6. "The Patent System and Research Freedom: A Comparative Study"

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Contents

I. Scope and Definitions

A. Scope and Issues

One of the primary goals of the patent system is to encourage research of all kinds – basic, applied and translational – by both granting rights to inventors and by excluding or limiting those rights so as to enable others to use and improve existing inventions. As legislatures and courts around the world have recognized, the exclusions and exceptions placed on patent rights are far from an oversight: they are essential to achieving the appropriate set of policies that best foster research and development.[1] This chapter investigates patent exclusions and exceptions which affect research and development in science and technology.

This chapter investigates two types of legal rules through which patent law affects research: 1) those that determine what can and cannot be patented (exclusions); and 2) those which exclude certain acts or certain actors from liability for infringement (exceptions).

The "patent system aims to promote scientific and technological progress by granting exclusive rights in new discoveries. But the enforcement of these exclusive rights against subsequent researchers can sometimes interfere with further progress in the field of the invention."[2] It thus becomes essential to understand both the effect of patent rights in providing an incentive to undertake research and on making subsequent research more difficult, time consuming or expensive. Exclusions and exceptions do not exist in isolation: they work within the context of legal rules governing what can be patented, the scope of patent rights and the means to enforce those rights, as well as practices that exist over the use and enforcement of patent rights.

Part I of this Chapter sets out important definitions and concepts. Part II then deals with exclusions and Part III with exceptions. Each of these parts begins by setting out the international instruments that deal with exclusions or exceptions – as the case may be –, including regional agreements. Before identifying commonalities and distinctions between countries from various regions, national provisions from a representative sample of countries will be set out in a tabular form. The presentation of these sample national provisions aims at achieving a balance between clarity and conciseness, on one hand, with exhaustiveness, on the other. Countries were selected to represent a variety of exclusions in different world regions.

This chapter's discussion of exclusions includes both specific, statutory, provisions as well as national interpretations of the requirements for patentability under national or regional law. Often, different countries use different routes to excluding some subject matter. For example, methods of medical treatment or business methods are excluded in some jurisdictions by

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[1] *Ariad Pharms., Inc. v. Eli Lilly & Co.*, 598 F. 3d 1336 (C.A. Fed., 2010) (U.S.); *Merck & Co. v. Apotex Inc.*, [2007] 3 F.C.R. 588 at para. 102 (Canada); *Daiichi Pharmaceutical Co., Ltd.* v. *Shiono Chemical K.K. & Choseido Pharmaceutical K.K.* (Japan) discussed in Shamnad Basheer & Coenraad Visser, *Background Information from Asia* (2010) [unpublished], p. 23 [Asian Report].

[2] Rebecca S. Eisenberg, "Patents and the Progress of Science: Exclusive Rights and Experimental Use" (1989) 56 U. Chi. L. Rev. 1017, p.1086.

specific exclusion while in others through the interpretation of one or more of the criteria of patentability. Thus, in order to undertake a complete study of exclusions and exceptions, one must pay attention not only to formal exclusions, but also those that arise through the interpretation of other patent rules, such as those pertaining to the criteria for patentability.

The discussion of exceptions includes the prior user exception, the non-commercial user exception, the experimental use exception and the exception for submission of information to the government (*Bolar/Safe Harbor*). For the prior user exception, a link between the first-to-file system, trade secrets and research will be made. The non-commercial user exception will be distinguished from the experimental use exception. As for experimental use exceptions, a distinction will be drawn between those that allow experiments *on* inventions and those that allow experiments *on* and *with* inventions. Distinctions will also be made based on the sources of experimental use exceptions (statutory vs. judicial) and on whether or not commercial purposes are allowed.

Part IV ties these sections together by focusing on the motivation behind major groups of exclusions and exceptions. It ends by discussing the overarching concept of balance that permeates judicial and policy treatments of patent law. Chapter IV plays particular attention to the experimental use exception/*Bolar* exception and disclosure/secrecy dualisms. It concludes by discussing the necessary relationship between the exclusions and exceptions needed to create successful research environments.

B. Definitions

Description requirement – Enablement requirement: While these two expressions might refer to different concepts, some jurisdictions do not differentiate between the two. The expression "description requirement" will hereby refer to all forms of description requirements, including what some distinguish as an enablement requirement.

Fundamental knowledge: Fundamental knowledge is derived from "experimental or theoretical work undertaken primarily to acquire new knowledge of the underlying foundation of phenomena and observable facts, without any particular application or use in view."[3]

Applied Knowledge (Practical applications): Applied knowledge results from an "original investigation undertaken in order to acquire new knowledge. It is, however, directed primarily towards a specific practical aim or objective."[4]

Research: As previously explained, one of the purposes of the patent system is to stimulate research of all kinds. Because the goal of this chapter is to study the relationship between research and the patent system, it is necessary to define what constitutes research. This will allow the reader to better understand the relationship which certain exclusions or exceptions have with research.

According to the *Oxford English Dictionary*, research may be defined as "the systematic study of materials and sources in order to establish facts and reach new conclusions." In other words,

[3] *The Measurement of Scientific and Technological Activities* Frascati Manual 2002 Proposed Standard Practice for Surveys on Research and Experimental Development (2002, OECD publishing).
[4] *Ibid.*

research may be defined as an organized investigation of physical or non-physical material, concepts or sources, in order to reach a conclusion.

Research may be applied or fundamental. Applied research is "concerned with action" and is "likely to be effective in real circumstances," while fundamental research is concerned with abstract concepts and *not directly applicable results*. "The primary criterion of success in applied research is contribution to the solution of specific practical problems."[5] "[Fundamental] research, on the other hand, is successful when it discovers new phenomena or new ideas of general interest."[6] The distinction between applied research and fundamental research does not map on to the distinction between what is patentable and what is not. There is some applied research – such as methods of surgery – that are not universally patentable and some fundamental research – such as DNA sequences – that are patentable in many jurisdictions.

II. Exclusions Affecting Research

This part of the chapter discusses how patentability exclusions may affect research. These exclusions originate from both national and international laws. Consequently, this section will discuss both the international legal framework to which countries adhere (**Part A**) and national regimes (**Part B**).

A. International Legal Framework

While international legal agreements do not deal specifically with research and patents, several instruments affect the ability of nations to enact specific exclusions. Thus, this Part A focuses on what international legal texts say about exclusions from patentable subject matter that may have an impact on research and development. After having discussed the general framework of international agreements (**i**), regional agreements will be examined in order to achieve a thorough understanding of the supranational obligations countries may have pertaining to exclusions affecting research and to learn more about the origin of these exclusions (**ii** to **v**).

i) Global Legal Framework

The *Trade Related Aspects of Intellectual Property Rights Agreement* (*TRIPS*) is an international substantive treaty that imposes certain limitations on the types of exclusions that may have an effect on research. Concluded in 1994 and having come into force in 1995, *TRIPS* encompasses a broad range of intellectual property regimes. Its main purpose is to set minimum standards for intellectual property for members of the World Trade Organization.[7]

Part II, Section 5 of *TRIPS* is dedicated to patents. This section requires member countries to grant patents for inventions (products or processes) in all fields of technology, as long as the

[5] Nils Roll- Hansen, "Why the distinction between basic (theoretical) and applied (practical) research is important in the politics of science" (2009) LSE Centre for the Philosophy of Natural and Social Science – Technical Report 04/09 [Nils Roll- Hansen, "Why the distinction between basic (theoretical) and applied (practical) research is important in the politics of science"].
[6] *Ibid.*
[7] Kevin J. Nowak, "Staying Within the Negotiated Framework: Abiding by the Non-Discrimination Clause in Trips Article 27" (2005) 26 Mich. J. Int'l L. 899, p. 902 [Nowak, "Staying Within the Negotiated Framework: Abiding by the Non-Discrimination Clause in Trips Article 27"].

invention is new, the product of an inventive step and possess an industrial application.[8] In other words, the breadth of patentable subject matter is very broad; only what is not an invention or not capable of meeting the three criteria of novelty, inventive step (or non-obviousness) and industrial application (or utility) can be excluded from patentability.[9] Nevertheless, Article 27 of *TRIPS* provides countries with the ability to enact some exclusions.

The first of these concerns "diagnostic, therapeutic and surgical methods for the treatment of humans or animals."[10] This exclusion does not encompass pharmaceutical products, however, as *TRIPS* explicitly requires that such products be patentable.[11] This exclusion allows, if brought into national law, doctors and healthcare professionals to use the above mentioned methods without the threat of infringing a patent. Similarly, it permits the use of these methods by medical researchers.

Second, member countries may exclude from the realm of patentability "plants and animals other than micro-organisms, and essentially biological processes for the production of plants or animals other than non-biological and microbiological processes."[12] However, "[m]embers shall provide for the protection of plant varieties either by patents or by an effective *sui generis* system or by any combination thereof."[13] Under this provisions, micro-organisms cannot be excluded from patenting, while animals and essentially biological processes for the production of plants or animals may be excluded. As for plants, a system for the protection of plant varieties "[meaning] a plant grouping within a single botanical taxon of the lowest known rank […],"[14] has to be implemented by member countries.[15] However, the term "plant," as opposed to the expression "plant varieties" probably refers to a grouping larger than a "single botanical taxon." Therefore, it seems as though member countries may exclude groupings larger than a "single botanical taxon" from patentable subject matter. As will be explained in the discussion on the *European Patent Convention*, this line of interpretation is consistent with that given by the Board of Appeal of the European Patent Office.

If brought into national law, the exclusion of plants, animals and of essentially biological processes for the production of plants or animals removes an entire field of research from the realm of patentability. All of the aforesaid subject matter may be the subject of research, but may also be used as research tools free from patent infringement.

Now that the common international framework for exclusions has been outlined in sub-part **i**), sub-parts **ii**) to **v**) will focus on regional agreements containing exclusions in Europe, North America, South America and Eurasia.

ii) Europe

[8] *Agreement on Trade-Related Aspects of Intellectual Property Rights*, 15 April 1994, Annex 1 C of the Marrakesh Agreement Establishing the World Trade Organization article 27 (1) [TRIPS].
[9] *Ibid*.
[10] *Ibid*., article 27 (3) a).
[11] *Ibid*., article 70 (8).
[12] *Ibid*., article 27 (3) b).
[13] *Ibid*.
[14] *International Convention for the Protection of New Varieties of Plants*, 19 March 1991, article 1 (iii) [UPOV 1991].
[15] TRIPS, *supra* note 8 article 27 (3) b).

This sub-part, subpart (ii), will discuss the *European Patent Convention (EPC)*[16] and, to a lesser extent, the *European Biotechnology Directive*,[17] which was meant to increase the competitiveness of European biotechnology research and to clarify certain articles of the *EPC*.

The European Patent Convention

The first *European Patent Convention (EPC),*[18] concluded in 1973, came into force in 1978.[19] This convention was replaced with a revised version[20] that came into force in 2007.[21] Only the revised version will be studied here, as it is the one currently in effect.

The *EPC*[22] institutes the European Patent Organisation and provides an autonomous legal system through which patents are granted in Europe. It defines rules pertaining to the patent-granting process[23] and promotes the adoption of common patent rules by Member States, especially regarding rules of patentability and validity.[24] However, there is no such thing as a European patent, as the granting of patents remains national. National patent laws also prescribe rules related to "[…] matters of infringement, enforcement, revocation, renewal and litigation […]."[25]

Articles 52 and 53 of the *EPC* affect research and experimentation by creating exclusions to what can be patented. Because each article contains several provisions, each with its own exclusion, they will be analyzed individually.

Article 52 (1)

Article 52 (1) of the EPC sets forth the four general requirements for patentability: an invention, novelty, the presence of an inventive step[26] and the potential for industrial application.

Article 52 (2)

Article 52 (2) sets out three types of exclusions relevant to this chapter: namely, the exclusion of "discoveries, scientific theories and mathematical methods," of "schemes, rules and methods for performing mental acts, playing games or doing business" and of "presentations of information." These pertain to "abstract and non-technical" concepts.[27]

[16] *European Patent Convention*, 29 November 2000, [EPC 2000].
[17] *Directive 98/44/EC*, 6 July 1998, [European Biotechnology Directive].
[18] *European Patent Convention*, 5 October 1973, [EPC 1973].
[19] WIPO's Study on Exclusions from Patentable Subject Matter and Exceptions and Limitations to the Rights for Europe, (2010), p. 1 [Unpublished] [European Report].
[20] EPC 2000 *supra* note 16.
[21] *Ibid.*
[22] *Ibid.*
[23] *Ibid.*
[24] European Report *supra* note 19 p. 2.
[25] *Ibid.*
[26] EPC 2000 *supra* note 16 article 52 (1).
[27] European Report *supra* note 19 p. 15.

Discoveries or natural substances are generally deemed not patentable. However, a discovery incorporated into an invention may be patented by putting the discovery to practical use.[28] As for natural substances, they may be patented when they have been "isolated from [their] surroundings [and] properly characterized either by [their] structure, by the processes by which [they are] obtained or by other parameters […]."[29]

The provision proscribing the patenting of "schemes, rules and methods for performing mental acts, playing games or doing business"[30] has been interpreted as forbidding the patenting of "cognitive, conceptual or intellectual processes conducted by the human mind."[31]

The two preceding paragraphs describe two forms of fundamental knowledge that cannot be patented. These exclusions affect researchers because they permit to make use of that knowledge without risk of patent infringement.

Animal Varieties and Plant Varieties - Article 53 (b)

Plants and animals are used by researchers in different circumstances. They may be the object of research or mere tools used to perform research. The exclusion of "plant or animal varieties […]" from patentable subject matter impacts research by eliminating the risk of patent infringement for researchers using them.[32]

The term "plant variety" refers to "individually characterized plants which would have the detailed taxonomy and the reproductive capacity which is required in general for a plant right."[33] More precisely, "the concept of plant variety under article 53(b) refers to any plant grouping with a single botanical taxon [or classification] of the lowest known rank."[34] This definition of plant variety can be explained by the intention of member countries to respect the *International Convention for the Protection of New Varieties of Plants*,[35] which allows them to protect plant varieties either by the patent system or by a separate plant variety protection system. However, the 1961 and 1978 versions of the *Convention* do not allow member countries to give dual protection to plant varieties.[36]

Article 53 (b) can be described as "the borderline between patent and plant variety protection" for countries bound by the versions of this convention prior to 1991.[37] Even though some excluded elements may be subject to breeders' rights, the *International Convention* prescribes some exceptions to these rights that are of interest for researchers, including a research exception.

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[28] *Ibid.*
[29] *Ibid.*, p. 16.
[30] EPC 2000 *supra* note 16 article 52 (2) c).
[31] *Odour Selection/QUEST INTERNATIONAL*, [2007] OJEPO 63, p.72.
[32] EPC 2000 *supra* note 16 article 53 (b).
[33] *Ciba-Geigy/Propagating material application*, T49/83 [1984] *OJEPO* 112, cited in European Report *supra* note 19 p. 22.
[34] *Plant Genetic Systems/Glutamine synthetase inhibitors*, T356/93 [1995] *OJEPO* 545 (TBA), cited in European Report *supra* note 19 p. 22.
[35] UPOV 1991, *supra* note 14; *International Convention for the Protection of New Varieties of Plants*, 3 October 1978 [UPOV 1978]; *International Convention for the Protection of New Varieties of Plants*, 1 December 1961 [UPOV 1961].
[36] UPOV 1978 *supra* note 36 article 2 (1); UPOV 1961 *supra* note 36 article 2 (1); European Report, *supra* note 19 p. 22.
[37] European Report, *supra* note 19 p. 24.

The exclusion of "animal varieties" has been defined by Board of Appeal jurisprudence.[38] The term "variety" refers to a "species or a subunit of a species"[39] (as in the case of plants) and only animals in general which constitute an invention may be patented. For example, the patenting of a specific breed of mice would not be acceptable; however, the patenting of transgenic rodents would.

Finally, one must remember that microbiological processes, along with the products originating from them, continue to be eligible to be patented.[40]

Essentially Biological Processes- Article 53 (b)

Researchers studying or working with biological processes may work, in certain circumstances, without fear of infringing a biological process patent. This exclusion pertains to non-microbiological (1) processes (as opposed to products) (2) for the production of animals or plants (3) that are essentially biological (4).[41]

These cumulative criteria, especially the requirement for the process to be essentially biological, may be considered ambiguous. When does a process cease to be essentially biological? The answer is unclear.[42] The Technical Board of Appeal said that the "drafters […] had deliberately chosen the adverb 'essentially' to replace the narrower term 'purely.'"[43] One could expect that the addition of an insignificant technical step to crossing or breeding procedures would not make a process eligible for protection by a patent. However, even the answer to this question is uncertain. There is currently a pending case on the issue[44] and it is thus difficult to identify the breadth of this exclusion.

Even though this exception is narrow, biological processes for the production of animals and plants are used in research. Hence, this exclusion could potentially impact this type of research.

Health related exclusions - Article 53 (c)

Article 53 (c) provides freedom from infringement for those conducting medical research and experimentation by excluding certain subject matter from the realm of patentability. According to this article, "methods for treatment of the human or animal body by surgery or therapy and diagnostic methods practiced on the human or animal body" are not patentable. This article only excludes methods (1) of medical or veterinary treatment (2) pertaining to surgery, therapy or diagnostic methods (3)[45] which are "practiced on or in the human or animal body" (4).[46]

[38] *Ibid.*, p. 20.
[39] *Ibid.*
[40] European Report, *supra* note 19 article 53 (b).
[41] *Ibid.*, p. 25.
[42] *Ibid.*, p. 26.
[43] *Plant Bioscience/Broccoli*, T83/05 (2007) *OJEPO* 644 discussed in European Report, *supra* note 19 p. 26-27.
[44] European Report *supra* note 19 p. 27.
[45] *Ibid.*, p. 7-8.
[46] *Salminen/Pigs III*, T58/87 (1989) *EPOR* 125 ; *Siemens/Flow measurement* (1989) *EPOR* 241; T254/87 (1989) *OJEPO* 171 discussed in European Report *supra* note 19 p. 12.

