of Individualism on Intellectual Property Protection." *International Business Research* 10, no. 11 (2017): 111-116. Available at https://pdfs.semanticscholar.org/a163/32a8cd200bb67e42dd71af12f15128177e83.pdf. Last accessed on 30 May 2022. The authors used data from 92 countries and concluded that individualism index has positive and significant effect on IPR protection.
[737] Yuriy Gorodnichenko and Gerard Roland. "Individualism, innovation, and long-run growth." *Proceedings of the National Academy of Sciences* 108, no. supplement_4 (2011): 21316-21319.
[738] *Ibid* p.1

from the Economist Intelligence Unit (EIU),[739] which combined with Hofstede's index of individualism,[740] results in higher individualism in cultures with higher number of patents filed by resident population. They also find that GDP per capita is higher in cultures with foster stronger individualism.[741] Similarly, Grossman and Na find that independence is prioritised in individualist cultures while in collectivist cultures, family relations and conformity are emphasised.[742]

It is this independence and allowance of nonconformism that enables individuals to change and improve the existing. When such changes and improvements are technological, they become eligible for patent protection. Having in mind the above-mentioned findings, it is safe to conclude that the grant of privileges for original developments boosts individualism in societies making more individuals to stive towards creativity and invention, thus further developing the society. Only, learning from the existing and changing it to fit the new challenges which come with the social and technological changes could lead to such development. This goes in line with Isaac Newton's very often quoted metaphor 'standing on the shoulders of giants' emphasizing that intellectual progress is made by using the gained wisdom and understanding of previous thinkers.[743]

On the other hand, Van Overwalle[744] considers individualism, collectiveness and patents through the licensing perspective of gene patents, thus addressing not only access to health[745] but also access to knowledge. She finds that individual (exclusive) licences have as negative effect on innovation as collective (multiple ownership) licences since the former have blocking effect while the latter may lead to hindering

[739] Economist Intelligence Unit (2007) Innovation: Transforming the Way Business Creates. Available at http://graphics.eiu.com/upload/portal/ciscoinnosmallfile.pdf. Last accessed on 28 May 2022. EIU constructs patents per million population as the sum of patents granted to applicants (by residence) from the 82 economies by three major government patent offices—the European Patent Office, the Japanese Patent Office, and the US Patent and Trademark Office. See *Ibid*, p. 2
[740] Geert Hofstede, Culture's consequences: Comparing values, behaviors, institutions and organizations across nations. sage, 2001. Individualism vs collectivism index explores the 'degree to which people in a society are integrated into groups.'
[741] Santos, *supra* note 736, p. 2
[742] Igor Grossmann and Jinkyung Na. "Research in culture and psychology: Past lessons and future challenges." *Wiley Interdisciplinary Reviews: Cognitive Science* 5, no. 1 (2014): 1-14.
[743] 'Standing on the shoulders of giants' https://www.phrases.org.uk/meanings/268025.html. Last accessed on 28 May 2022,
[744] Van Overwalle, *supra* note 704, at p. 112.
[745] *Ibid* at p. 111

patent tickets.[746] Approaching individualism and collectiveness from biotechnology standpoint, specifically, the 'open biotechnology'[747] concept, the positive effects of collaborative/collective models of sharing knowledge are more than evident as exemplified by the many open projects as open journals,[748] new bioinformatic tools,[749] databases,[750] big science projects,[751] projects to facilitate access to biotech research tools[752] or a combination of these.

This leads to the conclusion that although socio-economic and technological progress and development depend on specific individuals and their ability to think and act differently from their community, the collaborative activities between these individuals for the purpose of sharing acquired knowledge and ideas is the necessary ingredient for the benefit of the whole society. Thus, perhaps with a collective of individualists can the society achieve a better balance between the exclusive and the private.

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[746] For a discussion on patent thickets, often defines as 'a dense web of overlapping intellectual property rights that a company must hack its way through in order to actually commercialize new technology' see Bronwyn H. Hall, Christian Helmers, Georg Von Graevenitz, and Chiara Rosazza Bondibene. "A study of patent thickets." *Intellectual Property Office Research Paper* 2013/26 (2013). Available at https://web.archive.org/web/20170120235804id_/https://www.gov.uk/government/uploads/system/uploads/attachment_data/file/311234/ipresearch-thickets.pdf. Last accessed on 30 May 2022, citing Carl Shapiro, "Navigating the patent thicket: Cross licenses, patent pools, and standard setting." *Innovation policy and the economy* 1 (2000): 119-150. Available at https://www.nber.org/system/files/chapters/c10778/c10778.pdf. Last accessed on 30 May 2022.

[747] Yann Joly, "Open biotechnology: licenses needed." *Nature Biotechnology* 28, no. 5 (2010): 417-419.

[748] For e.g., Public Library of Science, see http://www.plos.org/. Last accessed on 30 May 2022.

[749] For e.g., BioMoby, which is an international research project involving biological data hosts, biological data service providers, and coders whose aim is to explore various methodologies for biological data representation, distribution, and discovery, see http://biomoby.open-bio.org/. Last accessed on 30 May 2022.

[750] NIH db GaP (**d**ata**b**ase of **G**enotypes and **P**henotypes) was developed to archive and distribute the results of studies that have investigated the interaction of genotype and phenotype, see https://www.ncbi.nlm.nih.gov/projects/gap/cgi-bin/about.html. Last accessed on 30 May 2022.

[751] HapMap, or a haplotype map, is a tool that allows researchers to find genes and genetic variations that affect health and disease, see https://www.genome.gov/10001688/international-hapmap-project and for the Human
Genome Project, see *Ibid*, *supra* note 34.

[752] Cambia BiOS Initiative, see Richard Jefferson, "Science as social enterprise: the CAMBIA biOS initiative." *Innovations: Technology, Governance, Globalization* 1, no. 4 (2006): 13-44. Available at https://click.endnote.com/viewer?doi=10.1162%2Fitgg.2006.1.4.13&token=WzM2MjQyMjcsIjEwLjExNjIvaXRnZy4yMDA2LjEuNC4xMyJd.5GrFlJUAfVBwfIczPI9YmMOUITI. Last accessed on 30 May 2022.

## 6.5. Knowledge, Education, and Innovation

Arguments pro patent protection highlight the importance of monopolies for furthering development. This is supported by the reward and incentive theory as the most prominent theoretical postulate of intellectual property,[753] further discussed by Oguamanam[754] arguing the existent belief that reward for creativity is vital for cultivating further creativity while maintaining rich public domain, which is the condition under which this theory offers the proper balance. However, the origin of development is not in the invention per se but in the knowledge and ingenuity underlying that invention.[755] Under the patent system, knowledge is not a subject to monopolist rights, as it should not be, however, nowadays it is fundamentally needed to obtain patent protectable products. Such products bring large monetary returns to their holders, thus investments in intellectual property development have become common place.[756] However, as these products are essentially dependent on the knowledge their inventors acquire before using that knowledge to innovative solutions, it is only reasonable that investments should also be directed towards the ingredient essential for the development of such inventions. Notwithstanding, in pharmaceutical and biotechnology settings, with the protection of regulatory and test data provided to this sector, interests of generic drug manufacturers are undermined as access to the knowledge necessary for the manufacturing of the generic medicines is denied beyond

