WIPO
WORLD
INTELLECTUAL PROPERTY
ORGANIZATION

E

SCP/29/3
ORIGINAL: ENGLISH
DATE: NOVEMBER 26, 2018

Standing Committee on the Law of Patents

Twenty-Ninth Session
Geneva, December 3 to 6, 2018

REFERENCE DOCUMENT ON RESEARCH EXCEPTION

Document prepared by the Secretariat

INTRODUCTION

1. At its twenty-eighth session, held in Geneva from July 9 to 12, 2018, the Standing Committee on the Law of Patents (SCP) agreed that the Secretariat would continue working on a draft reference document on exceptions and limitations, in accordance with the agreement reached at the twenty-sixth session of the SCP. In particular, it was agreed that the Secretariat would, *inter alia*, prepare and submit a draft reference document on the research exception to the twenty-ninth session of the SCP. In addition, it was agreed that the Secretariat would invite Member States to send any additional inputs for the preparation of the draft reference document (see document SCP/28/11, paragraph 21, first bullet point under "Exceptions and Limitations to Patent Rights").

2. Pursuant to the above decision, the Secretariat invited Member States and Regional Patent Offices, through its Note C. 8787, dated July 31, 2018, to submit to the International Bureau any additional inputs for the preparation of the draft reference document on research exception.

3. Accordingly, Annex I to this document contains the said draft reference document for the Committee's discussions at its twenty-ninth session to be held in Geneva from December 3 to 6, 2018. As mandated by the Committee, in the preparation of the draft reference document, the Secretariat made use of information submitted by the Member States to the twenty-ninth session of the SCP, available on the website of the SCP electronic forum at: http://www.wipo.int/scp/en/meetings/session_29/comments_received.html, as well as other information collected though the SCP activities, as indicated in document SCP/27/3.

4. The reference document contains the following sections: (i) overview of the research exception; (ii) objectives and goals of the research exception; (iii) research exception and international legal framework; (iv) research exception in the regional instruments; (v) national

implementation of the research exception; (vi) challenges faced by Member States in implementing the research exception; and (vii) results of implementation of the research exception. In addition, it contains an Appendix, in which various legal provisions on the research exception are compiled.

[Annex follows]

DRAFT REFERENCE DOCUMENT ON RESEARCH EXCEPTION

TABLE OF CONTENTS

APPENDIX

1. Overview of the Research Exception

1. Patents confer exclusive rights during a limited period to prevent others from, in general, making, using, offering for sale, selling or importing a patented invention without the patentee's consent. The grant of such rights is considered to be an incentive for investment in innovative activities and production of knowledge. However, in economic term, this creates deadweight losses.[1] To correct the potential inefficiencies of the market power created by such exclusive rights, a number of mechanisms are provided in the patent system.

2. In particular, to fine-tune the different interests among the stakeholders, subject to compliance with international obligations, provision of various exceptions and limitations to the rights in national/regional patent systems is allowed.[2] It is generally believed that granting full exclusive rights in all circumstances may not always meet the goal of promoting innovation and enhancing the public welfare in all circumstances. Therefore, the scope of the enforceable exclusive rights is carefully designed under national patent laws in order to strike the right balance between the legitimate interests of the right holders and the legitimate interests of third parties, who may be prevented from using the patented invention for a limited period of time.

3. Among those exceptions and limitations to the rights, a so-called "research exception" or "experimental use exception"[3] is one of the most widely provided exceptions in patent systems, either by statutory means or through case law. While the exact scope of the provisions differs under the national and regional laws, in general, the research exception enables researchers to examine the effects of patented inventions stated in the patents and improve such patented inventions without having to fear infringing the patent. Without such exception, it may occur that scientists are sued if they make use of the patented invention in the course of their research. Such a contribution to a positive environment for research activities is expected to facilitate the dissemination and advancement of technical knowledge and add to the development of technologies, thereby contributing to the objectives of the patent system.

2. Objectives and Goals of the Research Exception

4. Proponents of the research exception argue that the exception for research and experimental use is implicit in the patent system's *quid pro quo*, since no other reason would be able to explain the interest that the patent system places on the free availability of the disclosure of the invention.[4,5]

---

1 For general discussion on economic rational of the patent system, see Chapter II of the Report on International Patent System (SCP/12/3 Rev. 2).

2 Patentability or disclosure requirements, *inter alia*, are other mechanisms embedded in the system in the pre-grant phase.

3 The terminology used in how to call this concept is not unanimous: in some cases, the expression used is "research exemption", in others "research exception" and in others "experimental use exception"; in this paper, these terms will be used interchangeably.