The term "surgery" may be defined as a "physical intervention on the human or animal body in which maintaining the life and health of the subject is of paramount importance."[47] More precisely, surgical methods with curative purposes must be distinguished from surgical methods with non-curative purposes, such as cosmetic surgery. While the later are patentable,[48] the former are not.[49]

The term "therapy" can be defined as "the curing of a disease or malfunction of the human or animal body and includes prophylactic treatments with a view to maintaining health by preventing ill effects that would otherwise arise."[50] While the exclusion of therapeutic methods may affect research and experimentation, one should note that methods of treatment to prevent pregnancies have not been considered as being within the scope of the exclusion.[51]

The third "method" category is composed of diagnostic methods. According to the Enlarged Board of Appeal,[52] a diagnostic method has 4 steps:

1. "Examination" - Data collection.
2. "Comparison" - Compare to normal values.
3. "Identification" - Identifying any significant deviation from the norm (i.e. symptoms)."
4. "Diagnosis" - The "'deductive medical or veterinary decision phase' where the diagnosis for curative purposes is made (which represents a purely intellectual or non-technical exercise)."[53] The diagnosis must be "for curative purposes stricto sensu."[54]

It is the patenting of these four steps *together* that is forbidden. The patenting of one, two or three of these steps is not forbidden.[55] Thus, researchers studying or developing diagnostic tests may very well be open to an infringement action by a holder of a patent on one or a few (but not all) of these steps.

Finally, the three previously described methods must be practiced "*on* or *in*"[56] a human or animal body in order to be included in the exclusion prescribed in article 53 (c) of the *EPC*. To satisfy this last requirement, a step in the process must involve interaction with the body.[57] More precisely, in the case of diagnostic methods, the exclusion pertains to "steps of a technical nature," but not to those that are "intellectual exercises."[58] As for therapeutic methods, these fall within the exclusion if they are direct treatments, for instance if "there is a 'corresponding functional link' between the invention and human or animal health."[59] Even if subject matter can be used for purposes other than those within the exclusion, it cannot be patented.[60] Since *in vitro* diagnostic methods are not practiced *on* the human body,[61] these are

[47] *Diagnostic methods*, G 01/04 (2006) *OJEPO* 334 (EBA) cited in European Report *supra* note 19 p. 9.
[48] *General Hospital Corp/Hair removal method*, T 383/03 (2005) *OJEOPO* 159, discussed in European Report *supra* note 19 p. 9.
[49] *Diagnostic methods*, G 01/04 (2006) *OJEPO* 334 (EBA) discussed in European Report *supra* note 25 p. 9.
[50] *Ibid.*, p. 10.
[51] *British Technology Group/Contraceptive Method*, T74/93 [1995] *EPOR* 279 discussed in European Report *supra* note 19 p. 10.
[52] *Diagnostic methods*, G01/04 (2006) *OJEPO* 334 (EBA) discussed in European Report *supra* note 19 p. 11.
[53] European Report *supra* note 19 p. 11.
[54] *Ibid.*, p. 12.
[55] *Ibid.*, p. 11.
[56] *Salminen/Pigs III*, T58/87 [1989] *EPOR* 125; *Siemens/Flow measurement* [1989] *EPOR* 241; T254/87 [1989] *OJEPO* 171 discussed in European Report *supra* note 19 p. 11.
[57] European Report, *supra* note 19 p. 12.
[58] *Diagnostic methods*, G01/04 (2006) *OJEPO* 334 (EBA) discussed in European Report *supra* note 19 p. 13.
[59] *Ela Medical*, T789/96 [2002] *OJEPO* 364 discussed in European Report *supra* note 19 p. 13.
[60] European Report *supra* note 19 p. 13.

not considered as the type of diagnostic methods excluded by the EPC and thus may be patented.

European Biotechnology Directive

The *European Directive on the legal protection of biotechnological inventions* (the "*Directive*") was adopted by the European Parliament and Council for the purpose of harmonizing the laws of Member States as they relate to the patentability of biotechnological inventions. In effect, the Directive serves to clarify the nature and scope of exclusions prescribed in the *European Patent Convention.* In has now been translating into the national law of all Member States of the European Union as well as having been adopted, as a regulation, by the member states of the EPC through the *Implementing Regulations of the European Patent Convention.*[62]

The patenting of biotechnological inventions is furthered by the *Directive* and the *Implementing Regulations*. They require their respective member states to protect biotechnological inventions, as long as doing so does not violate *TRIPS* and the *Convention on Biodiversity.*[63] Article 3 of the *Directive* allows the patenting of inventions containing or consisting of biological material. Article 5 allows the use of isolation or of a technical process as a means of patenting human biological material originating from humans. Article 8 extends the protection conferred to biological material by a patent to material derived from that original material or, in the case of a process patent, to what is produced through that process. Article 9 extends the protection of a product including genetic information to "all material, save as provided in Article 5(1), in which the product is incorporated and in which the genetic information is contained and performs its function."

In addition to these provisions, the *Directive* contains certain exclusions from patentability. Article 4 reaffirms the exclusion of animal and plant varieties from the realm of patentability. Article 5(1) forbids the patenting of the human body at all stages of development. In addition, for a gene patent to satisfy the industrial application requirement, the "sequence or a partial sequence of [the] gene must be disclosed in the patent application."[64] Moreover, the extension of protection by articles 8 and 9 does not extend "to biological material obtained from the propagation or multiplication of biological material," when the biological material has been placed on the market by the patent owner, in a member state or, when the biological material is marketed for purposes of propagation or multiplication, as long as it "is not subsequently used for other propagation or multiplication."[65] Finally, article 6(2) prescribes that the following shall be deemed unpatentable:

(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;

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[61] Su-hua Lee, "Patent Protection for Essential Biomedical Inventions and Its Impacts on the Implementation of Public Health" (2010) 5 AJWH 115; Isabelle Huys, Nele Berthels, Gert Matthijs & Geertrui Van Overwalle, "Legal Uncertainty in the Area of Genetic Diagnostic Testing" (2009) 27:10 Nature Biotechnology 903.
[62] European Report, *supra* note 19 p. 18.
[63] European Biotechnology Directive *supra* note 17 article 1.
[64] *Ibid.*, article 5(3).
[65] *Ibid.*, article 10.

> (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.

Since some of these processes and resulting products are used in several medical research fields including stem cell research, their exclusion from patentability thus offers European researchers with freedom from potential patent infringement as compared to researchers in countries in which they are patentable.

It is important to note that the *Directive* (and hence the *Implementing Regulation*) states that a "[process] for the production of [a plant or an animal] is essentially biological if it consists entirely of natural phenomena such as crossing or selection."[66] This clarifies the exclusion of article 53(b) of the *EPC*, according to which processes that are essentially biological are not patentable. The ambiguity of the term "essentially" is discussed in the section on the *European Patent Convention* and this article clarifies the legislator's intent.

iii) North America

The *North American Free Trade Agreement* (*NAFTA*) is a multilateral agreement between Canada, Mexico and the United States that was concluded in 1994. It creates a trilateral free trade bloc and regulates different aspects of trade between them. With respect to intellectual property rights, its objective is to "provide adequate and effective protection and enforcement of intellectual property rights in each Party's territory."[67] The exclusions provided for by *NAFTA* are consistent with those in *TRIPS*.

Two optional provisions pertaining to exclusions may affect research. First, parties may implement measures in their national law to prevent abuse of intellectual property rights or anticompetitive measures.[68] Second, according to article 1709, member countries may exclude from patentability certain subject matter, including:

> (a) diagnostic, therapeutic and surgical methods for the treatment of humans or animals;
> (b) plants and animals other than microorganisms; and
> (c) essentially biological processes for the production of plants or animals, other than non-biological and microbiological processes for such production.[69]

However, if a member does not provide patent protection for plants, it must provide protection through a *sui generis* system.[70] Hence, one may conclude that *NAFTA* allows member countries to adopt certain exclusions that may provide freedom to conduct research without infringing. However, it should be noted that these exclusions are not mandatory.

[66] European Biotechnology Directive *supra* note 17 article 2.
[67] *North American Free Trade Agreement, Canada, Mexico and the United States of America*, 17 December 1992, article 102 [NAFTA].
[68] *Ibid.*, article 1704.
[69] *Ibid.*, article 1709 (3).
[70] *Ibid.*, article 1709 (3).

iv) South America

Mercosur

Mercosur is a regional trade agreement concluded in 1991 between Argentina, Brazil, Paraguay and Uruguay by the *Treaty of Asunciòn* and updated in 1994 by the *Treaty of Ouro Preto*. Its goal is to integrate the economies of these four countries by facilitating the free movement of goods, people and currency.[71] Bolivia, Colombia, Ecuador and Peru also have associate member status. Venezuela has signed a membership agreement. However, its entry has yet to be ratified by the Paraguayan parliament. Several agreements have been concluded in connection with Mercosur,[72] including the *Protocol of Harmonization of Intellectual Property Norms*.[73] However, this protocol does not cover patents.[74] Rather, it covers trademarks and geographical indications.[75] Other agreements on intellectual property rights have been concluded, including some pertaining to plant varieties, but no explicit mention of exclusions pertaining to research has been found.[76]

The Andean Community of Nations

The *Andean Community of Nations* (hereinafter: "*Andean Community*") is a trade bloc consisting of Bolivia, Colombia, Ecuador and Peru. It provides general IP rules for these countries.[77] Founded in 1969 by the *Cartagena Agreement*, the *Andean Community* was referred to as the *Andean Pact* until 1996.

The *Andean Agreements* (hereinafter: "*Decisions*") of the *Andean Community* prevail over national laws.[78] However, national laws can provide additional protection to intellectual property in addition to that provided in the *Decisions*.[79] Some of these *Decisions* contain exclusions that may affect research.

A common intellectual property regime has been adopted.[80] As were the cases of *NAFTA* and the *European Patent Convention*, inventions deemed patentable are new, involve an inventive step and are industrially applicable[81].

Article 15 of *Decision 486* negatively defines an invention by proscribing the patenting of:

a) discoveries, scientific theories, and mathematical methods;

[71] Laurenda L. Hicks & James R. Holbein, "Convergence of National Intellectual Property Norms in International Trading Agreements", 12 Am. U. J. Int'l L. & Pol'y 769, 1997, p. 801 [Laurenda L. Hicks & James R. Holbein, "Convergence of National Intellectual Property Norms in International Trading Agreements"].
[72] Denis Boges Barbarosa & Karin Grau-Kuntz, *WIPO's Study on Exclusions from Patentable Subject Matter and Exceptions and Limitation of the Rights for South America*, p. 5 [unpublished][South American Report].
[73] Laurenda L. Hicks & James R. Holbein, "Convergence of National Intellectual Property Norms in International Trading Agreements", *supra* note 72 p. 812.
[74] *Ibid.*, p. 812.
[75] *Ibid.*, p. 807.
[76] South American Report, *supra* note 73 p. 5.
[77] *Ibid.*, p. 15.
[78] *Ibid*.
[79] *Decision 689*, 3 August 2008 [*Decision 689*]; *South American Report*, *supra* note 73 p. 15.
[80] *Decision 486 Common Intellectual Property Regime*, 14 September 2000, art. 14 [Decision 486].
[81] *Ibid*.

b) any living thing, either complete or partial, as found in nature, natural biological processes, and biological material, as existing in nature, or able to be separated, including the genome or germ plasm of any living thing;
c) literary and artistic works or any other aesthetic creation protected by copyright;
d) plans, rules, and methods for the pursuit of intellectual activities, playing of games, or economic and business activities;
e) computer programs and software, as such; and,
f) methods for presenting information.[82]

Hence, a number of exclusions that provide freedom to conduct research without a license are imbedded in the very definition of "invention".

v) Eurasia

Eurasian Patent Convention
This convention on patents was signed in 1994. Its members include the Republic of Azerbaijan, the Republic of Armenia, the Republic of Belarus, Georgia, the Republic of Kazakhstan, the Kyrgyz Republic, the Republic of Moldova, the Russian Federation, the Republic of Tajikistan and Turkmenistan[83]. As in previously described conventions, patentable inventions must be new, involve and inventive step and be industrially applicable[84].

What may not be considered as an invention is set out in rule 3 (3):
"— discoveries;
— scientific theories and mathematical methods;
— presentation of information;
— methods of economic organization and management;
— symbols, schedules and rules;
— methods for performing mental acts;
— algorithms and computer programs;
— topographies of integrated circuits;
— projects and plans for structures and buildings and for land development;
— solutions concerning solely the outward appearance of manufactured goods and aimed at satisfying aesthetic requirements."

Fundamental knowledge is, therefore, precluded from being patented.

[82] *Ibid.*
[83] Eurasian Patent Organization, available online: http://www.eapo.org/eng/ea/about/members.html.
[84] Eurasian Patent Convention, September 9 1994, art. 6.

B. Exclusions Affecting Research

i) Tables comparing exclusions affecting research (national level)

These tables compare exclusions impacting research in national statutory laws and case law in selected countries. The tables include the name of countries, the existence of general or specific exclusions (e.g.: one cannot patent basic scientific principles, methods of medical treatments or mathematical methods) and the effect of patentability requirements.

Europe

	Europe
Patentability requirements	In the case of the *European Patent Convention*, innovations or discoveries are first required to be an invention before satisfying the other three patentability requirements. Indeed, "European patents shall be granted for any inventions […] provided that they are new, involve an inventive step and are susceptible of industrial application" (EPC, art. 52 (1).). The European Technical Board of Appeal concurred with this view by declaring that "[a]rticle 52(1) EPC sets out four requirements to be fulfilled by a patentable invention: there must be an invention, and if there is an invention, it must satisfy the requirements of novelty, inventive step, and industrial applicability." (Duns Licensing Associates, T 154/04 [2002] *OJEPO* 46) In other words, after identifying the four requirements for patentability in article 52 (1), the *European Patent Convention* identifies what does not constitute an *invention* in art. 52 (2). Hence, "discoveries, scientific theories and mathematical methods" as well as "schemes, rules and methods for performing mental acts, playing games or doing business, and programs for computers" are not invention and, incidentally, patentable. (EPC, art. 52 (2)). More precisely, even though elements listed in art. 52 (2) are not patentable *per se*, "paragraph 3 [of art. 52] actually enshrined the entitlement to patent protection for the non-inventions enumerated in paragraph 2 - albeit restricting the entitlement by excluding patentability "to the extent to which the European patent application or European patent relates to such subject matter or activities as such"."(Duns Licensing Associates, T 154/04 [2002] *OJEPO* 46) Hence, the elements of art. 52 (2) are protected only for their application to the patented subject matter or activities.
Specific exclusions	*Article 52 (2)* Article 52 *EPC* excludes "discoveries, scientific theories and mathematical methods… schemes, rules and methods for performing mental acts, playing games or doing business… [and] presentations of information" from the realm of patentability (article 52 (2) *EPC*). As all of these elements may be subject to academic inquiry, their exclusion from the realm of patentability may prevent accidental infringement by researchers. *Animal Varieties and Plant Varieties - Article 53 (b)* Plants and animals are used by researchers in different circumstances. They may be the object of research or the tools used to conduct research. The exclusion of "plant or animal varieties […]" from subject matter eligible for patenting is of interest because it eliminates some risks of infringement for researchers. (*EPC* article 53 (b)) Plants and animal varieties may not be protected by a patent. In the case of animal varieties, it is difficult to explain why they may not be patented. However, in the case of plants, this exclusion necessarily exists in countries that are bound by the *International Convention for the Protection of New Varieties of Plants* of 1978 or 1961. However, plants and animals in general are considered patentable. For more information, please see section on the *European Patent Convention*. *Essentially Biological Processes- Article 53 (b)* Researchers studying or working with biological processes may work, in certain circumstances, without fear of infringing a biological process patent. This exclusion pertains to non microbiological (1) processes

	(as opposed to products) (2) for the production of animals or plants (3) that are essentially biological (4). For more information, please see section on the *European Patent Convention*. *Health related exclusions - Article 53 (c)* Article 53 c) excludes medical or veterinary methods and experimentation. According to this article, methods (1) of medical or veterinary treatment (2) pertaining to surgery, therapy or diagnostic methods (3) "practiced on or in the human or animal body" (4) are excluded. When researchers use these methods, they cannot infringe a patent. For more information, please see the section on the *European Patent Convention*. *European Biotechnology Directive* This directive – which only applies to certain of the member states of the EPC – clarifies some ambiguities in the *European Patent Convention*. For more information, please see the section dealing with that convention.

	United Kingdom
Patentability requirements	The provisions of this act are based on the *European Patent Convention* and should be interpreted according to "the EPC and decisions there under." (*Patents Act 1977* (U.K.), 1977, c. 37, s. 91 (1), 130 (7), [*UK Patent Act*]discussed in European Report, *supra* note 19, p. 4) UK courts have acknowledged this fact and the European Patent Office EPO "has occasionally reciprocated by taking notice of the decisions of national offices and courts so as to avoid the lack of uniformity in the law of the EPC countries." (European Report *supra* note 19 p. 4.) "For example, Lord Justice Mustill of the England and Wales Court of Appeal observed in the judgment in re Genentech Inc.'s Patent [1989] R.P.C. 147, pages 262 f.: "This suggestion of a need to identify the invention leads me to a part of the case which I have found most perplexing. Most of the arguments have been concentrated on the three conditions precedent to the grant of a patent set out in paragraphs (a) to (c) of section 1(1) -- and understandably so, given the shape of the old law. But this approach tends to mask a more fundamental requirement which must be satisfied before a patent can be properly be granted, namely that the applicant has made an "invention"." (re Genentech Inc.'s Patent [1989] R.P.C. 147 cited in Duns Licensing Associates, T 154/04 [2008] *OJEPO* 46)
Specific exclusions	From reading the *UK Patents Act 1977*, it appears that exclusions are the same as those in the *European Patent Convention*. For exclusions of article 52 *EPC*, see s. 1 (2) *UK Patents* Act. For animal varieties and plant varieties – article 53 (b) *EPC*, see Schedule A2 s. 4 *UK Patents Act*. For health related exclusions – article 53 (c) *EPC*, see s. 4 A *UK Patents Act*.

North America

	Canada
Specific exclusions	**Theoretical/Scientific principles:** Not patentable according to s. 27(8) of the *Patent Act.* **Methods of medical and surgical treatment:** Methods of medical and surgical treatments are not patentable. As these are objects of research, this rule obviates what would otherwise be the problem of patent infringement by medical researchers. *Industries Ltd. v. Commissioner of Patents*, [1986] 3 F.C. 40 & *Tennessee Eastman Co. v. Commissioner of Patents*, [1974] S.C.R. 111 discussed in Canadian Intellectual Property Office, *Manual of Patent Office Practice*, chapter 17.02.03. **Biotechnology –Life Forms:** Biotechnological inventions can be protected through the Canadian patent system. For instance, unicellular micro-organisms and the processes to produce them are patentable. (*Re Application of Abitibi Co*. [1982], 62 C.P.R. (2d) 81)Moreover, genes are patentable because they are considered to be chemical compounds and claims covering them extend to the entire organism. (*Monsanto Canada Inc. v. Schmeiser* [2004], 1 S.C.R. 34) However, whole plants and animals do not constitute patentable subject-matter. This does not affect the patentability of components of whole plants or animals and does not limit the scope of claims over those components to less than the whole plant or animal. Thus, while whole plants and animals cannot be

	patented *de jure*, they can be patented *de facto* through claims over incorporated genes or cells. (*Monsanto Canada Inc. v. Schmeiser* [2004], 1 S.C.R. 34; *Harvard College v. Canada* (Commissioner of Patents) [2002], 4 S.C.R. 45.) Therefore, when a patent is not inserted into an animal or a plant, it cannot be covered by patent rights. In this regard, Canadian patent law ensures freedom from infringement for researchers working with non-modified plants or animal. **Methods:** "Advances in the concepts" of non-technological fields, "[m]ethods for influencing human interactions or behaviours" and methods of avoiding or reducing income tax are not patentable. (Canadian Intellectual Property Office, *Manual of Patent Office Practice*, Chapter 12.04.02). This prevents the infringement of patents by researchers performing fundamental research.