[753] A. Samuel Oddi, "Un-unified economic theories of patents--the not-quite-holy grail." *Notre Dame L. Rev.* 71 (1995): 267. Available at https://core.ac.uk/download/pdf/268210637.pdf. Last accessed on 28 May 2022.
[754] Oguamanam (2008), *supra* note 709, p. 117.
[755] *Ibid* at p. 142, 'Necessity, and not profit, is the mother of invention, as much as invention is the mother of necessity.' This is emphasised by the fact that patents are granted to inventions which solve an existing problem. The problem drives the invention and excites the inventor, not the monopoly that would be granted if the problem is inventively solved. Oguamanam also gives count of a jurist arguing that creative geniuses cannot be deterred from inventive activities even when threatened with imprisonment as a disincentive. This is ever so true activities of scientist working on predominantly illegal cloning.
[756] Marcel Seip, Anne Van Der Heijden, and Marleen Bax, "Scale-Ups And Intellectual Property Rights: The Role Of Technological And Commercialisation Capabilities In Firm Growth." *International Journal of Innovation Management* 26, no. 04 (2022): 2250033. Also, "High-growth firms and intellectual property rights: IPR profile of high-potential SMEs in Europe," (May 2019), published by EPO and EUIPO Munich, Germany, and Alicante, Spain, https://euipo.europa.eu/tunnel-web/secure/webdav/guest/document_library/observatory/documents/reports/2019_High-growth_firms_and_intellectual_property_rights/2019_High-growth_firms_and_intellectual_property_rights.pdf. Last accessed on 23 April 2023.

the patent term initially afforded.[757] This does not only effectively prevent affordable medicines to enter the market, cutting off access to these medicines indefinitely, or at least while the 'evergreening' period lasts,[758] but consequently knowledge gets 'proprietarised'[759] and out of the public domain where it is ought to be.

The education industry, which actually deals with knowledge, tends to get least funding worldwide.[760] Unlike the developed countries which arguably allocate sufficient funds for education, as they can afford it, education in less developed countries is not so fortunate. In its press release from 2021, the World Bank reports that two-thirds of poorer countries are cutting education budgets due to the COVID-19 pandemic.[761] This is in accordance with the joint World Bank – UNESCO Education Finance Watch (EFW), which finds that prior to the COVID-19 pandemic, in 2018-19, high-income countries were spending annually the equivalent of US$8,501 for every child or youth's education compared to US$48 in low-income countries.[762] The report also finds that 'the gap in spending per capita between low- and upper-middle-income countries increased from US$ 813 to US$ 1,045 in real terms between 2010–11 and 2018–19.[763]

[757] Carlos María Correa, Protection of data submitted for the registration of pharmaceuticals: implementing the standards of the TRIPS agreement. Geneva: South Centre, 2002. Available at https://www.researchgate.net/publication/252112121_Protection_of_Data_Submitted_for_the_Registration_of_Pharmaceuticals_Implementing_the_Standards_of_the_TripS_Agreement. Last accessed on 28 May 2022.
[758] Roger Collier, "Drug patents: the evergreening problem." (2013): E385-E386. Available at https://www.ncbi.nlm.nih.gov/pmc/articles/PMC3680578/. Last accessed on 28 May 2022.
[759] Oguamanam (2008), *supra* note 709, at 142.
[760] Each country allocates part of its budget to education, separately from the funds allocated for research and development. See COE - Education Expenditures by Country, available at https://nces.ed.gov/programs/coe/indicator/cmd for details on education expenditures per country. Last accessed on 14 Mar. 22.
[761] World Bank press release 'Two-Thirds of Poorer Countries Are Cutting Education Budgets Due to COVID-19' (22 February 2021). Available at https://www.worldbank.org/en/news/press-release/2021/02/22/two-thirds-of-poorer-countries-are-cutting-education-budgets-due-to-covid-19. Last accessed on 6 June 2022.
[762] Samer Al-Samarrai, Pedro Cerdan-Infantes, Aliya Bigarinova, Juanita Bodmer, Marianne Joy Anacleto Vital, Manos Antoninis, Bilal Fouad Barakat, and Yuki Murakami. "Education finance watch 2021." *World Bank Group and UNESCO. https://documents1. worldbank. org/curated/en/226481614027788096/pdf/Education-Finance-Watch-2021. pdf* (2021). Available at https://documents.worldbank.org/en/publication/documents-reports/documentdetail/226481614027788096/education-finance-watch-2021. Last accessed on 28 May 2022.
[763] *Ibid*, p. 5

This leads to the conclusion that although education is the basic driver of knowledge, and consequently, should be the most funded societal segment in order to achieve the development the society is so eager to obtain, exclusive control over knowledge, not development, is the driver behind strong patent protection.[764] However, it seems counterintuitive to allocate investments only in the middleman, it being research, while circumventing investment in the primary diver, education, as those research scientists, which created profit-generating patented inventions primarily require vast amount of education, especially in life-sciences.

As science has become the driver of inventions subject to patent protection, it is reasonable to conclude that what society needs to further develop is knowledge and better access to it. Knowledge transforms into inventions solving problems; Inventions are subject to exclusive rights which generate profits; Profits are based on the unwritten agreement of society to grant exclusivity to a portion of the market (monopoly) in exchange for knowledge.[765] However, this circle is missing a link, which is the distribution of that knowledge underlying patented inventions. And it is exactly that link that could possibly provide the balance between private and public interests.

The balance of rights is usually weighted in terms of IP rights and human rights, discussed in Part 1 of this Chapter. Human rights deal with access while IPRs with restrictions. The debate is deep and ongoing with no middle ground in sight. This has become especially true with the rise of pharmaceutical patents since such innovation effectively started touching the lives of individuals and there is a scientific agreement that the disconnection between the pharmaceutical research agenda and the global health crises is substantial.[766] When a patented product in any industry comes to the

[764] Insight into the concept of Global Knowledge Economy relating to the role of intellectual property can be found in Peter Drahos and John Braithwaite. *Information feudalism: Who owns the knowledge economy?*. Routledge, 2017.
[765] Within traditional philosophy there is a choice to be made between contractarian approaches to justice and utilitarian or consequentialist accounts of justice. *Ibid*, also Drahos, *supra* note 726, p. 200; also, Under the contractarian narrative, inventors agree to disclose their inventions to the state, usually by way of filing a patent specification in exchange for the exclusive right, that is, a monopoly, to exploit the invention for a fixed term. Upon this term expiration, the public is free to exploit the invention without the patent holder's consent. Oguamanam (2008), *supra* note 709, p. 112.
[766] Anup Shah, "pharmaceutical corporations and medical research—global issues." *Global Issues: Social, Political, Economic and Environmental Issues That Affect Us All—Global Issues* (2010). Available at https://www.globalissues.org/article/52/pharmaceutical-corporations-and-medical-research. Last accessed on 30 May 2022.

market, it is a privilege rather than necessity to use it. A simple comparison would be the advance in information technologies development, also due to the increase of knowledge in the sector, with the development of biotechnology. The latter produces often necessary products, the former, products which people can live without. In this light, perhaps a different balance is ought to be considered. Instead of the classical approach of balancing IPRs and human rights in terms of access to medicine, the above 'full circle' concerning knowledge should be considered in more depth.