	Mexico
Patentability requirements	Article 16 *Industrial Property Law of Mexico* says that only inventions are patentable. To see what does not constitute an invention, please see art. 19 *Industrial Property Law of Mexico* (discussed below).
Specific exclusions	**Theoretical/Scientific principles:** "Theoretical or scientific principles […] [f]indings that consist in making public or disclosing something that already existed in nature, even though it was previously unknown to man […] [d]iagrams, plans, rules and methods for carrying out mental processes, playing games or doing business, and mathematical methods" are not patentable (article 19 *Industrial Property Law of Mexico*). As all of these are subject to research enquiry, they may help prevent the infringement of patents by researchers. **Methods of treatment**: "Surgical and therapeutic treatment or diagnostic methods applicable to the human body and to animals" are not patentable (article 19 *Industrial Property Law of Mexico*). Thus, the use of these elements in research cannot be prevented by a patent. **Human body:** "The human body and the living matter constituting it" cannot be patented. This provision prevents the patenting of elements that are often subject to scientific enquiry and thereby procures some research freedom for the biomedical research community. (article 16 *Industrial Property Law of Mexico*) **Biotechnology:** "Biological and genetic material as found in nature" are not patentable. This provision also prevents the patenting of elements often subject to scientific enquiry may affect research. This includes naturally occurring DNA and proteins (article 16 *Industrial Property Law of Mexico*). **Life Forms:** Animal breeds & plant varieties are not patentable. Plant varieties are, however, protected by the *Federal Law on Plant Varieties* which has an experimental exemption stipulating that protected plant varieties used "as source or research material for the genetic improvement of other plant varieties" do not constitute infringement (article 5 *Federal Law on Plant Varieties*).

	United States
Patentability requirements	Much fundamental knowledge has always been considered as not patentable inventions but the distinction between fundamental knowledge and applied knowledge is not always clear as the following cases illustrate: *Mackay v. Radio Corp.*, 306 U.S. 86 (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." *Gottschalk v. Benson*, 409 U.S. 63 (1972): "Phenomena of nature, though just discovered, mental processes, and abstract intellectual concepts are not patentable, as they are the basic tools of scientific and technological work. As we stated in *Funk Bros. Seed Co*. v. *Kalo Co*., 333 U.S. 127, 130, "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." *Bilski v. Kappos*, 561 U. S. ____ (2010): "The Court's precedents provide three specific exceptions to §101's broad patent-eligibility principles: "laws of nature, physical phenomena, and abstract ideas." ... While these exceptions are not required by the statutory text, they are consistent with thenotion that a

	patentable process must be "new and useful." In addition, much fundamental knowledge cannot be patented because of the difficulty in fulfilling the separate description requirement of 35 U.S.C. 112. Indeed, as described in *Ariad Pharms., Inc. v. Eli Lilly & Co.*, 598 F. 3d 1336 (C.A. Fed., 2010), " [t]he written description requirement also ensures that when a patent claims a genus by its function or result, the specification recites sufficient materials to accomplish that function – a problem that is particularly acute in the biological arts. […] Ariad complains that the doctrine [(for a separate description requirement)] disadvantages universities to the extent that basic research cannot be patented. But the patent law has always been directed to the "useful Arts," U.S. Const. art. I, § 8, cl. 8, meaning inventions with a practical use, *see Brenner v. Manson*, 383 U.S. 519, 532-36, 86 S. Ct. 1033, 16 L. Ed. 2d 69, 1966 Dec. Comm'r Pat. 74 (1966). Much university research relates to basic research, including research into scientific principles and mechanisms of action, *see, e.g., Rochester*, 358 F.3d 916, and universities may not have the resources or inclination to work out the practical implications of all such research, *i.e.*, finding and identifying compounds able to affect the mechanism discovered. That is no failure of the law's interpretation, but its intention. Patents are not awarded for academic theories, no matter how groundbreaking or necessary to the later patentable inventions of others. '[A] patent is not a hunting license. It is not a reward for the search, but compensation for its successful conclusion.' ... Requiring a written description of the invention limits patent protection to those who actually perform the difficult work of "invention"--that is, conceive of the complete and final invention with all its claimed limitations--and disclose the fruits of that effort to the public."
Specific exclusions	**Biotechnology:** Genes and microorganisms are patentable as long as they possess utility (*Diamond* v. *Chakrabarty*, 447 U.S. 303 (1980), *In re Fisher*, No. 04-1465 (Fed.Cir. September 7, 2005)), unless they were obvious to try (*In Re Kubin No. 09-667,859* (Fed. Cir. April 3, 2009)). However, in *Association for Molecular Pathology et al. v. United States Patent and Trademark et al.*, the District Court for the Southern District of New York held that isolated human genes were not patentable subject matter since they were phenomena of nature. In arriving at this decision, the Court held that genes have both a physical and informational quality: "DNA represents the physical embodiment of biological information, distinct in its essential characteristics from any other chemical found in nature . . . [its] existence in an 'isolated' form alters neither this fundamental quality of DNA as it exists in the body nor the information it encodes." The District Court's decision could be overturned on appeal to the United States Court of Appeals for the Federal Circuit. **Life Forms:** The United States Patent and Trademark Office (USPTO) "now consider[s] non-naturally occurring, nonhuman multicellular living organisms, including animals, to be patentable subject matter within the scope of 35 U.S.C. 101": United States Patent and Trademark Office, *Manual of Patent Application Procedure*, s. 2105.

South America

	Argentina
Patentability requirements	**Patentability**: Inventions relating to products or processes shall be patentable provided that they are new, involve an inventive step and are susceptible of industrial application. (article 4, *Law 24.481*). What is not considered to be an *invention*: See specific exclusions of article 6, *Law 24.481*.
Specific exclusions	**Theoretical/Scientific principles:** Argentina's patent law does not consider "discoveries, scientific theories and mathematical methods" to be patentable (article 6, *Law 24.481*). **Scientific literature:** Argentina's patent law does not consider "scientific works" to be patentable (article 6, *Law 24.481*). **Intellectual activities – Data presentation:** Argentina's patent law does not consider "schemes, rules or methods for performing intellectual activities, playing games or engaging in economic and business activities; […] forms of data presentation" to be patentable (article 6, *Law 24.481*). **Methods of treatment:** Argentina's patent law does not consider "methods of surgical, therapeutic or diagnostic treatment applicable to the human body or to animals" to be patentable (article 6, *Law 24.481*).

	Living material: Argentina's patent law does not consider "any kind of live material or substances already existing in nature" to be patentable (article 6, *Law 24.481*). **Biological processes:** Argentina's patent law does not consider "biological and genetic material existing in nature or derived therefrom in biological processes associated with animal, plant and human reproduction, including genetic processes applied to the said material that are capable of bringing about the normal, free duplication thereof in the same way as in nature," to be patentable (article 7, *Law 24.481*).

	Brazil
Patentability requirements	**Patentability**: "An invention is patentable if it satisfies the requirements of novelty, inventive step, and industrial application." (article 8 of *Brazilian Industrial Property Law*). What is not considered to be an *invention*: see specific exclusions (art. 10 of Brazilian Industrial Property Law).
Specific exclusions	**Theoretical/Scientific principles:** According to Brazilian law, "discoveries, scientific theories, and mathematical methods" are not patentable (article 10 of *Brazilian Industrial Property Law*). **Scientific literature:** According to Brazilian law, "scientific works" are not patentable (article 10 of *Brazilian Industrial Property Law*). **Intellectual activities:** According to Brazilian law, "purely abstract conceptions […] [,] commercial, accounting, financial, educational, advertising, raffling, and inspection schemes, plans, principles or methods […] [,] presentation of information […] [,] rules of games" are not patentable (article 10 of *Brazilian Industrial Property Law*). **Methods of treatment:** According to Brazilian law, "surgical techniques and methods, as well as therapeutic or diagnostic methods, for application to human or animal body" are not patentable (article 10 of *Brazilian Industrial Property Law*). **Living material - Biological processes:** According to Brazilian law, "all or part of natural living beings and biological materials found in nature, even if isolated therefrom, including the genome or germoplasm of any natural living being, and the natural biological processes" are not patentable (article 10 of *Brazilian Industrial Property Law*). **Atomic nucleus:** According to Brazilian law, "substances, materials, mixtures, elements or products of any kind, as well as the modification of their physical- chemical properties and the respective processes for obtainment or modification, when resulting from the transformation of the atomic nucleus" are not patentable (article 18 of *Brazilian Industrial Property Law*). **Life forms:** According to Brazilian law, "all or part of living beings, except transgenic microorganisms that satisfy the three requirements of patentability" are not patentable (article 18 of *Brazilian Industrial Property Law*). "For the purposes of this Law, transgenic microorganisms are organisms, except for all or part of plants or animals, that express, by means of direct human intervention in their genetic composition, a characteristic normally not attainable by the species under natural conditions." (article 18 of *Brazilian Industrial Property Law*).

	Chile
Specific exclusions	**Theoretical/Scientific principles:** According to article 37 of *Law N^{o} 19.039*, "discoveries or other abstract knowledge" are not patentable (South American Report, *supra* note 72, p. 22). **Intellectual activities:** According to article 37 of *Law N^{o} 19.039*, "useful but non-technical creations as business methods and rules of games" are not patentable (South American Report, *supra* note 72, p. 22). **Methods of treatment:** According to article 37 of *Law N^{o} 19.039*, "surgical, diagnostic or therapeutic methods and for human or animal body" are not patentable (South American Report, *supra* note 72 p. 22). However, this does not include "products intended to implement those methods," which are patentable (South American Report, *supra* note 72 p. 23). **Living material - Biological processes – Life forms:** According to article 37 of *Law N^{o} 19.039*, "plants and animals and essentially biological processes for the production of plants and animal […] [,] parts of living beings as found in nature, natural biological processes and biological material found in nature even though isolated therefrom, including genome or germoplasm" are not patentable (South American Report, *supra* note 72 p. 22 – 23). **Juxtaposition - New uses for known products:** According to article 37 of *Law N^{o} 19.039*, "the new applications or formal changes introduced in known products" are not patentable (South American Report, *supra* note 72 p. 23). However, if a "new application of a known product solves a technical problem not hitherto solved on a (sic) equivalent manner, and furthermore, it is required to proceed formal changes or changes in material of the known product to solve such technical problem," then it is patentable. (South American Report, *supra* note 72 p. 23).

	Andean Community
Patentability requirements	This regime applies to Bolivia, Colombia, Ecuador and Peru. **Patentability**: The Member Countries shall grant patents for inventions, whether goods or processes, in all areas of technology, that are new, involve an inventive step, and are industrially applicable (*Decision 486* art. 14). For what does not constitute an *invention*, please see art. 15 (specific exclusions).
Specific exclusions	Article 15 of *Decision 486* defines what an invention is. **Theoretical/Scientific principles:** According to article 15 of *Decision 486* "discoveries, scientific theories, and mathematical methods" are not patentable. **Intellectual activities – Data presentation:** According to article 15 of *Decision 486* "plans, rules, and methods for the pursuit of intellectual activities, playing of games, or economic and business activities […] [and] methods for presenting information " are not patentable. **Living material - Biological processes - Life form:** According to article 15 of *Decision 486* "[a]ny living thing, either complete or partial, as found in nature, natural biological processes, and biological material, as existing in nature, or able to be separated, including the genome or germplasm of any living thing" are not patentable. **Juxtaposition and method of treatment:** "Plants, animals, and essentially biological processes for the production of plants or animals other than non-biological or microbiological processes [,] diagnostic, therapeutic, and surgical methods for the treatment of humans or animals" (*Decision 486* article 20) and new uses of already existing inventions cannot be patented (*Decision 486* article 21). **Bolivia**: Bolivia forbids the patenting of "chemical products or pharmaceutical or therapeutic compositions" (South American Report, *supra* note 72p. 20). However, if we take into account *Decision 486*, this exclusion does not seem to be in effect. (South American Report, *supra* note 72, p. 20).

Asia

	China
Specific exclusions	**Theoretical/Scientific principles:** According to article 25 (*Patent Law*), "scientific discoveries" are not patentable. **Intellectual activities:** According to article 25 (*Patent Law*), "rules and methods for mental activities" are not patentable. **Methods of treatment:** According to article 25 (*Patent Law*), "methods for the diagnosis or for the treatment of diseases" are not patentable. **Life form:** According to article 25 (*Patent Law*), "animal and plant varieties" are not patentable. However, processes producing animal and plant varieties are patentable.

	India
Patentability requirements	" (j) "invention" means any new and useful— (i) art, process, method or manner of manufacture; (ii) machine, apparatus or other article; (iii) substance produced by manufacture" s. 2 Patent Act For what does not constitute an invention, please see specific exclusions hereunder.
Specific exclusions	**Theoretical/Scientific principles:** According to s. 3(c) (*Patent Act*), "the mere discovery of a scientific principle or the formulation of an abstract theory or discovery of any living thing or non-living substances occurring in nature" is not patentable. **Known substance with new properties:** S. 3(d) (*Patent Act*): "[T]he mere discovery of a new form of a substance which does not result in the enhancement of a known efficacy of that substance or the mere discovery of a new property or new use of a known process, machine or apparatus unless such known process results in a new product or employs at least one new reactant [are not patentable]. Explanation: For the purpose of this clause, salts, esters, ethers, polymorphs, metabolites, pure form, particle size, isomers mixtures of isomers, complexes, combinations and other derivatives of known substance shall be considered to be the same substance, unless they differ significantly in properties with regard to efficacy." S. 3(e) (*Patent Act*): "[A] substance obtained by a mere admixture resulting only in the aggregation of the properties of the components thereof or a process for producing such substance" is not patentable. These paragraphs set minimal standards for the novelty criteria when an invention pertains to known substances. **Methods for Agriculture:** S. 3(g) (*Patent Act*): "A method of agriculture or horticulture" is not patentable. **Intellectual activities:** S. 3(j,l,m) (*Patent Act*): "[A] mathematical or business method or a computer program per se or algorithms […] a mere scheme or rule or method of performing mental act or method of playing game[…] a presentation of information" are all unpatentable. **Method of Treatment:** S. 3(h) (*Patent Act*): "[A]ny process for the medicinal, surgical, curative, prophylactic, diagnostic, therapeutic or other treatment of human beings or any process for a similar treatment of animals to render them free of disease or to increase their economic value or that of their products" are not unpatentable. **Living material - Biological processes - Life form:** S. 3(i) (*Patent Act*): "[P]lants and animals in whole or any part thereof other than micro-organisms but including seeds, varieties and species and essentially biological processes for production or propagation of plants and animals" are not patentable.

	Indonesia
Specific exclusions	**Theoretical/Scientific principles - Intellectual activities:** According to article 7 (c) *Law on Patents*, "any theory and method in the field of science and mathematics" is not patentable. **Method of Treatment:** According to article 7 (b) *Law on Patents*, "any method of examination, treatment, medication, and/or surgery applied to humans and/or animals" is not patentable. **Biological processes - Life form:** According to article 7 (d) *Law on Patents*, "all living creatures, except micro-organism […] any biological process which is essential in producing plant or animal, except non-biological process or microbiological process" are not patentable.

	Japan
Patentability requirements	**Patentability**: ""Inventions" in this Law means the highly advanced creation of technical ideas utilizing the laws of nature." Art. 2 Japan Patent Act. According to art. 29 Japan Patent Act, only an invention may be patented. As explained in the *Examination Guidelines for Patent and Utility Model in Japan* – Japan Patent Office - Part II – Chapter 1, the legal wording used in article 2 of the Japan Patent Act implicitly excludes the patenting of laws of nature, mere discoveries, non technical ideas, solutions of problems impossible to solve, innovations that do not rely on the laws of nature and innovations that are contrary to the laws of nature. Hence, fundamental knowledge is not patentable according to art. 2 of the Japan Patent Act.
Specific exclusions	None

	Pakistan
Patentability requirements	An invention is defined as "any new and useful product, including chemical products, art, process, method or manner of manufacture machine, apparatus or other article; substances or article or product produced by a manufacture and includes any new and useful improvement of any of them and an alleged invention." Article 2 , *Patents Ordinance*. What shall be deemed not being an *invention* is prescribed at art. 7 of the *Patent Ordinance*.
Specific exclusions	**Theoretical/Scientific principles:** According to article 7 (2) (a) *Patents Ordinance*, "a discovery, scientific theory or mathematical method" is not patentable. **Intellectual activities:** According to article 7 (2) (c) & (d) *Patents Ordinance*, "a scheme, rule or method for performing a mental act, playing a game or doing business […][or a] presentation of information" is not patentable. **Method of Treatment:** A patent may not be granted "for diagnostic therapeutic and surgical methods for the treatment of humans or animals" (article 7(4)(a) *Patents Ordinance*). **Living material - Biological processes - Life form:** A patent may not be granted "for animals or plants other than micro-organisms and essentially biological process for the production of animals or plants, but this prohibition shall not apply to microbiological processes or products of such processes" (article 7 (4) (b) *Patents Ordinance*).

	Republic of Korea
Patentability requirements	**Patentability**: "The definitions of terms used in this Act are as follows: (i) "invention" means the highly advanced creation of a technical idea using the rules of nature". Art. 2, *Patent Act of The Republic of Kore*a. According to article 29, only an invention may be patentable. Elements that are considered as a inventions because of article 2 of the *Patent Act* comprise laws of nature, mere discoveries, innovations contrary to the laws of nature, innovations that do not use laws of nature, personal skills, information presentation, aesthetic creations, incomplete inventions, etc. (Korean Intellectual Property Office, *Requirements for patentability*, January 2010, p. 2 – 4).
Specific exclusions	None

ii) Common Aspects and Distinctions

This section will identify the commonalities and trends in national patent laws pertaining to exclusions having an effect on research. The commonalities, distinctions and policy underpinnings of specific exclusions will be described first, followed by an analysis on patentability requirements.

Specific exclusions
Most jurisdictions have carved out specific exclusions from patentable subject matter. This section will discuss the effect that specific exclusions may have on scientific research.

I. Fundamental/Scientific principles: In most countries, scientific and fundamental principles, along with laws of nature, are explicitly excluded from patentability. This is the case for members of the *European Patent Convention*, Canada, Mexico, Argentina, Brazil, Chile, members of the Andean Community, India, Indonesia and Pakistan.[85] However, the United States, Japan and Korea have not enshrined this exclusion in an explicit provision although case law in the United States supports this exclusion.

II. Scientific literature: The specific exclusion for scientific literature, present in Argentina and Brazil,[86] is a logical consequence of the exclusion of fundamental and scientific principles.

[85] EPC 2000, *supra* note 16, art. 52 (2); Patent Act, s. 27 (8); Industrial Property Law of Mexico, article 19 ; Law 24.481of Argentina, article 6; Brazilian Industrial Property Law, article 10; Law N° 19.039 of Chile, article 37; Decision 486, article 15; Patent Law of the People's Republic of China, article 25; Patent Act of India, s. (3)(d); Law on Patents of Indonesia, article 7 c); Patents Ordinance No. LXI, s. 7(2) a) (Pakistan).
[86] Law 24.481of Argentina, article 6 ; Brazilian Industrial Property Law, article 10.

III. Intellectual Activities: Abstract concepts, intellectual activities, game playing are not patentable in many countries.[87]

These three types of provisions (I., II. and III.) exclude fundamental knowledge from patentability.

IV. Methods of medical and surgical treatment: the vast majority of countries have an exception for methods of medical and surgical treatment.[88] Countries that do not have similar exclusion are the United-States, Japan and the Republic of Korea.

The United States provides medical practitioners and their institutions with immunity from patent infringement in "the performance of a medical or surgical procedure on a body." [89] This immunity does not apply, however, with respect to "(i) the use of a patented machine, manufacture, or composition of matter in violation of such patent, (ii) the practice of a patented use of a composition of matter in violation of such patent, or (iii) the practice of a process in violation of a biotechnology patent."[90]

In Korea, methods of medical and surgical treatment are considered *not* to be industrially applicable,[91] except if their application is limited to animals.[92] In the case of Japan, methods of medical and surgical treatment are also considered *not* to be industrially applicable.[93]

Finally, the purpose of this exclusion varies amongst jurisdictions. Some countries may have created this exclusion in order to "ensure that people who carry out medical or veterinary treatments are not inhibited by patents."[94] For other countries, the justification may be public order.[95]

[87] Canadian Intellectual Property Office, Manual of Patent Office Practice, Chapter 12.04.02.; Law 24.481of Argentina, article 6; Brazilian Industrial Property Law, article 10; Law N° 19.039 of Chile, article 37; Decision 486, article 15; Patent Act of India, s. (3)(j,l,m).
[88] EPC 2000, *supra* note 16 art. 53 (c); *Industries Ltd. v. Commissioner of Patents,* [1986] 3 F.C. 40 & *Tennessee Eastman Co. v. Commissioner of Patents*, [1974] S.C.R. 111 discussed in Canadian Intellectual Property Office, *Manual of Patent Office Practice*, Chapter 17.02.03; Industrial Property Law of Mexico, article 19; Law 24.481of Argentina, article 6; Brazilian Industrial Property Law, article 10; Law N° 19.039 of Chile, article 37; Decision 486, article 20; Patent Law of the People's Republic of China, article 25; Patent Act of India, s. (3)(h); Law on Patents of Indonesia, article 7 b); Patents Ordinance No. LXI, s. 7(4) a) (Pakistan).
[89] 35 U.S.C. § 287 (c).
[90] *Ibid.*
[91] Korean Intellectual Property Office, *Requirements for patentability*, January 2010, p.7.
[92] Case No. 90Huh250 (Supreme Court, 12 Mar. 1991) cited in Korean Intellectual Property Office, *Requirements for patentability*, January 2010, p.7.
[93] Japan Patent Office, *Examination Guidelines for Patent and Utility Model in Japan* – Part II – Chapter 1 – 2.2.1.
[94] *Wellcome/Pigs I*, T116/85 [1989] *EPOR* 1; [1989] *OJEPO* 13; *Telectronics/Pacer*, T82/93 [1996] *EPOR* 409; *See-Shell/Blood flow*, T182/90 [1994] *EPOR* 32 discussed in European Report, *supra* note 19 p. 7.
[95] Law 17.164 of Uruguay, article 14.

V. Biotechnology: In some jurisdictions, life forms and/or genome (or genes), as found in nature, are not patentable.[96] Brazil and Chile even explicitly reject the doctrine of isolation, according to which isolated or purified products of nature are patentable.[97] Also, most jurisdictions exclude essentially and /or natural biological processes, for the production of plants or animals, from patentability.[98]

VI. Life forms: In some jurisdictions, only plant and animal varieties are not patentable (ex: the patenting of a specific breed of mice would not be acceptable; however, the patenting of transgenic rodents would),[99] while in other jurisdictions, plants and animals are not patentable in all cases (e.g. varieties or not).[100] For the former, the exclusion of plant varieties clearly allows these countries to respect the *International Convention for the Protection of New Varieties of Plants* of 1978 or 1971.

Although the last three categories (IV., V., VI) of exclusions were initially conceived to protect medical practitioners in their practice (e.g. a doctor performing a diagnostic test on a patient) or to reflect the moral values of a particular society (e.g. patenting life forms is sometimes seen as a slippery slope that could lead to the exploitation of human beings[101]), they can sometimes be invoked on behalf of biomedical researchers. From this perspective, it is obvious that such exclusions have an impact on research.

General exclusions resulting from patentability requirements

This section will only study patentability requirements which have an effect on research. Some requirements, such as the novelty and non-obviousness requirements, affect research by making what is known available[102]. However, because these requirements do not constitute exclusions *per se*, they will not be analyzed.

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[96] Industrial Property Law of Mexico, article 16; Law 24.481of Argentina, article 6; Brazilian Industrial Property Law, article 10; Law N° 19.039 of Chile, article 37; Decision 486, article 15.

[97] Brazilian Industrial Property Law, article 10; Law N° 19.039 of Chile, article 37.

[98] EPC 2000, 53 (b); Law 24.481of Argentina; Brazilian Industrial Property Law, article 10; Law N° 19.039 of Chile, article 37; Decision 486, article 15; Patent Act of India, s. (3)(i); Law on Patents of Indonesia, article 7 d); Patents Ordinance No. LXI, s. 7(4) b) (Pakistan)

[99] EPC 2000, 53 (b); Federal Law on Plant Varieties of Mexico, article 5.

[100] Brazilian Industrial Property Law, article 18; Law N° 19.039 of Chile, article 37; Decision 486, *supra* article 15; Patent Act of India, s. (3)(i); Law on Patents of Indonesia, article 7 d); Patents Ordinance No. LXI, s. 7(4) b). (Pakistan)

[101] David B. Resnik, "The Morality of Human Gene Patents" (1997) Kennedy Institute of Ethics Journal 7.1.

[102] A concept of interest is grace periods, as these affect research. A grace period for the disclosure of the invention may be described in the following way: "[t]he inventor is granted a specified period during which he does not prejudice his case by organizing realistic experiments, discussing the inventions with others, etc." (Oppenheim, *infra* note 215 p.184). An invention may voluntarily or inadvertently be disclosed by a person entitled to file a patent or an individual that has obtained, legally or not, information from that person. Some jurisdictions have a narrow grace period. For example, members of the *European Patent Convention* only grant a grace period in case of abuse of a relationship with the applicant (1) or in case of a presentation in an officially recognized exhibition (2). (EPC 2000, *supra* note 16 article 55) Some jurisdictions have a broader grace period. These jurisdictions allow inventors to disclose their invention up to 12 months before an application (Canada, Mexico, the United States, Argentina and Brazil)
As grace periods accelerate the disclosure of information, disclosure in turn accelerates aggregate innovation. (Suzanne Scotchmer, "Cumulative Research and the Patent Law", (1991) 5:1 The Journal of Economic Perspectives 29) For this reason, firms may be tempted to prevent disclosure, as the effort of inventing around the patent will be less demanding. Indeed, "[p]atent law requires disclosure for the same reason that innovators dislike it: it is the vehicle by which technical knowledge is passed from the patenting firm to its competitors." (Suzanne Scotchmer, "Cumulative Research and the Patent Law", (1991) 5:1 The Journal of Economic Perspectives 29) To the contrary, researchers in universities are encouraged to publish. While they may not publish everything, the

Defining what is an invention

The patentability requirement which has the most impact on research is that an innovation must be deemed an "invention" within the meaning of the national patent law. This may be explained by the fact that most countries require patentable subject matter to be inventions, and specify that fundamental knowledge cannot be described as an invention. While this is done through explicit provisions in most countries, others exclude fundamental knowledge from the concept of invention through interpretation. Finally, some countries simply exclude fundamental knowledge from patentability without referring to what an invention is.

Many examples may be given to illustrate the general rule according to which most countries require patentable subject matter to be inventions and specify that fundamental knowledge cannot be described as an invention. In the case of the *European Patent Convention*, innovations or discoveries are first required to be an invention before satisfying the other three patentability requirements. Indeed, "European patents shall be granted for any inventions […] provided that they are new, involve an inventive step and are susceptible of industrial application"[103]. The European Technical Board of Appeal concurred with this view by declaring that "[a]rticle 52(1) EPC sets out four requirements to be fulfilled by a patentable invention: there must be an invention, and if there is an invention, it must satisfy the requirements of novelty, inventive step, and industrial applicability."[104]

After identifying the four requirements for patentability in article 52 (1), the *EPC* identifies what does not constitute an "invention" in art. 52 (2). Hence, "discoveries, scientific theories and mathematical methods" as well as "schemes, rules and methods for performing mental acts, playing games or doing business, and programs for computers" are not invention and, incidentally, patentable.[105] More precisely, even though elements listed in art. 52 (2) are not patentable *per se*, "paragraph 3 [of art. 52] actually enshrined the entitlement to patent protection for the non-inventions enumerated in paragraph 2 - albeit restricting the entitlement by excluding patentability 'to the extent to which the European patent application or European patent relates to such subject matter or activities as such'."[106] Hence, the elements of art. 52 (2) are protected only for their application to the patented subject matter or activities. Most other countries also exclude fundamental knowledge by first requiring innovations to be inventions[107] subsequently prescribing fundamental knowledge as not being an invention[108].

There are some exceptions to this general rule. In some jurisdictions the exclusion of fundamental knowledge is implicit rather than explicit. In Korea and Japan, the term invention

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primary basis for promotion, tenure and research funding, for academic researchers is publishing (John A. Tessensohn & Shusaku Yamamoto, "Japan's Novelty Grace Period Solves the Dilemma of 'Publish and Perish'", (2007) 25:1 Nature Biotechnology 55). Therefore, the most prominent effect of grace periods is to allow university researchers to use the patent regime, without impeding academic activities and disclosure of research results.
This may explain why HUGO advocates the adoption of a grace period. (HUGO Intellectual Property Committee, Statement on Patenting Issued Related to Early Release of Raw Sequence Data, May 1997.)

[103] EPC 2000, article 52 (1).

[104] Duns Licensing Associates, T 154/04 [2008] *OJEPO* 46

[105] EPC 2000, article 52 (2).

[106] Duns Licensing Associates, T 154/04 [2008] *OJEPO* 46

[107] Industrial Property Law of Mexico, article 16; Law 24.481of Argentina, art. 4; Brazilian Industrial Property Law, article 8; Decision 486, article 14; Patent Act of India, s. 2; Patents Ordinance No. LXI, s. 2 (Pakistan).

[108] Industrial Property Law of Mexico, article 19; Law 24.481of Argentina, art. 6; Brazilian Industrial Property Law, article 10; Decision 486, article 15; Patent Act of India, s. 3; Patents Ordinance No. LXI, s. 7 (Pakistan).

refers to a "highly advanced creation of technical ideas utilizing the laws of nature."[109] In both cases, this definition is understood to exclude the patenting of laws of nature, mere discoveries, non technical ideas, solutions of problems impossible to solve, innovations that do not rely on the laws of nature and innovations that are contrary to the laws of nature.[110]

Finally, some exclude the patenting of fundamental knowledge without referring to the definition of invention. Case law from the United-States precludes the patenting of fundamental knowledge.[111] In Canada, China and Indonesia, however, the patenting of fundamental knowledge is precluded by statutory provisions[112].

Description requirement
In a noteworthy case, the United States Court of Appeals for the Federal Circuit stated as follows:

> The written description requirement also ensures that when a patent claims a genus by its function or result, the specification recites sufficient materials to accomplish that function – a problem that is particularly acute in the biological arts. […] We reasoned that because the specification did not describe any specific compound capable of performing the claimed method and the skilled artisan would not be able to identify any such compound based on the specification's function description, the specification did not provide an adequate written description of the claimed invention. *Id*. at 927-28. Such claims merely recite a description of the problem to be solved while claiming all solutions to it and, as in *Eli Lilly* and Ariad's claims, cover any compound later actually invented and determined to fall within the claim's functional boundaries - leaving it to the pharmaceutical industry to complete an unfinished invention. […] [P]atent law has always been directed to the "useful Arts," U.S. Const. art. I, § 8, cl. 8, meaning inventions with a practical use, *see Brenner v. Manson*, 383 U.S. 519, 532-36, 86 S. Ct. 1033, 16 L. Ed. 2d 69, 1966 Dec. Comm'r Pat. 74 (1966). Much university research relates to basic research, including research into scientific principles and mechanisms of action, *see, e.g., Rochester*, 358 F.3d 916, and universities may not have the resources or inclination to work out the practical implications of all such research, *i.e*., finding and identifying compounds able to affect the mechanism discovered. […] Requiring a written description of the invention limits patent protection to those who actually perform the difficult work of "invention"-that is, conceive of the complete and final invention with all its claimed limitations-and disclose the fruits of that effort to the public.[113]

According to this case, it seems that description requirements also provide a limitation on the patentability of fundamental knowledge. Indeed, patent criteria are closely linked to the description requirements in national patent laws. Abstract ideas are, by their nature, more

[109] Japan Patent Act, article 2.
[110] As explained in the *Examination Guidelines for Patent and Utility Model in Japan* – Japan Patent Office - Part II – Chapter 1; Korean Intellectual Property Office, *Requirements for patentability*, January 2010, p. 2 – 4.
[111] *Mackay v. Radio Corp.*, 306 U.S. 86 (1939); *Gottschalk v. Benson*, 409 U.S. 63 (1972); *Bilski v. Kappos*, 95 U.S.P.Q.2D (BNA) 1001 (U.S.C., 2010); *Ariad Pharms., Inc. v. Eli Lilly & Co.*, 598 F. 3d 1336 (C.A. Fed., 2010).
[112] *Patent Act of Canada*, s. 27 (8); Patent Law of the People's Republic of China, article 25; Law on Patents, art. 7 (Indonesia).
[113] *Ariad Pharms., Inc. v. Eli Lilly & Co.*, 598 F. 3d 1336 (C.A. Fed., 2010)

difficult to describe in a manner that another person skilled in the art will be able to identify and reproduce it based on the disclosure given in the patent application.

III. Exceptions to Patentee's Rights Affecting Research

This part of the chapter will discuss how exceptions to patentability may affect research. Exceptions that affect research may originate from national or international rules. This section will discuss the international legal framework to which countries adhere (**Part A**), as well as national regimes (**Part B**).

A. International Legal Framework

This part will focus on exceptions to patent rights that impact research and development in international legal texts. After having discussed the international framework (**i**), regional agreements will be studied in order to better understand the obligations countries can have pertaining to exceptions a research and the origin of these exceptions (**ii** to **v**).

i) Global Legal Framework

Only one general international treaty has provisions containing exceptions that have an effect on research: The *Trade Related Aspect of Intellectual Property Rights Agreement* (*TRIPS*).

TRIPS

TRIPS introduced previously in the section on exclusions, has two provisions which allow the adoption of research exceptions in party states. The general provision is article 30, according to which exceptions to a patentee's rights may be created, provided they "do not unreasonably conflict with a normal exploitation of the patent and do not unreasonably prejudice the legitimate interests of the patent owner, taking account of the legitimate interests of third parties."[114]

This provision was interpreted in a panel decision on patent protection for pharmaceutical products.[115] Following a complaint by the European Community regarding the provisions in Canada's *Patent Act* pertaining to a stockpiling exception (allowing the manufacture of a pharmaceutical compound before the expiry of a patent in order to distribute that product immediately following the end of the patent's exclusionary period and for research pursued in order to comply with regulatory requirement [116]), the panel held that three conditions must be fulfilled in order for an exception to be valid.

. The panel held that three conditions must be fulfilled in order for an exception to be valid. First, it must be limited to the point where it diminishes the rights it question in only minor respects. Second, an "exception must not unreasonably conflict with the normal exploitation"

[114] TRIPS, *supra* note 8 art. 30.
[115] *Canada – Patent Protection of Pharmaceutical Products*, 17 March 2000, WT/DS114/R, Panel Report, discussed in Australian Government – Advisory Council on Intellectual Property, *Patents and Experimental Use*, October 2005.
[116] *Ibid.*

of patents.[117] Finally, an "exception must not unreasonably prejudice the legitimate interests of the patent owner, taking into account interests of third parties."[118] More precisely, legitimate interests are not equivalent to legal interests.[119]

While allowing the adoption of some exceptions, article 30 must also be read in light of article 27(1) according to which the "discrimination as to the place of invention, the field of technology and whether products are imported or locally produced" is proscribed.[120] In other words, an exception cannot discriminate against a specific field of technology. However, this provision does not require the same treatment for all fields of innovation, as the word 'discrimination' was purposely used to communicate that legitimate differentiation can take place (e.g. pricing controls, exclusions, exceptions, etc.) as long it is reasonable. This also applies to article 31 of *TRIPS*.[121]

Article 31 enumerates a series of conditions that compulsory licenses should meet in order to be valid under *TRIPS*.[122] Article 31 does not, however, set out the reasons for a compulsory license. So, in theory, it could be used to grant a license to conduct certain types of research that would otherwise constitute infringement provided that the process and terms of that license complied with that article.