The core argument to grant patents is the incentive to invent, innovate and disclose in return for a patent. However, this is undermined by the investment incentive as companies are willing to invest in R&D which is most likely to result in a patent grant, thus promising return of investment and capitalisation.[767] Patent rights are only worthy if large returns are guaranteed, and the exclusive rights granted under the current IP regime are very much profitable. What needs weighting is the benefit society rips from such disclosure against the privileges it grants. Patent holders exercise their rights over the entirety of the population within a jurisdiction under which the patent is granted. Every single individual in this jurisdiction is a subject to the granted patent as none of them have the right to the patented invention otherwise than allowed by the patent holder. On the other hand, the benefit for every single individual from the disclosure provided by the patent holder is again limited, if any. The disclosure would benefit science, surely, but not the child who needs treatment with a patented medical technology. If every single individual is a subject to the monopoly, shouldn't every single individual benefit from the disclosure? If the balance should not be individual, then the agreement is flawed, or asymmetrical at best. Furthermore, intellectual property's emphasis on profit and reward has yielded a pharmaceutical research agenda that aims at a "cosmetic society," ignoring the sick and needy and targeting wealthy and healthy who can afford expensive cosmetic drugs and procedure, in turn, generating investment return.[768] So, individual balance for the wealthy, not so much

[767] Jon Elster, *Nuts and bolts for the social sciences*. Cambridge University Press, 1989, pp. 33-34 Available at http://epistemh.pbworks.com/f/C+(2).+Elster+Nuts+and+Bolts.pdf. Last accessed on 30 May 2022.
[768] Miriam Karmel, "A Drug for All Reasons: Why the pharmaceutical industry now targets healthy people." *UTNE-MINNEAPOLIS* (2003): 16-17. . Available at https://content.utne.com/2003-07-01/DrugforAllReasons. Last accessed on 30 May 2022.

for the less well off. This leads to the need for balancing the very essence of patent granting, but from within, rather than from without.

To evaluate such balancing, perhaps it is necessary to find a way for this disclosed knowledge to be more accessible to the general public, rather than to just a certain minority that can actually benefit from it. The only disposable tool society has got to achieve this goal is education, which leads back to the monopolisation of knowledge especially targeted by life sciences.[769]

### 6.5.1. Global Knowledge Economy

The terms 'knowledge economy' or 'knowledge society' have been used to describe a fundamental shift in how economic resources, value production and the bases of political, social and cultural life are viewed by modern societies.[770] Beginning in the late 1960s, this economy is characterised by innovation, research, development, stronger premium on skills and university knowledge,[771] which are indispensable tools for patented inventions. Consequently, the expanse of education leads to reshaping of the economic system and labour market, where non-material and creative skills become resources of critical importance.[772] A study conducted by Zapp indicates that

[769] Corea, *supra* note 757

[770] Mike Zapp, "Revisiting the Global Knowledge Economy: The Worldwide Expansion of Research and Development Personnel, 1980–2015." *Minerva* 60, no. 2 (2022): 181-208. Available at https://link.springer.com/article/10.1007/s11024-021-09455-4. Last accessed on 30 May 2022.

[771] See Peter Drucker, *The age of discontinuity: Guidelines to our changing society*. Routledge, 2017; also Leon H. Craig, "Daniel Bell, The Coming of Post-Industrial Society. New York: Basic Books [Don Mills: General Publishing], 1973, pp. xiii, 507." *Canadian Journal of Political Science/Revue canadienne de science politique* 7, no. 3 (1974): 593-595; Nico Stehr, "Knowledge societies." *The Wiley-Blackwell encyclopedia of globalization* (2012); Jussi Välimaa and David Hoffman. "Knowledge society discourse and higher education." *Higher education* 56 (2008): 265-285; David John Frank and John W. Meyer. "University expansion and the knowledge society." *Theory and society* 36 (2007): 287-311. Available at http://kieranhealy.org/files/misc/frank-meyer.pdf. Last accessed on 30 May 2022.

[772] David Baker, *The schooled society: The educational transformation of global culture*. Stanford University Press, 2014. Also, Claudia Goldin and Lawrence F. Katz, *The race between education and technology*. harvard university press, 2010; Ian D. Wyatt, "Occupational changes during the 20th century." *Monthly Lab. Rev.* 129 (2006): 35. Available at https://stats.bls.gov/opub/mlr/2006/03/art3full.pdf. Last accessed on 30 May 2022. Mike Zapp and Julia C. Lerch, "Imagining the world: Conceptions and determinants of internationalization in higher education curricula worldwide." *Sociology of Education* 93, no. 4 (2020): 372-392. Available at https://www.researchgate.net/profile/Mike-Zapp-2/publication/342179621_Imagining_the_World_Conceptions_and_Determinants_of_Internationalization_in_Higher_Education_Curricula_Worldwide/links/5ee79a37299bf1faac560e8c/Imagining-the-World-Conceptions-and-Determinants-of-Internationalization-in-Higher-Education-Curricula-Worldwide.pdf. Last accessed on 30 May 2022.

OECD countries more than tripled their R&D personnel since the 1980s, while the number of professional knowledge workers in non-OECD countries doubled since the mid-1990s but the global growth of a knowledge-intensive occupational field is conditioned by strong state support .[773]

On the other hand, technological breakthroughs in digitalisation and the growth of biotechnologies exact strong intellectual property regimes centred around an aggressive attempt to create artificial scarcity over information, thus 'propertising' knowledge.[774] Drahos and Braithwaite describe this as 'hegemony based on knowledge' further elaborating that 'the logic of hegemonic power based on knowledge is to lock up knowledge, to deal with ignorance selectively, to create a morality that judges knowledge to be a private good and to punish through the criminal apparatus of the state those who steal knowledge.'[775] Evidently, intellectual property generates knowledge, on the one hand, and locks it up on the other. This is further emphasised by the imposition of strong intellectual property rights enforcement via the TRIPS Agreement, also known as TRIPS-Plus Agreements, as well as the US bilateral trade agreements, before and after TRIPS alike, conditioning other countries with weaker economies to defer from using the TRIPS flexibilities.[776] Such hegemony has been felt at diverse intersections, including health and access to essential drugs; human rights, biodiversity conservation, bioprospecting and biopiracy; market access and balance of trade; and technology transfer and questions about indigenous knowledge.[777] Research itself is not unaffected by the said hegemony. Mgbeoji and Allen report on a survey of approximately 2100 life science researchers of which 18% reported delaying the publication of research results for intellectual property reasons for over six months.[778]

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[773] Zapp (2022), *supra* note 770, at p.3
[774] Peter Drahos and John Braithwaite, "Hegemony based on knowledge: the role of intellectual property." *Law in Context* 21, no. 1 (2004): 204-223. Available at https://search.informit.org/doi/pdf/10.3316/informit.154759180293640. Last accessed on 30 May 2022.
[775] *Ibid* at p. 204
[776] Drahos and Braithwaite (2004), *supra* note 774, at p. 214.
[777] Tshimanga Kongolo and Folarin Shyllon. "Panorama of the most controversial IP issues in developing countries." *European Intellectual Property Review* 26, no. 6 (2004): 258-262.
[778] Ikechi Mgbeoji and Byron Allen, "Patent First, Litigate Later! The Scramble for Speculative and Overly Broad Genetic Patents: Implications for Access to Health Care and Biomedical Research." *Canadian Journal for Law and Technology* (2003): 83-98, p. 87. Available at https://papers.ssrn.com/sol3/papers.cfm?abstract_id=1569635. Last accessed on 30 May 2022.