Finally, article 6 of *TRIPS* specifies that provisions in the agreement do not extend to exhaustion of rights (except for articles 3 and 4 that deal with discrimination based on citizenship).[123] This means that member countries do not have any obligation pertaining to parallel imports. Researchers, in jurisdictions that allow parallel importing could, therefore, have access to less costly patented products than those in other jurisdictions.

Now that the common international framework for exceptions has been outlined in sub-part **i)**, sub-parts **ii)** to **iv)** will focus on regional agreements pertaining to Europe, North America, South America and Eurasia.

ii) Europe

European Biotechnology Directive

The *European Biotechnology Directive* prescribes some rules concerning exceptions. The extension of protection by articles 8 and 9 do not extend "to biological material obtained from the propagation or multiplication of biological material," when the biological material has been placed on the market by the patent owner, in a member state (1) or, when the biological material is marketed for purposes of propagation or multiplication, as long as it "is not subsequently used for other propagation or multiplication" (2).[124] These exceptions are more

[117] *Ibid.*
[118] *Ibid.*
[119] *Ibid.*
[120] TRIPS, *supra* note 8 art. 27. Legitimate differentiation can still take place
[121] Kevin J. Nowak, "Staying within the Negotiated Framework: Abiding by the Non-Discrimination Clause in Trips Article 27", *supra* note 7 at p. 911.
[122] Sara M. Ford, "Compulsory Licensing Provisions Under the TRIPs Agreement: Balancing Pills and Patents", (1999-2000) 15 Am. U. Int'l L. Rev. 941, p.959 [Sara M. Ford, "Compulsory Licensing Provisions Under the TRIPs Agreement: Balancing Pills and Patents"].
[123] Amit Gupta, "Patent Rights on Pharmaceutical Products and Affordable Drugs : Can Trips Provide a Solution?", (2003-2004) 2 Buff. Intell. Pro. L. J. 127.
[124] European Biotechnology Directive *supra* note 16 art. 10.

relevant for farmers than for researchers. However, they may still be useful to the latter. Indeed, as researchers may use patented cell lines, this exception protects them against infringing a patented cell line by using it for the purposes for which it is sold.

Directive 2004/27/EC

This directive was passed to impose common European standards relating to the registration of generic products. It introduces new time periods for data exclusivity, introduces a new definition of a generic product, and contains "*Bolar*" provisions. According to article 1 (8) of the *Directive*: "Conducting the necessary studies and trials with a view to [satisfying the abbreviated regulatory approval process for generic medicines] and the consequential practical requirements shall not be regarded as contrary to patent rights or to supplementary protection certificates for medicinal products."[125]

The Community Patent Convention

This convention was concluded in 1975 between 9 member states of the European Union to allow individuals and companies to obtain a unitary patent throughout the European Union. The *Community Patent Convention* prescribes an exception for experimental use.[126] According to this provision, "[t]he rights conferred by a Community Patent shall not extend to acts done for experimental purposes relating to the subject matter of the invention."[127] However, the *Convention* never entered into force since it was not ratified by a sufficient number of Member States.

iii) North America

North America Free Trade Agreement (NAFTA)

Two *NAFTA* provisions pertaining to exceptions may apply to those conducting research. First, parties may implement measures in their national law to prevent abuse of intellectual property rights or anticompetitive measures.[128] Member countries may also prescribe limited exceptions to patent rights.[129] However, these exceptions must not "unreasonably conflict with a normal exploitation of the patent"[130] and must not unreasonably interfere with the legitimate interests of a patent owner.[131] No international jurisprudence on these matters has been found to further delineate the potential scope of exceptions, yet it is certain that such exceptions are optional under *NAFTA.*

iv) South America

The Andean Pact

Article 53 of the *Pact* limits the scope of patent rights and stipulates that a patent owner cannot forbid:

a) acts carried out in a private circle and for non-commercial purposes;

[125] Directive 2004/27/EC, art. 1 8), cited in Sean O'Connor, "Enabling Research or Unfair Competition? De Jure and De Facto Research Use Exceptions in Major Technology Countries", Research Roundtable: Law & Economics of Innovation, 2008.
[126] European Report *supra* note 19 p. 39.
[127] Community Patent Convention cited by European Report, *supra* note 19 p. 41.
[128] NAFTA, *supra* note 67 art. 1704.
[129] *Ibid.*, art. 1709 (6).
[130] *Ibid.*
[131] *Ibid.*

b) acts carried out exclusively to experiment with the subject matter of the patented invention;
c) acts carried out exclusively for the purposes of teaching or scientific or academic research;[…][132]

Paragraphs a), b) and c) serve, *prima facie*, to lower the risks of infringement by researchers.

v) Eurasia

Eurasian Patent Convention

This convention has provisions that have an impact on research. According to Rule 19, acts done for scientific, experimental or private non-profit-making purposes do constitute infringement. Moreover, good faith prior users "shall retain the right to proceed with that use free of charge, provided that the scope thereof is not increased"[133].

B. Exceptions Impacting Research

i) Table comparing exceptions affecting research (national level)

These tables compare exceptions that directly or by implication affect research in national statutory law and case law. They include the name of the country, whether or not there is an experimental exception, the scope of any such exceptions and whether or not there are alternatives when there is not experimental exception.

Europe

	General Exceptions
Europe	European countries tend to follow some version of what is contained in Article 27 b) of the *Community Patent Convention*. As explained earlier, the *Convention* never entered into force. However, it has had a great influence over member countries and member countries of the EU have enacted legislation which parallels its major provisions. (Organisation for Economic Co-Operation and Development, *Research Use of Patented Knowledge: A Review*, Chris Dent, Paul Jensen, Sophie Waller, and Beth Webster, 2006, p.18.) **Exceptions Partially Enumerated from Some European Countries:** **Experimental Uses – Germany**: There is a statutory provision for experimental uses of a patented invention, according to which "[t]he effect of the patent shall not extend to acts done for experimental purposes which are related to the subject matter of the patented invention." (s.11.2 *German Patent Act* 1981 cited in Advisory Council on Intellectual Property, *Patents and Experimental Use*, October 2005, p.41.) According to the Federal Supreme Court, "[s]ince the provision makes no limit, either qualitative or quantitative, on the experimental acts, it cannot matter whether the experiments are used only to check the statements made in the patent or else to obtain further research results, and whether they are employed for wider purposes, such as commercial interests."(*Klinische Versuche (Clinical Trials) I* (1997) RPC 623 cited in Advisory Council on Intellectual Property, *Patents and Experimental Use*, October 2005, p.42.) This was reaffirmed in a second case where the court stated that: "According to the memorandum of the agreement, Article 31 allows the invention protected by the Community patent to be used for experimental purposes "for example, to test its usability and possibility of further development." These examples contain commercially oriented goals. (*Klinische Versuche (Clinical Trials) II* (1998) RPC 423 cited in Advisory Council on Intellectual Property, *Patents and Experimental Use*, October 2005, p.42.)) In all cases, however, an experimental act qualifies for the exception only if its purpose is "to gain information and thus to carry out scientific research into the subject-matter of the invention, including its use."(*Klinische Versuche (Clinical*

[132] Decision 486, *supra* note 81 art. 53.
[133] Eurasian Patent Convention, September 9 1994, rule 20.

	Trials) I (1997) RPC 623 cited in E. Richard Gold et al., "The Research or Experimental Use Exception: A Comparative Analysis", *(Montreal: Centre for Intellectual Property Policy / Health Law Institute, 2005) available on line: < (*http://www.cipp.mcgill.ca/data/newsletters/00000050.pdf*) pp. 1- 52.*) **Exception for the submission of information to the government – Germany:** "The rights conferred by a patent shall not extend to ... studies and trials and the consequential practical requirements necessary for obtaining an authorization to market a drug in the European Union or for obtaining an authorization to market a drug in the Member States of the European Countries." Sean O'Connor, "Enabling Research or Unfair Competition? De Jure and De Facto Research Use Exceptions in Major Technology Countries" Research Roundtable: Law & Economics of Innovation, 2008) **Experimental Uses – Belgium** On the topic of the research exception, it is interesting to note that "(r)ecently, [...] Belgium has adopted an experimental use exception that extends very broadly to research "on and/or with" patented inventions."(Henrik Holzapfel & Joshua D. Sarnoff, "A Cross-Atlantic Dialog on Experimental Use and Research Tools" American University, WCL Research Paper No. 2008-13.)

	General Exceptions
United-Kingdom	**Private Non-Commercial Uses:** The private non-commercial use exception allows individuals to use a patent for non-commercial purposes (s. 60 (5) a) *UK Patents Act 1977*). If "an activity has both commercial and non-commercial benefits, it is necessary to ascertain the subjective intention of the user" (European Report *supra* note 19 p.39). The user must not be motivated by commercial benefits. **Experimental Uses:** An experimental use exemption is provided by s. 60 (5) b) *UK Patents Act 1977*. It protects against infringement actions when infringement is done for experimental purposes. "The distinction between the wording of sub-head (a) and the wording of sub-head (b) in section 60(5) indicates that experimental purposes in sub-head (b) may yet have a commercial end in view.... I would regard the sort of experimental activity which was considered by the Supreme Court of Canada in *Microchemicals Ltd v Smith Kline and French* ..., viz, a limited experiment to establish whether the experimenter could manufacture a quality product commercially in accordance with the specification of a patent, as being covered by the words 'for experimental purposes relating to the subject matter of the invention.'" *(Monsanto v. Stauffer Chemical* [1985] *RPC* 515 (CA) cited in Trevor Cook, *A European Perspective as to the Extent to which Experimental Use, and Certain Other, Defences to Patent Infringement, apply to Differing Types of Research*, March 2006, online: http://www.ipeg.com/_UPLOAD%20BLOG/Experimental%20Use%20for%20IPI%20Chapters%201%20to%209%20Final.pdf) [Trevor Cook]. To be eligible for this exception, an act must be experimental. However, trials carried out in order to demonstrate to a third party that a product works or, in order to amass information to satisfy a third party, whether a customer or a [regulatory] body ... that the product works as its maker claims are not ... to be regarded as acts done "for experimental purposes." (Trevor Cook) Moreover, the question of whether this exception may be used "to improve it, to invent around the patent, or to invent something else" has not been clarified. (European Report, *supra* note 19 p. 40.) This exception can be used to "1) discover something unknown; 2) test an hypothesis; 3) determine if the invention is workable under varied conditions; and 4) to determine if the patented product can be manufactured in accordance with the patent." (E. Richard Gold et al., "The Research or Experimental Use Exception: A Comparative Analysis", *(Montreal: Centre for Intellectual Property Policy / Health Law Institute, 2005) available on line : < (*http://www.cipp.mcgill.ca/data/newsletters/00000050.pdf*)> pp. 1- 52.*) **Prior User exception:** There is a prior user exception in s. 64 *UK Patents Act 1977*. This allows the prior user to continue using the invention. If the prior use took place "in the course of business, the prior user has the right to authorize the doing of the act by their partners for the time of the business" (*European Report, supra* note 19, p. 44.) even though this does not allow the prior user to license his right. (s. 64 (1) *UK Patents Act 1977*) This right acquired in a business may also be transmitted. (s. 64 (2) *UK Patents Act 1977*) However, this exception is very narrow. Indeed, six conditions must be meet in order to benefit from it: a. The prior use must have been private. Otherwise, the patent is invalid as it does not respect the novelty requirement.

	b. A prior use must have been made in the UK. c. The use must have been made in good faith. d. The prior use must have been "serious and effective." (*Lubrizol Corporation v. Esso Petroleum* [1998] *RPC* 727, 770 (CA); *Helitune v. Stewart Hughes* [1991] *FSR* 171 discussed in European Report *supra* note 19, p. 44.) e. There must be a ""chain of causation" between the prior use and the infringing use."(*Hadley Industries v. Metal Sections* (13 Nov. 1998) cited in the European Report *supra* note 19, p. 44.) f. This is a personal defense that can only be used by the prior user himself.(European Report, *supra* note 19 p. 44.) **Exhaustion of Biological Patent:** Codified at paragraph 10 of Schedule *A2 UK Patents Act*, this exception is the same as the one provided by Article 10 of the *European Biotechnology Directive*. **Exception for the submission of information to the government:** "An act which, apart from this subsection, would constitute an infringement of a patent for an invention shall not do so if … it consist of (i) An act done in conducting a study, test or trial which is necessary for and is conducted with a view to the application of [the regulatory approval processes of various EU Directives], or (ii) Any other act which is required for the purpose of the application of those paragraphs [of the various EU Directives]" (*Patent Act of 1970*, s. 60(5) (i) cited in Sean O'Connor, "Enabling Research or Unfair Competition? De Jure and De Facto Research Use Exceptions in Major Technology Countries" Research Roundtable: Law & Economics of Innovation, 2008).

North America

	General Exceptions
Canada	**Experimental Use:** In *Micro Chemicals Ltd. v. Smith Kline & French Inter-American Corp.*, [1972] S.C.R. 506, the Supreme Court of Canada applied a common law exemption, dating back to the case *Frearson* v. *Loe* [(1878), 9 Ch. D. 48.] pertaining to an experimental use of patents. The Supreme Court declared in *Micro Chemicals* that "[a]n experimental user without a licence in the course of bona fide experiments with a patented article is not in law an infringer." The court later declared: "I cannot see that this sort of experimentation and preparation is an infringement. It appears to me to be the logical result of the right to apply for a compulsory licence." Through the former quote, the Supreme Court had imported the experimental use exemption from British law. However, with the latter quote, the Supreme Court shed doubt on the existence of an experimental use exemption for purposes other than applying for a compulsory licence. The existence of the exemption became even more dubious when the federal government abolished s. 43 (1) *Patent Act*, R.S.C. 1952, c. 203. The Supreme Court expressed doubts on its existence: "The CBAC recognizes that this Court established a common law experimental use exception in the context of research aimed at sustaining a compulsory licence: see *Micro Chemicals Ltd. v. Smith Kline & French Inter-American Corp.*, [1972] S.C.R. 506. Nonetheless, the scope and nature of this exception is uncertain, particularly since Canada has since eliminated its compulsory licence provisions." *Harvard College v. Canada (Commissioner of Patents)*, (2002) 4 S.C.R. 45, para. 174. Four years later, the Federal Court dealt with this issue in *Merck & Co. v. Apotex Inc.*, [2006] F.C.A. 671, paras. 161-163: "The Supreme Court in *Micro Chemicals* held it to be significant that the Trial Judge had found that small amounts of the patented compound had been produced, put in bottles, kept by Micro Chemicals and never entered into commerce and no damage was suffered by the patentee and no profits made by Micro Chemicals. […] In this case, the evidence shows that there has been a use of lisinopril that should be considered in the circumstance of "fair dealing." That is, the use of lisinopril in ongoing research and development of alternate formulae, alternate techniques for tablet making and the like. As to this research and development material, I find that it clearly falls within the "fair dealing" exemption provided by the Supreme Court of Canada in *Micro Chemicals.*" This interpretation of the Supreme Court case was approved by the Federal Court of Appeal in *Merck & Co. v. Apotex Inc.*, [2007] 3 F.C.A. 588, para. 109: "I reject this assertion that the *Micro Chemicals* exception is limited and only applies as an adjunct to the grant of compulsory licences. Although the grant of a compulsory licence was at issue in *Micro Chemicals*, certainly it did not form the basis of the exemption.

Moreover, the case *Frearson v. Loe* (1878), 9 Ch. D. 48, was relied on by the Supreme Court in *Micro Chemicals*, and in that case, the grant of a compulsory licence was not at issue. In my analysis, all that is required is that the infringing product was made merely by way of *bona fide* experiment, and not with the intention of selling and making use of the product in the commercial market."

While the addition a *Bolar*-type exception in section 55.2(6) of the *Patent Act* does not undermine the existence of the common law experimental use exception (*Apotex Inc. v. Merck & Co.*, [2008] F.C.J. 1465), it remains somewhat unclear how broad the common law exception is. The Federal Court of Appeal in *Merck & Co. v. Apotex Inc.*, [2007] 3 F.C.A. 588 stated at paragraphs that it was 111-112: "...inclined to agree... that this ongoing research should be exempt as it meets the test in *Micro Chemicals*, particularly, because Apotex was trying to establish if it could manufacture a quality product [according to the patent specifications]…In any event, even if this Court applied the United States test [in *Madey* v. *Duke*] in this case, I am satisfied that Apotex's research was used to satisfy their curiosity as to whether they could in fact manufacture a product with the specifications disclosed in the application of the '350 patent." In particular, it remains uncertain whether Canada has imported the notion of furthering one's business into the Canadian common law exception.

Private acts, non-commercial use and acts for teaching: "A patented article may be repaired, modified, or customized without infringement. Extensive repairs or changes that amount to reconstructing the article substantially, however, infringe…" David Vaver, *Intellectual Property Law – Copyright, Patents, Trademark* (Concord: Irwin Law, 1997). See also *Rucker Co v. Gravels Vulcanizing Ltd.* (1985), 7 C.P.R. (3d) 294.

Prior User Exception: Section 56 of the *Patent Act* provides that prior users are exempt from patent infringement if they have "purchased, constructed or acquired any invention for which a patent is afterwards obtained" in respect of the use or sale of "the specific article, machine, manufacture or composition of matter patented and so purchased, constructed or acquired." According to the Federal Court of Appeal in *Merck & Co. v. Apotex Inc.*, [2007] 3 F.C.R. 588 at para. 78, the article purchased, constructed or acquired need not be in its final state: "It follows for our purposes that the right to use a chemical compound encompasses the right to use and sell compositions that are created by applying the compound to its intended use. The fact that the use of a chemical compound may become incorporated into subsequently created products is therefore immaterial. Accordingly, the form taken by an invention is not governing for the purpose of section 56," provided that the product purchased, constructed or acquired is of the appropriate quality. In addition, s. 56 provides that a prior user's "purchase, construction or acquisition or use of the invention" may invalidate a patent if "it was purchased, constructed, acquired or used for a longer period than two years before the application for a patent" was filed.

Further, if an invention has been publicly disclosed by a third party before the claim date or by the applicant more than a year before the filing date (or a person deriving its knowledge from the applicant), a patent is deemed invalid. *Patent Act*, R.S.C. 1985, c. P-4, ss. 28.2 (1)(a) & 28.2 (1)(b).

Exception for the submission of information to the government (Bolar exception): "**55.2** (1) It is not an infringement of a patent for any person to make, construct, use or sell the patented invention solely for uses reasonably related to the development and submission of information required under any law of Canada, a province or a country other than Canada that regulates the manufacture, construction, use or sale of any product."

Any use of an invention to file information to any federal, provincial or foreign regulator in respect of the sale of any product is exempt from patent infringement. "The Canadian exception is unrestricted as to subject matter of the patent, it applies to medicines, bicycles and anything patented, and unrestricted as to any country not just Canada or province in which regulatory approval may be sought.": *Apotex Inc.* v. *Merck & Co. Inc.* 2008 FC 1185 at para. 21. This exception is thus broader than that in the US as interpreted in *Merck KG* v. *Integra Lifesciences Ltd.* 545 US 1 (2005). "That United States statute is more restrictive as it speaks only of requirements under United States law and is limited to drugs.": *Merck & Co. Inc.* v. *Apotex Inc.* 2006 FC 524 at para. 154.

This exemption applies to both pre-market and post-market activities undertaken to comply with regulation: *Merck & Co. v. Apotex Inc.*, [2007] 3 F.C.R. 588 at para. 100. Further, the provision does not exempt only activity that actually results in submitted information: "Any samples which are reasonably related to the

	development and submission of information under legislation or regulations are exempt by the provision. It does not limit the exemption to information actually submitted:" *Merck & Co. v. Apotex Inc.*, [2007] 3 F.C.R. 588 at para. 103. Section 55.2(1) is "not an exemption from the purpose of the Act, but is an integral part thereof by seeking to balance the rights of patentees with those of the public": *Merck & Co. v. Apotex Inc.*, [2007] 3 F.C.R. 588 at para. 102. The section should not, therefore, be given a narrow interpretation but should be interpreted in the same way as provisions granting the patent itself. Further, if an invention has been publicly disclosed by a third party before the claim date or by the applicant more than a year before the filing date (or a person deriving its knowledge from the applicant), a patent is deemed invalid. *Patent Act*, R.S.C. 1985, c. P-4, ss. 28.2 (1)(a) & 28.2 (1)(b).

	General Exceptions
Mexico	**Private Non-Commercial Uses – Acts for Teaching – Experimental Use:** According to Article 22 *Industrial Property Law*, "[t]he right conferred by a patent shall not have any effect against… a third party who, in the private or academic sphere and for non-commercial purposes, engages in scientific or technological research activities for purely experimental, testing or teaching purposes, and to that end manufactures or uses a product or a process identical to the one patented." This provision will prevent the infringement of the patent by some researchers. **Prior User exception:** According to Article 22 *Industrial Property Law* any person who, prior to the filing date, uses "the patented process, manufactures the patented product or undertakes the necessary preparations for such use or manufacture" does not infringe the patent. This exemption might be useful, especially when inventions are kept secret. Because these secret inventions might be the object of research or used as a tool, this may prevent some researchers from infringing a patent. **Plants:** The breeder's consent is not necessary when the plant is used as research material for improving other plants and for the multiplication of propagating material for personal use (art. 5 *Federal Law on Plant Varieties*).

	General Exceptions
United-States	**Experimental Use:** Only personal uses of an invention, unconnected with the goals and missions of one's enterprise, fall within this exception. Patent holders thus have significant discretion about which forms of research to permit. However, rarely do they use that discretion to curtail academic research. Academic activities pertaining to research are considered business activities. As the Court of Appeals for the Federal Circuit ruled in *Madey v. Duke University, United States Court of Appeal*, 307 F.3d 1351 (2002): "In short, regardless of whether a particular institution or entity is engaged in an endeavor for commercial gain, so long as the act is in furtherance of the alleged infringer's legitimate business and is not solely for amusement, to satisfy idle curiosity, or for strictly philosophical inquiry, the act does not qualify for the very narrow and strictly limited experimental use defense." **Private Non-Commercial Uses:** The owner of a purchased patented item has a right to repair the item – including replacing an essential part of the invention – but not to reconstruct it. Nevertheless, the line between repair and reconstruction is not clear: "Despite the number of cases concerning repair and reconstruction, difficult questions remain. One of these arises from the necessity of determining what constitutes replacement of a part of the device, which is repair or akin to repair, and what constitutes reconstruction of an entire device, which would be neither repair nor akin to repair. Certain situations suggest an obvious answer. For example, if a patent is obtained on an automobile, the replacement of the spark plugs would constitute a permissible repair, but few would argue that the retention of the spark plugs and the replacement of the remainder of the car at a single stroke was permissible activity akin to repair. Thus, there may be some concept of proportionality inherent in the distinction between repair and reconstruction." *Injection Molding Systems Ltd. v. R&D Tool & Engineering Co.*, 291 F.3d 780 (Fed. Cir. 2002). See also *Madey v. Duke* for more on non-commercial research exemption.

	Prior User exception: 35 U.S.C. § 102 establishes a first-to-invent system. Any publication prior to the invention date protects a prior user against patent infringements suits. Under 35 U.S.C. § 273, it is not an infringement for a person to use a "method of doing or conducting business" if that person "had, acting in good faith, actually reduced the subject matter to practice at least 1 year before the effective filing date of such patent, and commercially used the subject matter before the effective filing date of such patent." Congress enacted section 273 following the United States Court of Appeals for the Federal Circuit's decision in *State Street Bank v. Signature Financial Group*, Inc., 149 F.3d 1368 (Fed.Cir. 1998). **Exception for the submission of information to the government:** 35 U.S.C. § 271 (e)(1): "(1) It shall not be an act of infringement to make, use, offer to sell, or sell within the United States or import into the United States a patented invention (other than a new animal drug or veterinary biological product (as those terms are used in the *Federal Food, Drug, and Cosmetic Act* and the Act of March 4, 1913) which is primarily manufactured using recombinant DNA, recombinant RNA, hybridoma technology, or other processes involving site specific genetic manipulation techniques) solely for uses reasonably related to the development and submission of information under a Federal law which regulates the manufacture, use, or sale of drugs or veterinary biological products." Research that may result in information being filed under federal food and drug laws does not constitute infringement. To qualify, the researcher need only have the intention of eventually filing an application. The research need not be mandated by federal authorities. 35 U.S.C. § 271 (e)(1) *Merck KGaA v. Integra Lifesciences Ltd*., 545 U.S. 193 (2005). The purpose of this provision is to allow generic drug companies to manufacture patented drugs. However, the provision was interpreted broadly by the Supreme Court of the United States as allowing any research where there is a legitimate belief that a filing will be made.

South America

	General Exceptions
Argentina	**Private Non commercial Use – Experimental Use:** Article 36 of law 24.481 states that "[t]he right conferred by a patent does not produce any effect against: a) a third party who, in private or academic and non-commercial purposes, perform scientific research or technological purely experimental, testing or teaching and manufactured or used this product or use as the patented process" (South American Report, *supra* note 73 p. 53). **Exception for the submission of information to the government:** None (South American Report, *supra* note 73)

	General Exceptions
Brazil	**Private Non commercial Use:** "[…]acts carried out by unauthorized third parties, privately and without commercial purposes, provided these acts do not prejudice the economic interests of the patent holder […]" are not infringements (art. 43 of *Brazilian Industrial Property Law*). Hence, this exception pertains to use for private and non commercial purposes. **Experimental Use:** "[…]acts carried out by unauthorized third parties for experimental purposes, in connection with scientific or technological studies or researches […]" are not infringements (art. 43 of *Brazilian Industrial Property Law*). According to the report on intellectual property laws from South America, this exception needs to be "interpreted extensively" (South American Report, *supra* note 73 p. 46). However, it is not clear if experimentation may be undertaken for commercial purposes with this provision. **Prior User Exception:** "A person who in good faith, prior to the filing or priority date of a patent application, used to exploit the subject matter thereof within the Country, shall be entitled to continue such exploitation under the same form and conditions, without liability. Paragraph 1 - The right afforded by this Article may only be assigned together with the enterprise or part

	thereof that is directly related to the exploitation of the subject matter of the patent, by sale or lease. Paragraph 2 - The right afforded by this Article shall not be enjoyed by a person who obtained knowledge of the subject matter of the patent as a result of disclosure, in accordance with Article 12, provided that the application was filed within 1 (one) year of the disclosure." (art. 45 cited in South American Report, *supra* note 73 p. 64) **Biological material:** "[P]ersons who, in the case of patents related to living matter, use the patented product, without economic purpose, as an initial source of variation or propagation in order to obtain other products" cannot infringe a patent. (South American Report, *supra* note 73 p. 64). **Exception for the submission of information to the government:** "Article 43 – The provisions of the previous article shall not apply (…) VII - to acts performed by unauthorized third parties related to the invention protected by patent, exclusively for the production of information, data and test results in order to obtain the registration of trade in Brazil or in another country, for the exploitation and marketing of the patented product after the expiry of the periods stipulated in art. 40. (Included by Law 10.196 of 2001)" (South American Report, *supra* note 73 p. 66).

	General Exceptions
Chile	Apart from the possibility of parallel imports (art 49, *Law N° 19.039*), the exceptions provided under the *Chilean Law N° 19.039* are not relevant for research.

	General Exceptions
Andean Community	This regime applies to Bolivia, Colombia, Ecuador and Peru. **Private Non-Commercial Uses:** "a) acts carried out in a private circle and for non-commercial purposes" (*Decision 486*, art. 53). **Experimental Use:** "b) acts carried out exclusively to experiment with the subject matter of the patented invention" (*Decision 486*, art. 53). "c) acts carried out exclusively for the purposes of teaching or scientific or academic research; […]" (*Decision 486*, art. 53). **Prior User exception:** "Without prejudice to the provisions stipulated in this Decision with respect to patent nullity, the rights conferred by a patent may not be asserted against a third party that, in good faith and before the priority date or the filing date of the application on which the patent was granted, was already using or exploiting the invention, or had already made effective and serious preparations for such use or exploitation. In such case, the said third party shall have the right to start or continue using or exploiting the invention, but that right may only be assigned or transferred together with the business or company in which that use or exploitation is taking place." (*Decision 486*, art. 55, cited in South American Report, *supra* note 73p. 74 - 75). **Biological material:** "A patent owner may not exercise the right referred to in the previous article with respect to the following acts: […] e) where the patent protects biological material that is capable of being reproduced, except for plants, using that material as a basis for obtaining a viable new material, except where the patented material must be used repeatedly to obtain the new material." (*Decision 486*, art. 53). **Experimental Use in Ecuador**: Ecuador's intellectual property law adds to the experimental use exemption by specifying that it only covers acts not made for profit (South American Report, *supra* note 73 p. 51). **For all exceptions in Peru**: "When the limited exceptions provided for in Article 53 of *Decision 486* of the Andean Community Commission [interfere] unreasonably with the normal exploitation of the patent or causing unreasonably prejudice the legitimate interests of the patentee, taking into account the legitimate interests of third parties, the patent holder may exercise the rights provided in Article 52 of that decision."

	(South American Report, *supra* note 73 p. 54 – 55). Here, article 52 prescribes rights conferred by patents. Hence, when the legitimate interests of the patentee are unreasonably prejudiced, exceptions do not apply.

Asia

	General Exceptions
China	**Experimental Use:** According to article 69 (2) (*Patent Law of the People's Republic of China*), "using relevant patents solely for the purposes of scientific research and experiment" does not constitute infringement. **Prior User exception:** According to article 69 (2) (*Patent Law of the People's Republic of China*), "having made identical product or having used the identical process or having made necessary preparations for making such a product or using such a process prior to the date of application, and continuing making such product or using such a process only within the original scope," does not constitute infringement. **Exception for the submission of information to the government:** According to article 69 (5) (*Patent Law of the People's Republic of China*), "producing, using or importing patented medicine or patented medicinal equipment for the purpose of providing the information as required for administrative examination and approval, and producing and importing the patented medicine or patented medicinal equipment exclusively for the said purpose," does not constitute infringement.

	General Exceptions
India	**Experimental Use:** According to s. 47(3): "[A]ny machine, apparatus or other article in respect of which the patent is granted or any article made by the use of the process in respect of which the patent is granted, may be made or used, and any process in respect of which the patent is granted may be used, by any person, for the purpose merely of experiment or research including the imparting of instructions to pupils". Unfortunately, this exception has not yet been interpreted by the courts. Moreover, this experimental use exception does not make the difference between experimenting "on" vs. experimenting "with." (Shamnad Basheer & Prashant Reddy, "The "Experimental Use" Exception Through a Developmental Lens" (2010) 50 IDEA 831.) **Exception for the submission of information to the government:** "For the purpose of this Act, - (a) any act of making, constructing, using, selling or importing a patented invention solely for uses reasonably relating to the development and submission of information required under any law for the time being in force, in India, or in a country other than India, that regulates the manufacture, construction, use, sale or import of any product; shall not be an infringement of patent rights."(Art. 107A (a) of Indian Patent Act) According to a Joint Committee of the Indian Government, "[t]his provision has been made to ensure prompt availability of products, particularly generic drugs, immediately after the expiry of the term of the patent." (Joint Comm. Of the Rajya Sabha & the Lok Sabha, comm.. 91, Report on the Patents (Second Amendment) Bill, 1999, (Comm. Print 2001) (India) cited in Shamnad Basheer & Prashant Reddy, "The "Experimental Use" Exception Through a Developmental Lens" (2010) 50 IDEA 831) "Section 107A is wider than the corresponding U.S. provision because it permits the making, constructing, using or selling of a "patented invention" for the purpose of generating regulatory data to comply with both domestic (Indian) drug regulatory law, and any corresponding foreign law. U.S. law on the other hand permits a defense only in so far as the activities are connected with a regulatory submission within the United States." (Shamnad Basheer & Prashant Reddy, "The "Experimental Use" Exception Through a Developmental Lens" (2010) 50 IDEA 831)

	General Exceptions
Indonesia	**Experimental Use:** There is no patent infringement when an invention is used "for the sake of education, research, experiment, or analysis, as long as it does not harm the normal interest of the Patent holder." (*Law on Patent* art. 16 (3)). **Prior User exception:** "By obeying the other provisions under this Law, a party who exploits an Invention at the time a similar Invention is filed for Patent shall still be entitled to exploit the Invention as a prior user, even though the similar Invention is then granted a Patent." (*Law on Patent* art. 13 (1)).

	General Exceptions
Japan	**Experimental Use:** According to art. 69 (1) of the *Japan Patent Act*, "[a] patent right shall not be effective against the working of the patented invention for experimental or research purposes." **Leading cases**: "The Tokyo District Court emphasized the incentive to innovate [as a] justification of patent law and the policy purposes underlying section 69(1), namely to strike a balance between the interests of the patentee and the general public and to allow for the improvement of technology and the development of industry. The court held that section 69(1) [experimental use exception] is not limited to experiments or research directed at working improvements to existing technology. The court held that if generic drug manufacturers were required to wait until the expiration of the patent on the brand name drug before they were permitted to undertake the tests and manufacturing necessary to secure regulatory approval, this would grant the patent holder a de facto period of market exclusivity beyond the end of the patent term. This, the court held, is contrary to the very purposes of the patent regime." [*emphasis added*] (*Daiichi Pharmaceutical Co., Ltd*. v. *Shiono Chemical K.K. & Choseido Pharmaceutical K.K.* discussed in Shamnad Basheer & Coenraad Visser, *Background Information on Asia*, 2010, p. 23) [Background Information on Asia] "The Tokyo District Court granted a permanent injunction to prevent a third party from experimenting on a patented herbicide for the purpose of obtaining data for regulatory approval and also to prevent use of such data as well as the manufacture, importation, use and sale of the herbicide. This was a hiccup in the Japanese holdings, which was later clarified in *Ono Pharma cases* and the case of *Otuska Pharma* (discussed hereunder). The pharmaceutical field had not seen a similar holding. But the Nagoya District Court in the case discussed hereunder extended this trend against a wide interpretation of experimental use of a protected compound." (*Monsanto Co*. v. *Stoffer Japan K.K*, 1246 Hanrei Jiho 128 (Tokyo Dist. Ct. 1987) discussed in Background Information on Asia p. 23) "The Nagoya District Court decided differently than the Tokyo District Court in *Wellcome* (discussed hereunder) and *Daiichi* (discussed above). The Nagoya court found that clinical tests conducted solely for the purposes of obtaining regulatory approval amounted to patent infringement. However, the court refused to grant a preliminary injunction against the generic manufacturer and instead granted compensation for damages." (*Ono Pharmaceutical* v. *Malco Pharmaceutical K.K.* discussed in Background Information on Asia p. 24) "In *Ono Pharmaceuticals Co., Ltd. v. Kyoto Pharmaceutical Industries, Ltd*. the Japanese Supreme Court discussed this issue of experimental use exemption and generic drugs. Section 69(1) of the Japanese Patent Law provides an exemption for "the working of the patented invention for experiment and research." Ono asserted that Kyoto Pharmaceutical is selling the drugs of same efficaciousness as the patented drug during the patent term for the purpose of obtaining data that accompany an application for the approval of manufacture under section 14 of the *Pharmaceutical Affairs Law*. The Japanese Supreme Court decided that the use of drugs having the technical scope of the patented invention is "working of the patented invention for experiment and research" provided in Section 69(1) of the Japanese Patent Law and would not constitute patent infringement because: The Pharmaceutical Affairs Law stipulates that a prior approval by the Minister of Health and Welfare is to be obtained for the manufacture of drugs for ensuring safety, etc., and that upon carrying out various experiments, data, etc. on the experimental results must accompany an application when requesting such an approval. … If under the Patent law such experiments are not be interpreted as "experiments" stipulated in Section 69(1) of the Patent Law and therefore such manufacture, etc. are not possible during the patent term, the third party cannot, as a result, freely exploit the invention for a substantial period of time even after the term of the patent expires. This result is against the basis of the patent system mentioned above.[...] it is possible to exclude others from carrying out manufacture, etc. for the experiments required in applying the patent term for a substantial period of time, such extension of the patent term goes beyond what is expected under the patent law as benefits to be given to the patentee." (*Ono Pharms. Co., Ltd. v. Kyoto Pharm. Indus., Ltd.*, 24 AIPPI J. 106 (1999) discussed in Background Information on Asia p. 24) "The Japanese Supreme Court has aligned itself with the Tokyo District Court decisions and has held that the use of a patented invention for the purpose of obtaining a licence to market the generic equivalent of a patented medicine will fall within the scope of the statutory exemption. Finally, the Court concluded that experiments to obtain regulatory approval would also qualify as experiments within art. 69(1) of the

	Japanese Patent Law." (*Otsuka Pharmaceutical Co., Ltd. v. Towa Yakuhin K.K.*, 22 AIPPI Journal 296 (Nov. 1997) discussed in Background Information on Asia p. 25) "The Tokyo District Court had to determine whether Sawai, a Japanese pharmaceutical company, had infringed Wellcome's patent by applying for manufacturing approval and conducting tests and research on drugs similar to Wellcome's patented drug during the subsistence of the Wellcome patent. The court found that Sawai's research was aimed at achieving technical progress in terms of Article 69(1). Sawai did not earn any direct profit from these activities, nor did it compete in the same economic market as Wellcome. However, activities directed towards manufacturing or selling the product before the expiration of the patent would fall outside of section 69(1)." (*Wellcome Foundation Ltd* v. *Sawai Pharmaceutical* discussed in Background Information on Asia p. 26) **Prior User exception:** According to art. 69 (2), "[a] patent right shall not be effective against the following products: (ii) products existing in Japan prior to the filing of the patent application."