Fagerberg finds that knowledge has always been important for economic development, however, the operation of knowledge today is comparably different from its operation a century ago.[779] Innovation is found as the primary factor for this difference combined with R&D infrastructure, also known as 'systems of innovation'[780] as well as massification of higher (tertiary) education and the advance of ICT.[781] The extent to which countries benefit from this process, however, is not linear, which is evident from the increase in the difference in GDP per capita between the dynamic (mostly rich) and less dynamic (mostly poor) parts of the world.[782] It is interesting that this divergence is not along the classical line of developed versus developing countries but evidence suggest that the European Union is behind the US and some Asian parts in this regard and has adopted a policy to raise R&D investments to address this concern.[783] However, R&D alone cannot change much without changing anything else. What Fagerberg is suggesting is transforming the public sectors, such as education, health, communication, etc., into powerhouses for innovation and to do so, he suggests 'transition to an experimental economy; in which experiments with new solutions/technologies would be the normal state of affairs, not the exception.'[784] The following part entertains one such 'experimentation'.

### 6.5.2. Higher Education IP Contribution

The academic pursuit of striking a balance between patents and society is justified only if it is true. Historically, people with inventive capacities were recognised by wealthy rulers in power to adopt laws in favour of these scarce, talented people.[785] Today,

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[779] Jan Fagerberg, "Innovation, technology and the global knowledge economy: Challenges for future growth." In *Green Roads to Growth" Project and Conference, Copenhagen*. 2006. Available at https://www.researchgate.net/profile/Jan-Fagerberg-2/publication/24134945_Innovation_technology_and_the_global_knowledge_economy_Challenges_for_future_growth/links/54038cc80cf23d9765a5cf19/Innovation-technology-and-the-global-knowledge-economy-Challenges-for-future-growth.pdf. Last accessed on 30 May 2022.

[780] Charles Edquist, "Reflections on the systems of innovation approach." *Science and public policy* 31, no. 6 (2004): 485-489. Available at https://www.researchgate.net/profile/Charles-Edquist-2/publication/250198762_Final_Remarks_Reflections_on_the_systems_of_innovation_approach/links/549826910cf2c5a7e342a048/Final-Remarks-Reflections-on-the-systems-of-innovation-approach.pdf. Last accessed on 30 May 2022.

[781] Fagerberg, *supra* note 779, at p. 21.

[782] Ibid

[783] Ibid

[784] Ibid

[785] *See*, for example, Paul A David,. "Patronage, Reputation, and Common Agency Contracting in the Scientific Revolution: From Keeping 'Nature's Secrets' to the Institutionalization of 'Open Science." *SIEPR Policy paper* 03-039 (2004). Available at https://www.researchgate.net/profile/Paul-

thanks to those rights granted, these people can make a living without giving up on their abilities but exploit them. Were the end here, this would have been a success story worthy of being an architype of how diversity, not uniformity, enables society to prosper. Instead, there is a demand seduced by marketing powers fuelled by mass psychology guaranteeing mass demand for innovation of life exploited by, not the inventors, but the ever-vigilant investors in high-demand products.

As the incentive to invest in innovations is the monopoly to be granted, perhaps the profits from the monopoly, which are justified as being used for investment in further innovation, could be redirected to the financing of the higher knowledge distribution system as a form of mandatory contribution or, rather, an early investment in future innovation.

In his revisit of the knowledge economy, Zapp discusses the social advantages people with higher education bring about as they possess the analytical and creative skills found to be the core of the knowledge economy, hence arguing that infrastructure capacity for academic training can be seen as the essential for the increase of knowledge-intensive personnel.[786] Furthermore, in its most prevalent interpretation, intellectual property rights are justified on the utilitarian premises that economic growth is driven by R&D, which uses science 'as a national, systemically-planned and economically viable tool to foster progress.'[787] As such, science and education as drivers of social and economic development require further nourishment.

Investment in education produces higher quality graduates which become part of the labour market equipped with better skills and faced with more opportunities to find better paying jobs because of it. The more educated individuals are generated, the more scientists who will develop future inventions on the market. Today, investment in higher education mainly originates from national funding, which is rarely enough. Even patenting universities, which have their own research and development leading

David/publication/228553891_Patronage_Reputation_and_Common_Agency_Contracting_in_the_Scientific_Revolution_From_Keeping_'Nature's_Secrets'_to_the_Institutionalization_of_'Open/links/00b4952153eaab0309000000/Patronage-Reputation-and-Common-Agency-Contracting-in-the-Scientific-Revolution-From-Keeping-Natures-Secrets-to-the-Institutionalization-of-Open.pdf. Last accessed on 15 May 2023.

[786] Zapp (2022), *supra* note 770, p. 187

[787] *Ibid*, quoting Gili S. Drori, "Science in the modern world polity: Institutionalization and globalization." (2003).

to patented inventions, and in turn are being licenced to private companies, get additional income that amounts to about 10% of their research budget.[788]

Financing education is a long-term investment in future scientists and individuals with bigger purchasing power, which can later afford to buy the patented products placed on their market. The more inventions on the market, the higher the profits of the patent holders, which nowadays are mostly large corporations employing scientists who usually only hold the moral rights in patents, that is, there name is written on the patent application, and they get the moral credit for the invention, otherwise receiving a salary just like everyone else.[789] Investing in the education of low- and middle-income countries opens new markets for the patent holders where they can place their patented products and where the purchasing power of the new markets' population should gradually increase as they acquire better skills and get better paying jobs.

Education solves many problems, some of which include higher awareness of more global problems like, climate change issues, better ability to discriminate between fake and true new, a step forward to eradicating poverty as well.

Such a contribution would balance the scales between the private and public interests and even ennoble the role of intellectual property in the society, perhaps allow it to gain a function of enlightenment, perhaps similar to the enlightenment and vast changes brought about by the French revolution of 1789 when 'Freedom of press' was

[788] 'Licensing income, even at the best performing institutions, is an extra benefit for research and education and rarely represents more than 10% of research budgets,' Organisation for Economic Co-operation and Development. *Patents and innovation: trends and policy challenges*. OECD Publishing, 2004. Available at https://www.oecd.org/science/inno/24508541.pdf. Last accessed on 28 May 2022.
[789] At the end of the 20th and beginning of the 21st century, many European countries extended the employers' rights to employee inventions to the university area. Nowadays universities as employers may have a right to inventions made by professors and other academic staff researching at universities. *See* further Andreas von Falck and Christiane Schmaltz, "University inventions: Classification and remuneration in Germany, the Netherlands, France, the UK, the US and Japan." *IIC-INTERNATIONAL REVIEW OF INTELLECTUAL PROPERTY AND COMPETITION LAW* 36, no. 8 (2005): 912-927, pp. 912–927 and Christian Gero Stallberg, "The Legal Status of Academic Employees' Inventions in Britain and Germany and its Consequences for R&D Agreements." *Intellectual property quarterly* 4 (2007): 489, in van Overwelle, *supra* note 704, p. 323

declared and literary privileges abrogated.[790] At the time of the revolution, authors were widely celebrated as civic heroes, servants of public enlightenment.[791]

With mandatory higher education contribution for intellectual property holders the whole IP system obtains a social role and could, indeed, ascribe itself the attribute driver of development.

Overdiek, Rausch and Gramke find that some patents have more meaningful contribution in society than other.[792] Namely, their study shows that only 10% of the most important patents ('world-class patents')[793] have contributory role in society. If only 10% of the patents bear meaning and importance, and yet, raise market barriers just as meaningful patents do, demanding a contribution from such patent holders for educational purposed seems only fair so as to restore the public-private balance. If anything, the finding just strengthens the argument that patents impede knowledge dissemination while having a hegemony over them.