	General Exceptions
Pakistan	**Experimental Use:** "[A]cts done only for experimental purposes relating to a patented invention" do not constitute infringement (*Patents Ordinance No. LXI*,, art. 30 (5) (Pakistan)). **Prior User exception:** "[A]cts performed by any person who in good faith, before the filling or, where priority is claimed, the priority date of the application on which the patent is granted in Pakistan, was using the invention or was making effective and serious preparations for such use." (*Patents Ordinance No. LXI*,, art. 30 (5) (Pakistan))

	General Exceptions
Republic of Korea	**Experimental Use:** "The effect of a patent right does not extend to any of the following subparagraphs: (i) Working a patented invention for research or experimental purposes[…]" (*Patent Act of the Republic of Korea* art. 96 (1) (i)) **Prior User exception:** "The effect of a patent right does not extend to any of the following subparagraphs: […] (iii) articles existing in the Republic of Korea when the patent application was filed." (*Patent Act of the Republic of Korea* art. 96 (1) (i)) There is also a prior user exception at art. 103: "When filing a patent application, a person who has made an invention without prior knowledge of the contents of an invention described in an existing patent application, or who has learned how to make the invention from such a person and has been working the invention commercially or industrially in the Republic of Korea in good faith or has been making preparations to work the invention is entitled to have a nonexclusive license on the patent right for the invention under the patent application. The nonexclusive license must be limited to the invention being worked, or for which preparations for working have been made, and to the purpose of such working or preparations."

ii) Common Aspects and Distinctions

This section will identify the commonalities and trends in national patent laws pertaining to exceptions affecting research. It will also succinctly address the main divergences between studied world regions/individual countries.

While exceptions applying to research and development must comply with the *TRIPS* requirement that they be "limited to certain uses, [ensure] that it does not conflict with the normal exploitation of patents and [that it facilitates] public policies such as the advancement

of science and technology,"[134] there remains considerable room to enact them. Further, while they must not discriminate against a specific field of technology,[135] there is no requirement that they apply in the same way in all fields. The *Bolar* exception provides one example of this as it is often – but certainly not uniformly – limited to pharmaceutical and similar products.

Prior User

The exception for prior users (e.g.: United Kingdom,[136] Canada,[137] Mexico,[138], Brazil,[139] China,[140] Indonesia,[141] Japan,[142] Pakistan,[143] Korea,[144] and members of the Andean Community[145]) has an impact on research practices. For example, an individual may discover an invention that is already known elsewhere, such as a trade-secret. In this situation, the prior user exception may help trade-secret holders, since they may be interested in continuing to experiment with the invention without having to obtain permission from the patent holder (as long as it had not been disclosed). The prior user exception is narrow in scope and will only have an impact on research in limited circumstances.

Some countries, such as Chile and Argentina, do not seem to have such an exception.

Non Commercial Users

Some jurisdictions have a non-commercial user exception. The United Kingdom,[146] Mexico,[147] Brazil[148] and members of the Andean Community[149] have a statutory non-commercial user exemption. As for Canada[150] and the United-States,[151] they have an exception that originates from case law.

This exception may be considered similar to an experimental exception by some. It is, in fact, different. While some researchers may use an invention for non-commercial purposes, not all non-commercial users are *experimenting*. This type of exception often pertains to acts other than experimental act (e.g. repairs in the case of Canada and the United States).

Experimental Exception

Experimental use exceptions vary in breadth from country to country. The emphasis must be laid on three characteristics that define different types of experimental exceptions: 1) whether it

[134] *Canada – Patent Protection of Pharmaceutical Products*, 17 March 2000, WT/DS114/R, Panel Report, discussed in Australian Government – Advisory Council on Intellectual Property, *Patents and Experimental Use*, October 2005, p. 28.
[135] TRIPS, *supra* note 8, art. 27.1.
[136] UK 1977 Patents Act, s. 64
[137] *Patent Act*, R.S.C. 1985, c. P-4, s. 56.
[138] Industrial Property Law of Mexico, art. 22.
[139] Brazilian Industrial Property Law, art. 45.
[140] Patent Law of the People's Republic of China, art. 69 (2).
[141] Law on patents, art. 13 (1).
[142] Japan Patent Act, art. 69 (2).
[143] Patents Ordinance No. LXI,, s. 30 (5) (Pakistan).
[144] Patent Act of the Republic of Korea, art. 96 (1) (i).
[145] Decision 486, *supra* note 80 art. 55.
[146] UK 1977 Patents Act, s. 65 (5) b)
[147] Industrial Property Law of Mexico, art. 22.
[148] Brazilian Industrial Property Law, art. 43.
[149] Decision 486, *supra* note 80 art. 53.
[150] David Vaver, *Intellectual Property Law – Copyright, Patents, Trademark* (Concord: Irwin Law, 1997). See also *Rucker Co v. Gravels Vulcanizing Ltd.* (1985), 7 C.P.R. (3d) 294.
[151] *Injection Molding Systems Ltd. v. R&D Tool & Engineering Co.*, 291 F.3d 780 (Fed. Cir. 2002).

allows for experimentation *on* or *with* an invention, 2) whether or not the exception applies to experiments with a commercial purpose (the definition of what is commercial or not being itself a source of controversy in some jurisdictions) and 3) whether it is statutory or judicial.

An experimental exception may be designed only to allow experiments *on* an invention, rather than *with* an invention. This distinction is important because, when it is possible to experiment *with* an invention without infringing a patent, researchers have greater access to research tools without a licence, especially when it is difficult to invent around an invention. For example, "[s]ome of the most important genetic research tools are fundamental research platforms that open up new and uncharted areas of investigation."[152] However, because researchers may constitute an important market, the possibility of experimenting *with* research tools without buying the tool may lower the incentive to improve or develop new research tools.

The expression "relating to the subject-matter of the patented invention" (used by Germany[153] and the United-Kingdom[154]) indicates that an individual may only experiment *on* an invention.[155] The consequence is that an individual may experiment *on* a research tool, but not *with* it.[156] Other countries have different approaches. Some allow researchers to experiment *on* and *with* an invention (Belgium[157]). However, in many countries, the distinction is not made (ex: India,[158] China,[159] etc.).

Another important distinction is whether or not experimental acts are undertaken for a commercial purpose. Some countries do have an exception that covers experimental acts done for commercial purposes (e.g., Germany[160] and the United-Kingdom[161]). Other countries have narrower exceptions covering only non-commercial research. The latter exceptions preclude the use of patented knowledge for commercial research without a license from the patent holder (e.g., Mexico[162], Argentina[163]). Many countries, however, do not specify if experiments done for commercial purposes are encompassed within the exception (e.g. Brazil,[164] members of the Andean Community,[165] China,[166] Pakistan,[167] etc.).

The third distinction that exists between jurisdictions is that some provide an experimental use exception by statutory means (Germany,[168] United-Kingdom,[169] Brazil,[170] members of the

[152] E. Richard Gold, Yann Joly & Timothy Caulfield, "Genetic Research Tools, the Research Exception and Open Science" (2005) 3:2 *GenEdit*, 1-8.
[153] German Patent Act 1981, s. 11.2.
[154] UK 1977 Patents Act, s. 60 (5) b).
[155] Henrik Holzapfel & Joshua D. Sarnoff, "A Cross-Atlantic Dialog on Experimental Use and Research Tools" American University, WCL Research Paper No. 2008-13. [Henrik Holzapfel & Joshua D. Sarnoff, "A Cross-Atlantic Dialog on Experimental Use and Research Tools"]
[156] Henrik Holzapfel & Joshua D. Sarnoff, "A Cross-Atlantic Dialog on Experimental Use and Research Tools", *supra* note 171.
[157] *Ibid.*
[158] Patent Act of India, s. 47(3).
[159] Patent Law of the People's Republic of China, art. 69 (2).
[160] German Patent Act 1981, s. 11.2.
[161] UK Patent Act of 1977, s. 60 (5) b).
[162] Industrial Property Law of Mexico, art. 22.
[163] Law 24.481, art. 36.
[164] Brazilian Industrial Property Law, art. 43.
[165] Decision 486, *supra* note 81 art. 53.
[166] Patent Law of the People's Republic of China, art. 69 (2).
[167] Patents Ordinance No. LXI,, s. 30 (5) (Pakistan).
[168] German Patent Act 1981, s. 11.2.

Andean Community,[171] China,[172] India,[173] Japan,[174] Pakistan,[175] etc.), while others provide an experimental use exception through case law (Canada[176] and the United States[177]). While a certain level of uncertainty exists in both types of jurisdictions, those that provide an experimental use exception through case law tend to show greater uncertainty as to the existence and scope of the exception. For example, in the case of Canada, even the Supreme Court expressed doubts about whether or not this exception existed in 2002.[178] It was not until recently that the existence of that exception was confirmed.[179] Still, its scope remains uncertain. As for Australia, even the existence of an experimental use exception is uncertain.[180]

Uncertainty is not, however, only characteristic of case law experimental use exceptions; statutory experimental use exceptions are also characterized by uncertainty, since in many cases, it is unclear whether or not the exception covers experiments *with* a patented invention or if experimental acts may be done for commercial purposes. This uncertainty impacts clinical trials as these often cross the line between experiments *with* and *on* a patented invention. Indeed, as explained further in the chapter, it is uncertain in many countries whether these fall into the research exception (as opposed to a *Bolar* exception).

Moreover, in many cases, it is unclear what constitutes an *experiment*. Even though the exception only applies to experimental acts, this type of act is not clearly defined in many jurisdictions. This lack of description as to what is an experiment partially explains why in so many cases, it is unclear whether or not the exception in question covers experiments *with* a patented invention or if experimental acts may be done for commercial purposes (ex: India,[181] China,[182] Brazil,[183] members of the Andean Community,[184] etc.).

Exceptions for regulatory approval (Bolar/ Safe Harbor)

Many jurisdictions have an exception that allows individuals to use a patented invention in order to satisfy regulatory requirements. In addition to the "stockpiling case"[185] that deemed Canada's regulatory review provision acceptable for art. 30 of *TRIPS*, a recent *European Directive*[186] has encouraged many jurisdictions to adopt an exception to patent infringement for regulatory review.

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[169] Patent Act of 1977, s. 60 (5) b).
[170] Brazilian Industrial Property Law, art. 43.
[171] Decision 486, *supra* note 80 art. 53.
[172] Patent Law of the People's Republic of China, art. 69 (2).
[173] Patent Act of India, s. 47(3).
[174] Japan Patent Act, art. 69 (1).
[175] Patents Ordinance No. LXI,, s. 30 (5) (Pakistan).
[176] *Frearson v. Loe* (1878), 9 Ch. D. 48; *Micro Chemicals Ltd. v. Smith Kline & French Inter-American Corp.*, [1972] S.C.R. 506; *Merck & Co. v. Apotex Inc.*, [2007] 3 F.C.A. 588, par. 109.
[177] *Madey v. Duke University, United States Court of Appeal*, 307 F.3d 1351 (2002).
[178] *Harvard College v. Canada (Commissioner of Patents)*, (2002) 4 S.C.R. 45, par. 174.
[179] *Merck & Co. v. Apotex Inc.*, [2007] 3 F.C.A. 588, par. 109.
[180] Australian Government – Advisory Council on Intellectual Property, *Patents and Experimental Use*, October 2005, p. 28.
[181] Patent Act of India, s. 47(3).
[182] Patent Law of the People's Republic of China, art. 69 (2).
[183] Brazilian Industrial Property Law, art. 43.
[184] Decision 486, *supra* note 80 art. 53.
[185] *Canada – Patent Protection of Pharmaceutical Products*, 17 March 2000, WT/DS114/R
[186] Directive 2004/27/EC, *supra* note 127.

While not always limited in this manner, regulatory review exceptions are made to accelerate the sale of generic drugs. According to a Joint Committee of the Indian Government, this type of "provision has been made to ensure prompt availability of products, particularly generic drugs, immediately after the expiry of the term of the patent."[187] Moreover, as pointed out by a Japanese court, "[i]f under the Patent law such experiments are not [...] possible during the patent term, the third party cannot, as a result, freely exploit the invention for a substantial period of time even after the term of the patent expires. [...][S]uch extension of the patent term goes beyond what is expected under the patent law as benefits to be given to the patentee."[188]

The scope of provisions for regulatory review varies from country to country. Some countries have safe harbour provisions with a broad scope. This is the case in Canada where an individual may "make, construct, use or sell the patented invention solely for uses reasonably related to the development and submission of information required under any law of Canada, a province or a country other than Canada that regulates the manufacture, construction, use or sale of any product."[189] In the United-States, this provision has a narrower but still large scope: research that may result in information being filed under federal food and drug laws does not constitute infringement.[190] Hungary,[191] Italy,[192] Spain,[193] and Brazil[194] have adopted a similar approach.

Other countries have exceptions that are limited to acts showing the safety and efficacy of new compounds (e.g., exceptions proposed in Belgium, Netherlands, Sweden and the UK), rather than encompassing all research activity that may lead to a product eventually being submitted for regulatory review (e.g. Canada and the United States).[195] Some have no regulatory review exceptions at all (e.g. Argentina and Chile[196]).

A last, small, distinction must be made. Some countries allow the use of patents for regulatory requirements within the jurisdiction itself (e.g. the United-States), while in others, the exception may be used to satisfy domestic as well as foreign regulatory requirement (e.g. India)[197].

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[187] Joint Comm. Of the Rajya Sabha & the Lok Sabha, comm. 91, Report on the Patents (Second Amendment) Bill, 1999, (Comm. Print 2001) (India) cited in Shamnad Basheer & Prashant Reddy, "The "Experimental Use" Exception Through a Developmental Lens", (2010) 50 IDEA 831.

[188] *Ono Pharms. Co., Ltd. v. Kyoto Pharm. Indus., Ltd.*, 24 AIPPI J. 106 (1999) discussed in Background Information on Asia p. 24

[189] Patent Act of Canada, art. 55.2 (1).

[190] 35 U.S.C. § 271 (e)(1); *Merck KGaA v. Integra Lifesciences Ltd*., 545 U.S. 193 (2005).

[191] Trevor Cook, *A European Perspective as to the Extent to which Experimental Use, and Certain Other, Defences to Patent Infringement, apply to Differing Types of Research*, March 2006, p68 online: http://www.ipeg.com/_UPLOAD%20BLOG/Experimental%20Use%20for%20IPI%20Chapters%201%20to%209%20Final.pdf [Trevor Cook, *A European Perspective as to the Extent to which Experimental Use, and Certain Other, Defences to Patent Infringement, apply to Differing Types of Research*]

[192] *Ibid.*

[193] *Ibid.*

[194] Brazilian Industrial Property Law, art. 43.

[195] Trevor Cook, *A European Perspective as to the Extent to which Experimental Use, and Certain Other, Defences to Patent Infringement, apply to Differing Types of Research*, *supra* note 191.

[196] South American Report, *supra* note 73 p.66.

[197] Shamnad Basheer & Prashant Reddy, "The "Experimental Use" Exception Through a Developmental Lens" (2010) 50 IDEA 831

IV. Interactions between Matters of Patentability and Exceptions to Patentee's Rights

A. Commentary on major exclusions and exceptions

This section covers the major groups of exclusions and exceptions presented in the previous parts of our chapter. It presents the main motivations behind them along with relevant critiques. Case law and legal doctrine from selected countries are used to illustrate our discussion.

Invention definition – Exclusion of Fundamental Knowledge
Most countries require patentable subject matter to be inventions and specify that fundamental knowledge cannot be defined as an invention. While some countries achieve the same result though different means, all studied jurisdictions exclude fundamental knowledge from the patent regime.

This is a traditional exclusion within patent law.[198] The decision of the United States Courts of Appeal for the Federal Circuit in *Ariad* illustrate the importance of maintaining scientific norms such as "communalism," a notion based on the importance of collaborating and sharing fundamental results between members of the scientific community without restriction.[199]

However, the traditional exclusion of fundamental research from patentability has not remained unquestioned. In his historical account on "proposals for formal property rights in scientific discoveries," Robert Merges emphasizes two attempts to bring this type of research within the patent system.[200]

A proposal was introduced into the French Chamber of Deputies, by J. Barthemely in 1922.[201] If that proposal had been adopted, a scientist would have been able to claim part of the profits from the application of a patent based on his discovery of a fundamental principle.[202] Moreover, a scientist would have been able to "obtain a patent of principle. […] Anyone would be free to utilize the invention or discovery, so long as he or she paid royalties to the scientist who had discovered it."[203] The same year, another proposal made at the League of Nations' Committee on Intellectual Cooperation suggested a term of protection identical to that of Barthelemy's plan: life plus fifty years."[204]

Advocates for a protection regime for fundamental discoveries argue that there is a ""quasi-contractual obligation" to remunerate the discoverer of [a] principle."[205] Critics raise several objections: "First, it is very often difficult to trace the scientific origins of a particular industrial application. Second, there is a significant lag of time between the disclosure of a scientific discovery and the development of the first application […]. Third, very often it can be assumed that scientific disclosure will be missed by industrialists; they will thus end up paying royalties

[198] Robert P. Merges, "Scientific Innovation, Philosophy, and Public Policy", (1996) 13:2 Social Philosophy & Policy 145. [Robert P. Merges, "Scientific Innovation, Philosophy, and Public Policy"]
[199] *Ibid.*
[200] *Ibid.*
[201] *Ibid.*
[202] *Ibid.*
[203] *Ibid.*
[204] *Ibid.*
[205] *Ibid.*

for a scientific discovery which in fact, was not relied upon in creating their industrial application. [Moreover], the very significant burdens on scientific communication that a system of property rights would create represent perhaps, the most severe problem."[206] Finally, many of these critics argue that it is counter-productive to grant rights "for discoveries that scientist *would have made anyway.*"[207] Indeed, researchers are motivated by other incentives, such as reputation, and promotion. These arguments may explain why none of the studied jurisdictions have chosen to grant property rights over abstract ideas resulting from fundamental research through property rights.

Specific exclusions

Some specific exclusions having an impact on research may be classified into two different categories. The first category relates to the choice made by all studied jurisdictions to not protect results from fundamental research through property rights. The category includes scientific and fundamental principles, laws of nature, scientific literature, abstract concepts, intellectual activities, mathematical equations, game strategies and data presentations.