### 6.5.3. University patents

Universities, like companies, are entitled to patent rights over their inventions stemming from their research work. This practice originates in the US with the enactment of the Bayh-Dole Act in 1980.[794] The act encourages utilisation of inventions produced under U.S. federal funding, promotes participation of universities and small businesses in the development and commercialisation process and allows

[790] See Carla Hesse, "The rise of intellectual property, 700 BC-AD 2000: An idea in the balance." *Daedalus* 131, no. 2 (2002): 26-45, p. 38. Available at https://www.amacad.org/publication/intellectual-property-700-bc-ad-2000. Last accessed on 31 May 2022.

[791] See more in Carla Hesse, Publishing and Cultural Politics in Revolutionary Paris. In *Publishing and Cultural Politics in Revolutionary Paris*. University of California Press, 2020. Available at https://publishing.cdlib.org/ucpressebooks/view?docId=ft0z09n7hf;brand=ucpress. Last accessed on 31 May 2022.

[792] Markus Overdiek, Thomas Rausch, and Kai Gramke, "World Class Patents—The Gold of the Knowledge Economy?." *Wirtschaftsdienst* 100 (2020): 718-723, p. 719. Available at https://link.springer.com/content/pdf/10.1007/s10273-020-2744-x.pdf. Last accessed on 31 May 2022.

[793] World-class patents based on the approach by Holger Ernst and Nils Omland. "The Patent Asset Index–A new approach to benchmark patent portfolios." *World Patent Information* 33, no. 1 (2011): 34-41, p. 40. Available at https://cdn2.hubspot.net/hubfs/4012648/Publications%20PDF/3_Ernst,%20Omland%20(2010)%20-%20WPI%20-%20The%20Patent%20Asset%20Index.pdf. Last accessed on 31 May 2022.

[794] PUBLIC LAW 96-517-DEC. 12, 1980. Public Law 96-517. 94 STAT. 3015. 96th Congress. An Act. To amend the patent and trademark laws. Available at https://www.govinfo.gov/content/pkg/STATUTE-94/pdf/STATUTE-94-Pg3015.pdf#page=14. Last accessed on 31 May 2022.

exclusive licensing by transferring inventions to the marketplace for the public good while the US government enjoys royalty-free, nonexclusive licenses to use such inventions for government purposes,[795] including use by government contractors.[796] As a result, the last 40 years have been marked by a considerable increase in university interest to commercialise new technologies.[797] The Bayh-Dole Act is considered to have given a new role to universities aside from the classical role of contributing to society by providing education and performing basic research,[798] thus shifting the aim of universities towards a more direct contribution to economic development, also referred to as a pursuit of a 'third mission', by engaging in activities of technology transfer from universities to industry.[799] Such activities involve marked growth in filing university patent applications.[800]

As the practice of transfer of technologies from universities to industry proved successful in the US, the European counties started to adopt legislation similar to the

[795] Bayh-Dole Act, § 202(c)(4). Disposition of rights reads: '[w]ith respect to any invention in which the contractor elects rights, the Federal agency shall have a nonexclusive, nontransferable, irrevocable, paid-up license to practice or have practiced for or on behalf of the United States any subject invention throughout the world.'

[796] *Ibid* "§ 200. Policy and objective. Also see Anatole Krattiger, Richard T. Mahoney, Lita Nelsen, Jennifer A. Thomson, Alan B. Bennett, Kanikaram Satyanarayana, Gregory D. Graff, Carlos Fernandez, and Stanley Kowalski, "Intellectual Property Management in Health and Agricultural Innovation: A Handbook of Best Practices, Vol. 1." (2007), p.1077 Available at https://www.ipmall.info/sites/default/files/hosted_resources/IP_handbook/iphandbook_volume_2.pdf. Last accessed on 31 May 2022.

[797] Donald S. Siegel, Paul Westhead, and Mike Wright, "Assessing the impact of university science parks on research productivity: exploratory firm-level evidence from the United Kingdom." *International journal of industrial organization* 21, no. 9 (2003): 1357-1369. Available at https://www.krannert.purdue.edu/centers/ijio/accepted/sww.pdf. Last accessed on 31 May 2022.

[798] Nathan Rosenberg and Richard R. Nelson, "American universities and technical advance in industry." *Research policy* 23, no. 3 (1994): 323-348. Available at http://sciencepolicy.colorado.edu/students/envs_5100/rosenberg_1994.pdf. Last accessed on 31 May 2022; also Rebecca Henderson, Adam B. Jaffe, and Manuel Trajtenberg, "Universities as a source of commercial technology: a detailed analysis of university patenting, 1965–1988." *Review of Economics and statistics* 80, no. 1 (1998): 119-127. Available at https://www.nber.org/system/files/working_papers/w5068/w5068.pdf. Last accessed on 31 May 2022; Ajay Agrawal and Rebecca Henderson, "Putting patents in context: Exploring knowledge transfer from MIT." *Management science* 48, no. 1 (2002): 44-60. Available at https://dspace.mit.edu/bitstream/handle/1721.1/3957/IB_Putting+Patents.pdf?sequence=2. Last accessed on 31 May 2022.

[799] Henry Etzkowitz and Loet Leydesdorff, "The dynamics of innovation: from National Systems and "Mode 2" to a Triple Helix of university–industry–government relations." *Research policy* 29, no. 2 (2000): 109-123. Available at https://ams-forschungsnetzwerk.at/downloadpub/Etzk.pdf. Last accessed on 31 May 2022.

[800] Aldo Geuna and Lionel JJ Nesta, "University patenting and its effects on academic research: The emerging European evidence." *Research policy* 35, no. 6 (2006): 790-807. Available at https://ftp.zew.de/pub/zew-docs/veranstaltungen/inno_patenting_conf/GeunaNesta.pdf. Last accessed on 31 May 2022.

Bayh-Dole Act in order to achieve greater social and economic benefits from research as placing the outputs of publicly funded research in the public domain proved insufficient to fulfil that role.[801] The trend did not stop with the western economies but took a worldwide effect, evidenced by the research done on university patents in Asia[802] and especially China.[803] Wong and Singh also researched the relationship between patenting and publishing finding a positive correlation despite the evidence that researchers refrain from publishing before patenting.[804] Trends in university patenting activities have been largely studied and generated a growing academic literature on university transfer of technology.[805] A study conducted in 2015 comparing university technology transfer of 300 top universities worldwide found that

[801] Nicola Baldini, "Implementing Bayh–Dole-like laws: Faculty problems and their impact on university patenting activity." *Research policy* 38, no. 8 (2009): 1217-1224. Available at https://papers.ssrn.com/sol3/papers.cfm?abstract_id=1395680. Last accessed on 31 May 2022.

[802] Mei-Chih Hu and John A. Mathews, "National innovative capacity in East Asia." *Research policy* 34, no. 9 (2005): 1322-1349. Available at https://d1wqtxts1xzle7.cloudfront.net/32646369/1-s2.0-S0048733305001393-main-libre.pdf?1391089278=&response-content-disposition=inline%3B+filename%3Dnational_innovation_capacity_in_east_asi.pdf&Expires=1654031095&Signature=RVFaGzweX6OgWPJT5Onja3KdVLjSU8poPKWJNZ9nOYUQ1O8dDRvrje83izX1IWnDqCAHusphMiK-s8HX-TUJsznGlOxuzhswEB5ukSG7x3kUzuA4xpefrQBaxNLBPFW3O9so0vk-Y305imzLQ~AQsIw7QmixJdGqKCMLE5m~a1cGkZIjpzefSyscbnV8G8CPPTtDq~1o6VCzGQSDt-F3hrrDluZV50peRB-2BkuMSO3AYrKQW-YjyN8tKldTMhW44guRkzQtnbrpuo~mBP9UP8IdKHtYpiY3dT42GVKW4N0GwEKW0qXUdPIknPZPPGA9IlDccyzbAo3YPTwDetw1PQ__&Key-Pair-Id=APKAJLOHF5GGSLRBV4ZA. Last accessed on 31 May 2022.

[803] Christian O. Fisch, Joern H. Block, and Philipp G. Sandner, "Chinese university patents: quantity, quality, and the role of subsidy programs." *The Journal of Technology Transfer* 41 (2016): 60-84. Available at https://www.researchgate.net/profile/Christian-Fisch/publication/314479441_Chinese_University_Patents_Quantity_and_Quality_1985-2010/links/5c00f8b3a6fdcc1b8d4ab14a/Chinese-University-Patents-Quantity-and-Quality-1985-2010.pdf. Last accessed on 31 May 2022.

[804] Poh Wong and Annette Singh. "University patenting activities and their link to the quantity and quality of scientific publications." *Scientometrics* 83, no. 1 (2010): 271-294. Available at https://web2-bschool.nus.edu.sg/wp-content/uploads/media_rp/publications/MX8Rm1422877585.pdf. Last accessed on 31 May 2022.

[805] David C. Mowery, Richard R. Nelson, Bhaven N. Sampat, and Arvids A. Ziedonis, "The growth of patenting and licensing by US universities: an assessment of the effects of the Bayh–Dole act of 1980." *Research policy* 30, no. 1 (2001): 99-119. Available at https://www.researchgate.net/profile/Arvids-Ziedonis/publication/2399056_The_Effects_of_the_Bayh-Dole_Act_on_US_University_Research_and_Technology_Transfer_An_Analysis_of_Data_from_Columbia_University_the_University_of_California_and_Stanford_University/links/5cded95992851c4eaba97ab8/The-Effects-of-the-Bayh-Dole-Act-on-US-University-Research-and-Technology-Transfer-An-Analysis-of-Data-from-Columbia-University-the-University-of-California-and-Stanford-University.pdf. Last accessed on 31 May 2022; Bhaven N. Sampat, David C. Mowery, and Arvids A. Ziedonis, "Changes in university patent quality after the Bayh–Dole act: a re-examination." *International Journal of Industrial Organization* 21, no. 9 (2003): 1371-1390. Available at https://www.mgmt.purdue.edu/centers/ijio/accepted/SMZ.pdf. Last accessed on 1 June 2022; Jerry G. Thursby and Marie C. Thursby, "Who is selling the ivory tower? Sources of growth in university licensing." *Management science* 48, no. 1 (2002): 90-104.

European universities file fewer patent applications than do US and Asian universities.[806] More importantly, the corelation of university size and patenting activities was found to be also positive,[807] confirming previous studies of the same characteristic.[808] This is ascribe to the larger fundings and availability of more resources[809] to universities of greater size, however, begs the question of how smaller sized universities, especially those in developing regions, could receive more funding and resources in order to catch up with the already well funded and patenting universities in the developed world.

While the above confirms it is true that universities like companies own patents and some of them are even major patent holders, unlike universities, private companies innovate to obtain market position. Inventions invented at universities would end up in the public domain anyways since published research does not leave space for a monopoly, hence does not allow for high return of innovative products.[810] However, this is not true for inventions developed by private companies. Universities tend to innovate for innovation's sake, unlike companies which innovate for the post-inventive competitive and market benefits. It is exactly these benefits that patent law implies when it grants monopoly right to patent holders.

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[806] Christian O. Fisch, Tobias M. Hassel, Philipp G. Sandner, and Joern H. Block, "University patenting: a comparison of 300 leading universities worldwide." *The Journal of Technology Transfer* 40 (2015): 318-345. Available at https://www.nber.org/system/files/working_papers/w7718/w7718.pdf. Last accessed on 1 June 2022.

[807] *Ibid*, p. 322.

[808] Rejean Landry, Nabil Amara, and Mathieu Ouimet, "Determinants of knowledge transfer: evidence from Canadian university researchers in natural sciences and engineering." *The Journal of Technology Transfer* 32 (2007): 561-592 (based on a survey of 1554 researchers in Canada, it was found that university-industry knowledge exchange is significantly determined by the size of the university). Also supportive of the same finding is the work of Nola Hewitt-Dundas, "Research intensity and knowledge transfer activity in UK universities." *Research policy* 41, no. 2 (2012): 262-275. The positive correlation between university size and technology transfer was also confirmed by Bo Carlsson and Ann-Charlotte Fridh, "Technology transfer in United States universities." *Journal of Evolutionary Economics* 12 (2002): 199-232. Available at https://www.researchgate.net/profile/Bo-Carlsson/publication/225899001_Technology_transfer_in_United_States_universities/links/00b7d518147604eabc000000/Technology-transfer-in-United-States-universities.pdf. Last accessed on 1 June 2022; see also Harun Bulut and GianCarlo Moschini, "US universities' net returns from patenting and licensing: A quantile regression analysis." *Economics of Innovation and New Technology* 18, no. 2 (2009): 123-137. Available at https://web.archive.org/web/20170818133435id_/http://ageconsearch.umn.edu/record/18441/files/wp060432.pdf?version=1. Last accessed on 1 June 2022.

[809] Fisch, *supra* note 806, at p. 322.

[810] Biagioli, *supra* note 691, p. 156.

In their seminal Triple Helix model, Etzkowitz and Leydesdorff compare two modes of research, that is Mode 1 based on research dealing with issues in separate disciplines and Mode 2 based on collaborative intradisciplinary research addressing practical issues.[811] They find it paradoxical that Mode 2 currently derives from Mode 1 as the former was the format of science in the 17th century, however, justify the development of Mode 1 as a defence mechanism against the undermining of university autonomy by holders of great industrial fortunes, who at the time donated funds for the foundation of new universities.[812] However, with the strong government intervention in education, science and research, such consequences did not come to pass, which might again arise if IP holders are obliged to contribute to education once again. On the other hand, the triple helix of university-industry-government can form stronger ties and enable the development of more compact and balanced society.

By applying the proposed IP education contribution and linking patent-generated company funds to universities, a measurable value could be created. That is, the number of students educated by funds generated from the monopolies they as part of the public grant to companies which own the rights to such monopolies could be a measurable value. The rational would be that these graduates themselves would become part of the innovation generating population at best or become global citizens who can utilize their university skills in other parts of the market. In other words, instead of constantly attacking a system that seems to be impervious to attacks, the said system could be reutilised. Conditioning patent holders to invest specific funds in universities, thus ensuring higher quality education and opening the way to cheaper or even free education for the general population could possibly return the much sought-after balance between patents and society.