The distinction between fundamental knowledge and applied knowledge is not always clear. In fact, some argue that the relationship between fundamental knowledge and applied knowledge has changed over time and that the gap between a discovery and its commercialization is much shorter[208], and "commercial interest[s]" tend to intervene at an earlier stage."[209] This changing relationship between the two types of knowledge might explain why there has been some uncertainty regarding the nature of some inventions. This has been the case for biotechnological inventions[210] (especially DNA related inventions) and for computers.[211]

Moreover, research may be "guided both by understanding and by use",[212] thereby resulting in a mixture of fundamental and applied knowledge. Indeed, "[s]ome of the most important achievements, both in [fundamental] and applied research, have their origin in settings which include both."[213]

The last two paragraphs may explain why certain exclusions pertain to specific research sectors: some sectors (e.g. genetics, computers) are difficult to categorize within the traditional dichotomy of fundamental knowledge and applied knowledge. This could explain why some jurisdictions, for example, reject the doctrine of isolation in respect of genetic sequences.

Finally, a second category of exclusions will have a particular impact on the practices of biomedical researchers. This category includes methods of medical and surgical treatments, *in*

[206] *Ibid.*
[207] *Ibid.*
[208] Australian Government – Advisory Council on Intellectual Property, *Patents and Experimental Use*, October 2005, p.13; Robert P. Merges, "Scientific Innovation, Philosophy, and Public Policy", (1996) 13:2 Social Philosophy & Policy 145.
[209] Rebecca S. Eisenberg, "Patents and the Progress of Science: Exclusive Rights and Experimental Use" *supra* note 2, p. 1018.
[210] Michael S. Carolan, "From patent law to regulation: the ontological gerrymandering of biotechnology", (2008) 17:5 Environmental Politics 749 – 765.
[211] Brienna Dolmage, "The Evolution of Patentable Subject Matter in the United States" (2005-2006) 27 Whittier L. Rev. 1023; Sigrid Sterckx & Julian Cockbain, "the patentability of Computer Programs in Europe: An Improved Interpretation of Articles 52 (2) and (3) of the European Patent Convention".
[212] Nils Roll- Hansen, "Why the distinction between basic (theoretical) and applied (practical) research is important in the politics of science" *supra* note 5.
[213] *Ibid.*

vivo diagnostics as well life forms. Although these exclusions were initially conceived to protect medical practitioners in their practice (e.g. a doctor performing a diagnostic test on a patient) or to reflect the moral values of a particular society (e.g. patenting life forms is sometimes seen as a slippery slope that could lead to the exploitation of human beings), they can sometimes be invoked on behalf of biomedical researchers. For instance, the patenting of the transgenic Harvard Oncomouse, a genetically modified mouse useful for cancer research, was contested on the ground of morality in Europe and because it constituted a "higher life form" in Canada. Thus, it appears that these "medical exclusions", in a number of instances, could have the effect ensuring the ability of biomedical researchers to conduct research without fear of an infringement action.

Prior User Rights[214]

A prior user may be defined as an individual who has "actually used or worked [the invention] prior to the priority date."[215] Several conditions must be fulfilled before the rights of a prior user may be invoked: 1) a valid patent must have been granted to an individual, 2) the other individual must have been using the invention before the priority date, 3) this prior use does not constitute invalidating prior art, 4) this prior use continues after the grant of the patent and 5) the patent owner sues the prior user for infringement.[216] Prior user rights have been traditionally associated with first-to-file patent regimes.[217]

Proponents of prior user rights make several arguments. First, trade secrets become more attractive because of prior user rights.[218] As previously discussed, there are some advantages to concealing information from competitors. In jurisdictions where prior user rights exist, reliance on trade secrets to protect an invention becomes less risky if someone else patents the invention. In addition, advocates for prior user rights say that they do not decrease the incentive of obtaining a patent,[219] that they may decrease preventive applications of poor quality[220] and that the entire matter is one of fairness.[221] Critics reply that it encourages secrecy[222] and is a source of litigation.[223]

As explained below, countries try to strike a balance between incentives to invent and users' rights through the patent system, in order to optimize innovation. Because prior user rights diminish the costs associated with trade secret practices by allowing use of patents after it has

[214] For more information on the requirements for eligibility to prior user rights, please see the following articles: Keith M. Kupferschmid, "Prior User Rights : The Inventor's Lottery Ticket" (1993) 21 AIPLA Q. J. 213 [Keith M. Kupferschmid, "Prior User Rights : The Inventor's Lottery Ticket"]; Gary L. Griswold & F. Andrew Ubel, "Prior User Rights – A Necessary Part of a First-to-File System", (1992-1993) 26 J. Marshall L. Rev. 567. [Gary L. Griswold & F. Andrew Ubel, "Prior User Rights – A Necessary Part of a First-to-File System"]

[215] Charles Oppenheim, "Patent Novelty; proposals for change and their possible impact on information scientists", (1985) 10 Journal of Information Science 181 [Charles Oppenheim, "Patent Novelty; proposals for change and their possible impact on information scientists"].

[216] Keith M. Kupferschmid, "Prior User Rights : The Inventor's Lottery Ticket", *supra* note 214.

[217] Gary L. Griswold & F. Andrew Ubel, "Prior User Rights – A Necessary Part of a First-to-File System", *supra* note 214.

[218] Keith M. Kupferschmid, "Prior User Rights : The Inventor's Lottery Ticket", *supra* note 214; Gary L. Griswold & F. Andrew Ubel, "Prior User Rights – A Necessary Part of a First-to-File System", *supra* note 214.

[219] *Ibid.*

[220] Keith M. Kupferschmid, "Prior User Rights : The Inventor's Lottery Ticket", *supra* note 214.

[221] *Ibid.*; Gary L. Griswold & F. Andrew Ubel, "Prior User Rights – A Necessary Part of a First-to-File System", *supra* note 214.

[222] *Ibid.*

[223] *Ibid.*

been granted, this exception to patent rights transforms trade secrets into stronger protection mechanisms. This might make trade secrets more attractive, which tend to lower knowledge dissemination. Incidentally, reducing the dissemination of inventions could affect aggregate innovation, research for possible improvements and other forms of research.

Experimental Use

The effects of experimental use exceptions on research may be understood by analyzing its effects on fundamental knowledge and applied knowledge (as defined Part I). New applied knowledge may lead to questioning fundamental knowledge or to application of this knowledge in a new direction. The main purpose of the experimental use exception is to recognize this two-way connection between fundamental and applied knowledge.

The difference between fundamental knowledge and applied knowledge is not obvious in many situations.[224] Therefore, an experimental use exception may serve to compensate for patents granted on subject matter that might fall within the grey zone between fundamental knowledge and applications. From this point of view, an experimental use exception could make available for research fundamental discoveries that could also be considered a valuable research tool by some. For instance, genetic tools that are considered as fundamental knowledge (e.g. genes, etc.) in some jurisdictions could be made accessible for research by a broad experimental use exception while preserving lucrative applications (e.g., genes incorporated into a therapeutic).

As for the exception's effect on applications, it will vary according to its breath. If wide enough, an experimental use exception may make patented applied knowledge available for fundamental research, especially in the case of research tools. Thus, the experimental use exception is often viewed as having the role of promoting open academic research. Contrary to the *Bolar* exception, which is mostly used by private pharmaceutical companies (or universities working closely with them), this exception is perceived as ensuring the necessary freedom of research for scientific progress within the walls of academia. Moreover, as some jurisdictions have experimental use exceptions that cover experimental acts done for commercial purposes, this type of exception can make patented applied knowledge available for applied research.[225] From these observations, it is possible to conclude that experimental use exceptions will also affect research by influencing the availability of patented applied knowledge.

Detractors point to recent studies demonstrating that university researchers generally tend to ignore patents in their research practices,[226] and that private companies rarely launch lawsuits for patent infringement against academics in order to question the necessity of the experimental use exception. Moreover university research has become increasingly commercial and universities themselves now seek and enforce patents quite aggressively when it is to their own advantage. Thus the clear demarcation between "private, commercial research" and "public, non-commercial research" has disappeared during the 20th century, making this exception outdated in their view. They feel universities should not be allowed to benefit from an

[224] Australian Government – Advisory Council on Intellectual Property, *Patents and Experimental Use*, October 2005, p.19; Robert P. Merges, "Scientific Innovation, Philosophy, and Public Policy", (1996) 13:2 Social Philosophy & Policy 145.
[225] *Ibid*.
[226] Mark A. Lemley, "Ignoring Patents", (2008) Mich. St. L. Rev. 19 ; John P. Walsh, Wesley Cohen & Charlene Cho, "Where Excludability Matters: Material versus Intellectual Property in Academic Biomedical Research" (2007) 36 Research Policy 1184; Final report to the National Academy of Sciences' Committee Intellectual Property Rights in Genomic and Protein-Related Inventions, by John P. Walsh, Charlene Cho & Wesley Cohen, "Patents, Material Transfers and Access to Research Inputs in Biomedical Research", (2005).

exception intended to protect fundamental research.[227] It should be noted that the same argument on the disappearing frontier between fundamental research and applied innovations is thus used as a justification by both proponents and detractors of the exception.

Finally, government exceptions could also be used to create greater freedom from infringement for researchers.[228] For example, an experimental use exception could be combined with a governmental use exception that includes governmental affiliated research institutions. If designed with this in mind, research funded by governments that are exempt from patent infringement could allow some researchers to have access to patented knowledge when conducting research supported by government.[229]

Since experimental use exceptions currently in force vary "in […] nature, scope and judicial interpretation between the various members of the international community"[230] this is an area in which harmonization could make the state of the law clearer to the scientific community. Indeed, as international research collaborations tend to increase, harmonizing this exception would make the understanding of foreign law easier for scientists. Further, as research collaborations often cross national boundaries, harmonising experimental use exceptions would lower legal uncertainty over which law applies and hence lower transaction costs.

The benefits of harmonisation of the experimental use exception may be outweighed, in the opinion of certain countries, by their costs. First, policy makers would need to agree on whether the exception is limited to research on or includes research with the invention.[231] Second, developing countries may prefer broader exceptions as they build a research infrastructure, thus making agreement on the scope of these exceptions difficult.

Bolar exemption

Many jurisdictions have an exception that allows individuals to use a patented invention in order to satisfy regulatory requirements. As previously explained, regulatory review exceptions are generally made to accelerate the sale of generic drugs but may, as in Canada, apply in other settings.

Some countries with broad experimental use exceptions have narrower *Bolar* exceptions (e.g., the United Kingdom, where clinical trials are covered by the experimental use exception,[232] but not the regulatory review exception[233]), while countries with narrower experimental use exceptions tend to have extremely broad *Bolar* exceptions (e.g. Canada, where the scope of the experimental use exception is unclear and the United States). In these countries, the end result is the same: researchers in the health care field enjoy broad protection from patent

[227] David B. Resnik, "Patents and the Research Exemption", (2003) 299 Science 821.
[228] Sean O'Connor, "Enabling Research or Unfair Competition? De Jure and De Facto Research Use Exceptions in Major Technology Countries" Research Roundtable: Law & Economics of Innovation, 2008.
[229] *Ibid.*
[230] Richard Gold, Yann Joly & Timothy Caulfield, "Genetic Research Tools, the Research Exception and Open Science" *supra* note 152.
[231] *Ibid.*
[232] E. Richard Gold et al., "The Research or Experimental Use Exception: A Comparative Analysis", *(Montreal: Centre for Intellectual Property Policy / Health Law Institute, 2005) available on line : <* (http://www.cipp.mcgill.ca/data/newsletters/00000050.pdf*)> pp. 1- 52.*[E. Richard Gold et al., "The Research or Experimental Use Exception: A Comparative Analysis",]
[233] Trevor Cook, *A European Perspective as to the Extent to which Experimental Use, and Certain Other, Defences to Patent Infringement, apply to Differing Types of Research*, *supra* note 207.

infringement.[234] However, this general rule should be viewed with a degree of caution because it is not clear if the scope of the experimental use exception encompasses clinical trials in some countries (e.g. Argentina, etc.) or because there is no experimental use exception or regulatory review exception in others (e.g. Chile).

B. Commentary on Socio-Economic Issues

What emanates from this study on exclusions and exemption is a common will in all jurisdictions to strike a balance between incentives to invent and users' rights, in order to optimize innovation.

A first balance aims to be struck between secrecy and patents. For instance, the vast majority of jurisdictions require patents to be disclosed and thereby, encourage knowledge dissemination. However, many countries have prior user rights (e.g. United Kingdom, Canada, Mexico, Brazil, China, Indonesia, Japan, Pakistan, Korea and members of the Andean Community) and thus, strengthen trade secrets. Since trade secrets also have a high value[235], two protection mechanisms are offered to inventors. In the end, some authors have deemed these two mechanisms complimentary as "trade secret law complements patent law in earlier stages of the innovation process by allowing innovators to work on their ideas until they become patentable."[236] Moreover, it could be that patents "protect patentable inventions, and [trade secrets], the volumes of important, if not essential, collateral know-how associated with such inventions."[237]

A second balance might be needed between harmonization and diversification. For instance, differences in intellectual property have been observed and harmonization might play a positive role. Indeed, "[…] national innovation systems themselves are becoming internationalized, even if the institutions that support them remain country-specific."[238] As research and development initiatives tend to globalize, harmonization of national patent laws will make legal issues more accessible to researchers and make collaboration easier. For example, presumptions about whether a university researcher or the university holds a patent in different countries can complicate both the carrying on of joint research and the transfer of any results of the joint research. Other differences may also cause difficulty in ensuring that research collaborations - which the OECD recognizes in its recent Innovation Strategy are key to further innovation - operate smoothly, at least across international borders.[239]

[234] E. Richard Gold et al., "The Research or Experimental Use Exception: A Comparative Analysis", *supra* note 232.
[235] Anthony Arundel, "The relative effectiveness of patents and secrecy for appropriation" (2001) 30 Research Policy 611. Wesley Cohen, Richard Nelson & John Walsh, "Protecting their intellectual assests: approproability conditions and why U.S. manufacturing firms patent (or not)" (2000) NBER Working Paper Series No. 7552.
[236] Nisvan Erkal, "On The Interaction Between Patent Policy and Trade Secret Policy" (2004) Intelelctual Property Research Institute of Australia Working Paper No. 14/4.
[237] Karl F. Jorda, "Patent and Trade Secret Complementariness : An Unsuspected Synergy" (2009) 48 Washburn L.J. 1.
[238] Bo Carlsson, "Internationalization of innovation systems: A survey of the literature" (2006) 35 Research Policy 56.
[239] The OECD Innovation Stategy: Getting a Head Start on Tommorrow, May 2010, OECD Publishing.

However, some fear that harmonization might pre-empt the adoption of protective regimes specific to certain types of technologies, and that a "single, global regime would thus require a reduction in the diversity of the innovation systems themselves".[240]

Further, even within very similar fields, the effect of exclusions and exceptions on research may vary greatly. A good example of this phenomenon is with respect to patents over gene sequences. As used in the development of clinical genetic tests, patents seem not to provide a needed incentive in making new tests available.[241] Moreover, exclusive licensing does not appear to be essential to the marketing of genetic tests.[242] On the other hand, the use of gene sequences as a component of a therapeutic may require a patent to attract investment and development. Thus, excluding gene patents altogether would have significantly different effects in these two markets.

A third observed balance is that between patentees' rights and user's rights. Some argue that a stronger patent system – one with fewer exclusions and exemptions that permit researchers to conduct research without a licence – would increase innovation,.[243] Others argue that cumulative innovation may actually be hindered by some or too many patents.[244] Some have even argued that "subsidizing imitation may increase the economy-wide rate of technological progress."[245] Overall, there is no consensus on what strength patents ought to have in order maximize innovation.

Finally, striking a balance may depend on the level of economic development of different jurisdictions. Research resources and infrastructure have an impact on innovation, the ability to identify patent holders and enter into licences. According to a report from the OECD,[246] knowledge networks and human resources play an important role in that regard. Jurisdictions with higher research and infrastructure resources may seek one form of balance between patentees' rights and users' rights while those countries with fewer resources may wish to favour user rights more in order to build a scientific infrastructure.. The same can be said of countries with small or inexistent generic medicine production capacities: to fully take advantage of research exceptions and exclusions, jurisdictions must have some research resources. While it could be argued that exclusions and exceptions might help attract research and development resources in developing countries, such an argument is more applicable to a middle-income country than to one with limited scientific infrasture in the first place.

[240] Bo Carlsson, "Internationalization of innovation systems: A survey of the literature" *supra* note 238.
[241] Julia Carbone, E Richard Gold, Bhaven Sampat, Subhashini Chandrasekharan, Lori Knowles, Misha Angrist & Robert Cook-Degan, "DNA patents and diagnostics: not a pretty Picture", (2010) 28:8 Nature Biotechnology.
[242] *Ibid.*
[243] Dana Rohrabacher and Paul Crilly, "The case for a strong patent system" (1995) 8:2 Harv. J. L. & Tech. 263.
[244] James Bessen, "Holdup and licensing of cumulative innovations with private information" (2003) 82 Economics Letters 321.
[245] Toshihiko Mukoyama, "Innovation, imitation, and growth with cumulative technology" (2003) 50 Journal of Monetary Economics 361.
[246] The OECD Innovation Stategy: Getting a Head Start on Tommorrow, May 2010, OECD Publishing.

Conclusion

This chapter analyzed the exclusions and exception that impact on research and development. It examined international and regional legal agreements to identify concrete examples of each of these mechanisms.

What emanates from this study is that incentives to innovate vary in form according to jurisdiction; this is also the case for limitations. For instance, some countries offer stronger experimental use exceptions, while others offer stronger regulatory approval exceptions.

While incentives and limitations may vary, common points may be highlighted. First, all studied jurisdictions exclude fundamental knowledge from patentable subject matter. Second, a balance between disclosure and secrecy is also struck. Finally, most countries have exceptions (although they differ in nature) to accelerate the approval of generic pharmaceuticals for the market, which could otherwise be significantly delayed.

A balance between harmonization and space for diversity might be desirable. Perhaps, this could be attained by setting common objectives, while allowing different means to attain them. In any case, it is clear from this chapter that exceptions and exclusions are considered an integral part of a healthy patent regime in all jurisdictions studied. The tradeoffs sometimes differ, but there is a common will between jurisdictions to ensure that researchers can avail themselves of the necessary freedom to progress in their research. This policy choice is in line with one of the main function of intellectual property which is to promote research that is beneficial to society.

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