The slight change in investment practices has a lot to contribute. The industry prides itself with its investment in research and development, thus justifying its strong advocacy of intellectual property protection. However, the current practice leaves a

[811] Etzkowitz & Leydesdorff (2000), *supra* note 799, p. 112; also, Henry Etzkowitz and Chunyan Zhou, *The triple helix: University–industry–government innovation and entrepreneurship*. Routledge, 2017, p. 141-142
[812] *Ibid* Etzkowitz and Zhou, p. 142.

dark stain on its reputation as it effectively protects its profits while its opposition advocates human rights.

Industry advantages:

1. Early investment of just a fraction
2. Inevitable market expansion
3. Guaranteed human resources of intellectual value
4. Power to dictate societal changes and directions

Societal advantages:

1. Better access to education
2. Improved chances of employment due to increased skillset
3. Incremental but progressive departure from poverty
4. Mid-term and long-term improved access to medicines

To achieve such balancing, the general framework of patent law should undergo certain changes. Given that worldwide minimum requirements are governed by the TRIPS agreement, it is exactly through this mechanism that these changes should be put through. Amending TRIPS would provide for worldwide implementation of the said conditioning thus achieving effects on the largest scale.

'Modifying one component may require adjustment of others if the components are to continue to work effectively.'[813] The introduction of a compulsory financing of universities by patent holding companies, could disturb the balance which allows the system to work effectively.

[813] Daniel J. Gervais, "The Compatibility of the" Skill and Labour" Originality Standard with the Berne Convention and the TRIPs Agreement." *European Intellectual Property Review* 26, no. 2 (2004): 75-80.

# CONCLUSION

The goal of this work was to challenge the long-standing promise that intellectual property protection, specifically patent protection, promotes and incentivises technological development, and to prove that in the digital, knowledge-based era, patent protection in its current form only impedes rather than advances technological as well as economic development. In order to achieve these goals, national, regional and international legislation is considered in Chapters 2 through 5 finding that these issues have so far been addressed by countless number of academics, policy makers, NGOs, individuals etc. However, the results of the efforts to bring about meaningful changes have so far been minimal.

As the patent system is analysed through biotechnology lens here, Chapter 2 is dedicated to the first such change which came to pass in July 2013 with the narrowing of the scope of gene patents in the US when the US Supreme Court invalidated the Myriad patent claims in the BRCA genes and 'isolated and purified' inventions became non-patentable subject matter in the US. The chapter studies the case of *Myriad* and the decisions adopted on all three levels by the US courts as well as the reasoning and the history of patenting 'products of nature' and 'isolated and purified' discoveries in the US. *Myriad* was proceeded by *Mayo vs Prometheus*, another case in which patent scope was narrowed down and diagnostic methods were found not to be patentable subject matter in the US. Though these decisions seem like a huge win for the pro-access cause, as the chapters goes into the details of the *Myriad* case, the cracks begin to show when the Supreme Courts finds cDNA to be patentable subject matter, which is practically the same as the 'isolated and purified' gDNA but without the inactive parts of it. Effectively, gene patents remain patentable in the US just like before *Myriad*, it just needed some working around the Myriad Supreme Court decision.

As Myriad was 'internationally infamous,' it found itself before the Australian courts, too. The Australian courts looked at the same subject matter as did the US courts, however, unlike in the US, they reflected on the notion of 'manner of manufacture' and found that the BRCA patents fell outside the scope of patentable subject matter under the Australian Statute of Monopolies 1624. As a result, today, according to the

Australian Patent Office Manual of Practice and Procedure, if 'genetic information' in a man-made molecule, for example cDNA, is the same as that in the genome, the molecule is not patent eligible.' The win in Australia was bigger.

Europe had its own experience with Myriad's BRCA patents, however, unlike the US and the Australian courts, European courts never got to decide on the matter of patentability, but decided on the validity of claims, which when filed contained errors in the disclosed sequence for which patent protection was sought. The said claims were invalidated and the BRCA patent scope was narrowed down in Europe, too, albeit, on completely different ground from the US and Australia.

The CRISPR patent disputes are also included in this chapter further exemplifying the complexity of the science the patent system is still attempting to accommodate. The concept of 'non-obviousness' or 'inventive step' is examined through the CRISPR patent prism, especially because, like *Myriad*, it has found itself in dispute on more than one continent, but unlike *Myriad*, came to be a subject of opposition on morality grounds in Europe as the potential of this groundbreaking technology to improve human is highly promising.

Chapter 3 goes to the cradle of intellectual property to examine biotechnology patents in Europe and how the Biotechnology Directive came to be. The questions of accesses kept this piece of legislation from being adopted for almost a decade and the chapter looks at the issues, discussions and conclusions before its adoption only to find that the main issue in Europe was the '*ordre public*' or morality of patenting biotechnology. As gene patents are patentable subject matter if isolated and purified, Europeans don't seem to find this to be an immoral practice but are of a different opinion when it comes to human embryos, which are excluded from patentability under the Directive. The same issue persisted after the adoption of the Directive and its incorporation in the European Patent Convention, thus becoming a subject to the EPO Boards of Appeal, which also deliberated on the subject of '*ordre public*' and morality. However, the CRISPR opposition on morality grounds in Europe was dismissed, upholding the CRISPR patents in amended form. One might think that a region which concerns itself with morality so much would most likely take access to medicine and the human right to health closer to heart, however, as Chapter 5 later on shows, Europe was the main

obstacle to the COVID-19 patent waiver, which was of most crucial importance to stop the pandemic worldwide.

Chapter 4 looks at the case of Türkiye and its approach to patent protection from Ottoman times to the current state of affairs and finds that Ottoman times were very much familiar with monopolies and not unlike the western societies, relied on these monopolies to secure market power, which was especially pronounced among the crafts. The first real Turkish patent law was based on the French one and excluded pharmaceuticals from patent protection, thus effectively providing the Turkish population access to affordable medication. Türkiye held on to this practice until the TRIPS Agreement took effect and imposed patenting of inventions in all fields of technology, including pharmaceuticals, when they became patentable subject matter in Türkiye, too. Chapter 4 concludes the examination of national and regional legislation before international aspects are examined in the following part as all three chapters indicate that the problem spans throughout jurisdictions and requires to be addressed internationally rather than nationally or regionally.

Chapter 5 marks the beginning of Part II and identifies the real culprit in this story. It sets off to provide just a brief overview of the purpose and main characteristics of the TRIPS Agreement, which have been thoroughly examined in the past by numerous commentators, and goes on to the amendment of the Agreement, which addresses the loud voices demanding access to affordable medications led by India and South Africa. This amendment is known as the Doha Declaration and at the time of its adoption was considered a great win as it heralded a new era of better access to medications. Disenchantment took place when countries got faced with the cumbersome procedure provided for under the 'Article 6 Protocol' coupled with the bilateral trade agreements, known as the TRIPS-plus Agreements, imposing waivers to the TRIPS flexibilities and effectively conditioning the weaker parties to give up access to medications for the benefits of international trade. This is further pronounced when the TRIPS Agreement is applied to the COVID-19 pandemic and its teeth and claws become plain as a day. India and South Africa lead the battle against TRIPS again and demand access-blocking life-science patent rights to be waived in order to fight off the pandemic that has affected billions worldwide only to be faced with a very firm 'NO' from the European Union. The Chapter finds that the European Union has agreed to a

patent waiver to the vaccine patents, but this is just a fraction of what was asked for and what is needed as the agreed patent waiver only applies to preventive medication, that is, vaccines, while diagnostic and therapeutic medications were not found to be as needed to stop the pandemic.

In the search for a solution to the access problem, Chapter 6 looks into some of the aspects that have been addressed in the attempt to strike a balance between the private and the public interest entertaining the human rights perspective, the economic interests, individualism/collectiveness dichotomy, philosophical contractarian and utilitarian theories of intellectual property, information and knowledge as core ingredients for intellectual property rights, all leading to the view of the global knowledge economy through which intellectual property has penetrated every single pore of society. The problem with the access to affordable medicines meets the problem with the access to knowledge over which intellectual property is found to have almost hegemonic power.

The Chapter finds that high interest in innovation is based on the monopolies afforded to innovative solutions as returns of investments guarantee further investment in research and development of innovative products, thus enabling overall societal technological development. However, it also finds that if there is no demand for such innovative solutions, the investment would not generate any returns and thus prove to be unjustified from profits point of view. The case with the 2003 SARS pandemic is just a single example for this.[814] Otherwise, why is the vaccine being developed so rashly right now and not in the past decade and a half? What comes to light in a pandemic ridden world are the disadvantages of investing in inventions instead of knowledge. The profitless investment in knowledge of the SARS virus could have possibly prevented the COVID health and economic crisis which deepened by the

[814] For details about the attempts to develop a vaccine against SARS-CoV, see Chien-Te Tseng, Elena Sbrana, Naoko Iwata-Yoshikawa, Patrick C. Newman, Tania Garron, Robert L. Atmar, Clarence J. Peters, and Robert B. Couch, "Immunization with SARS coronavirus vaccines leads to pulmonary immunopathology on challenge with the SARS virus." *PloS one* 7, no. 4 (2012): e35421. Available at https://journals.plos.org/plosone/article?id=10.1371/journal.pone.0035421

day.[815] Had it not been for the pandemic, these disadvantages would have stayed only hypothetical arguments against patent protection.

To address global issues of this size, concerning both access to medicine as well as accesses to knowledge, it is not national patent laws which require amending but the overall international patent system, which serves trade purposes so well that it disregards, and even endangers human health.

When weighing of whether investment in education as the basis for future inventions is more profitable than direct investment into promising inventions, the former would inarguably bear fruits much later than the latter, however, education does not only promise possibility of new inventors but also a better educated population with better job opportunities, effectively producing population with higher purchasing power which would later be able to afford patented products, including medications. This would suggest that knowledge obtained through education without the subsequent profit generating inventions seems like a pointless investment since by itself does not generate nothing but the promise of development. This might be true only in the short run as in the long run, it is inarguable that the investment deserving party is knowledge. In the short run, inventions can guarantee faster investment return, thus proving to be the more deserving investment party. The consequences of such calculated investments are evident in the current COVID pandemic allowing for development of novel vaccine, diagnostic and therapeutic technologies which most of the global population cannot afford, as discussed in Chapter 5.

The COVID-19 pandemic is a crisis which emphasizes the imbalance deeply engrained into our society. So deep that it has taken a face of normalcy and has left everyone powerless to fight it. The fight against that which is found to be normal is a hard one. Challenging standards which promise stability is even harder. But a stability pillared on such an injustice is doomed to be pulled down, sooner or later.

[815] UNDP, COVID-19, SOCIO-ECONOMIC IMPACT. Available at https://www.undp.org/coronavirus/socio-economic-impact-covid-19?utm_source=EN&utm_medium=GSR&utm_content=US_UNDP_PaidSearch_Brand_English&utm_campaign=CENTRAL&c_src=CENTRAL&c_src2=GSR&gclid=Cj0KCQjwspKUBhCvARIsAB2IYutPb-3u7hyDul1zct9_fkY0gxw_4U01fS5zYcUuF1bzIfcm1J3bMGIaAuNnEALw_wcB. Last accessed on 22 Apr. 23.

And the patent system is old, too old to be challenged or, far from it, taken down. It has evolved and has had every and any argument in support of it.[816] The COVID-19 pandemic brings forth almost all of the disadvantages of the patent system. Only when faced with a crisis that affects those who are well off, as much it does those who aren't, can we see the inequality that the present system supports. Patent rights are forfeited temporarily if not permanently, knowledge is freely shared for the 'greater good' and global organisations are created to fight off an enemy not known before.[817] Because the unknown is theat.

Much effort has been made to tackle this inequality for decades, but the quest for balance, albeit so advocated and pursued, has never been really put forth. It would seem that the human strive for economic development could never adequately be confronted so as to really strike that balance between the economy and the wellbeing of society.

This work clings on only one aspect of society that intellectual property rights might have any merit in developing, and this is the individualism that they have put forth and managed to maintain in the last two centuries. Patents are granted based on a name of a certain inventor, whose name is a mandatory segment of a patent application. It is that one individual who gets an idea which is perhaps further developed by a larger group, but rarely does a whole group of people get a single idea simultaneously. If so, the likelihood of it being a patentable subject matter decreases as it would probably not meet the patentability criteria. The part addressing individualism above finds that individualism is stimulated by the reward the patent system provides for the inventor's disclosure of their invention as a contribution to society. Such societal reward system leads to increase of individualism and stimulation of development through rewards. Not unlike the rise and prominence of intellectual property, individualism is relatively new global phenomenon and as such subject to manipulation and exploitation by economic factors. As discussed in the human rights part above, nowadays material rights in patents are largely owned by companies, not individuals. Nonetheless, empirical evidence show that development of individualism goes in line with

[816] Shobita Parthasarathy, *Patent Politics: Life Forms, Markets, and the Public Interest in the United States and Europe*. University of Chicago Press, 2017.
[817] Moderna statement that would not enforce its patent rights during the pandemic. Creation of international organisations to supply covid vaccine globally.

development of intellectual property rights and finds the latter to be a contibutive factor for the rise of the former.

However, this observation leads to the conclusion that with the patent system in place, the more individuals (versus the collective) develop, the more patents might be generated as individual and creative inventions lead to the promised rewards. Such inventions nowadays are developed by the scientific community, hence the previously advocated investment in education, rather than in profit-generating research is further justified.

As patent law is a western construct as it is, it served the purpose of developing individualism at a time when individualism almost did not exist. It provided society an insight and development only a few could provide and brought about prosperity which ushered forth the advantages of the 20th century. The 21st century needs more. As life sciences make their progresses, the fact that individualism is not only a mindset, but a physiological fact becomes ever so evident and the need for personalised medicine with it. Advances made in the development of individual medications paint the picture of what future healthcare may look like. It is very much individual since, though we might be plagued by same ailments, we do seem to respond differently to different treatments.[818] Individualised treatments coupled with patents could arguably herald an era with even deeper inequality if the patent system does not undergo certain changes. So, instead of dismantling it, the idea is to empower the global population to afford it.

For this purpose, and having in mind all the above, this work concludes with the proposal for amendment of the TRIPS Agreement so as to incorporate provisions which could potentially set the balance between private and public interests. The only currently available tool for empowerment is education and this 'marriage proposal' aims at better balanced relationship between patents and knowledge. As never before have the patent holders, or intellectual property holder for that matter, been asked for anything in return for the privileges conferred to them by the society, introduction of provisions which obligate these holders to contribute to the education of the global population, in return potentially opening new markets for them, could represent a step forward towards striking the balance between the interests of society and those of IPRs

[818] There is no medication with 100% effectiveness.

holders. The manner in which such provision could be versed and the aspect which should be considered for such an amendment would surely require further research and consideration of all possible advantages and disadvantages that it could bring about.

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