4 Rebecca S. Eisenberg, 'Patents and the Progress of Science: Exclusive rights and Experimental use'. *Chicago Law Review* (1989), Vol 56, p. 1017. See also J. C. Lai et all "Intellectual Property and Access to Im/material Goods", 2016, p. 103.

5 Most patent laws require that the invention is described in a manner sufficiently clear and complete for the invention to be carried out by a person skilled in the art and, in certain jurisdictions, be described by indicating the best mode for carrying out the invention.

5. Patent holders are given exclusive rights to prevent others from exploiting the patented inventions and, in return for the exclusive rights, patent holders are required to disclose information relating to the invention. The disclosure of information is considered as an essential element of the patent system. It is the basis of the balance between inventor's interests and those of society. For each patent, applicants are required to provide technical details of the invention, which are made publicly available through the publication of a patent application after 18 months from its filing date.[6]

6. It is argued that some unauthorized use during the patent term must be permitted to verify the veracity of the patent disclosure and whether it is sufficient for the purposes of enablement. In this regard, professor Bently explains that the "experimental use" exception is needed to maintain the functioning of the patent system itself. He explains:

> *"As it is a universal premise of modern patent systems that the patentee disclose the invention to the public so that they can perform the invention, it is clearly necessary that persons can experiment with the invention to ascertaining whether it in fact works (and is sufficiently disclosed). As patent offices do not undertake this task, this freedom must be conferred on competitors, as it is they who have the incentive to investigate and ultimately challenge the validity of the patent. Moreover, this capacity to investigate the invention must be given from the moment the patent is granted. After all, there would be no point in requiring these competitors to wait until after the patent had lapsed before they could challenge the patent."* [7]

Box 1. Policy objectives of the exception in Canada

"When inventors submit a patent application they agree to the disclosure of their invention. An experimental use exception permits other individuals to investigate that invention, making use of that disclosure. As such it is part of the balance of rights and obligations under the patent system".[8]

7. In this regard, the responses from some countries to the Questionnaire on Exceptions and Limitations to Patent Rights, carried out within the WIPO Standing Committee on the Law of Patents (SCP) (hereinafter referred to as "the Questionnaire") also state that third parties should be allowed to work the invention in order to better understand the contents and the stated effects of a patented invention in order to, for example, acquire knowledge, facilitate licensing or challenge the validity of patents.[9]

8. In addition, the "balancing" dimension is also used to explain the rational of the research exceptions. That is, for the purpose of serving the public interest as a whole, this exception is intended to provide appropriate balance between the interest of producers and users of technological knowledge as to maximize the social benefits. As most of the inventions (if not all) build on prior research or knowledge, not to allow other researchers to use patented inventions in any way for the entirety of the

---

6 Public disclosure after 18 months is the norm in most jurisdictions. However, timing may be different in certain countries.

7 Professor L. Bently et all. "Exclusions from Patentability and Exceptions and Limitations to Patentees' Rights, SCP/15/3. Bently further explains that "[t]his justification for the experimental use exception would, of course, justify only a narrow exception to experiment "on the subject matter" of the invention. It would, however, be completely compatible with experiments which ultimately have a commercial purpose. After all, the competitor's motivation is to compete." p.59, available at: http://www.wipo.int/edocs/mdocs/scp/en/scp_15/scp_15_3-annex1.pdf.

8 In the response of Canada to the Questionnaire.

9 See, e.g, the responses to the Questionnaire from the Republic of Korea and the Russian Federation. In certain cases, a patentee may have better opportunities to license or assign his/her patented invention if third parties can examine the effect of the patented invention before such transaction. See, e.g. the response to the Questionnaire from the Russian Federation.

patent protection is argued to be a disproportionate restriction on follow-on invention.[10] In particular, the argument is that uses of a patented invention for research and science directed to producing new inventions should not be restricted. If the overall social goal is to maximise invention, then this is one area where patent laws should be limited: otherwise patent laws would end up restricting precisely the sorts of activity that they are intended to maximise.[11] Accordingly, in many countries, the public policy objectives for the provision of the experimental use or research exception are to promote scientific research and technological progress and to encourage inventive activities.[12]

Box 2. Policy objectives of the exception in the Republic of Korea

"To better understand the contents and effects of a patented invention, a third party shall be allowed to work the invention. Also, there are possibilities of developing an advanced invention based on the working of the patented invention. The working of a patented invention contributes greatly to the advancement of technologies and as long as a product developed based on the results of the working of the invention is not put on the market, the patentee does not suffer a direct loss."[13]

9. In this regard, some commentators also note that, as a matter of public policy, the cumulative nature of technological development in most sectors require the preservation of the ability to innovate and that a "patent regime that impedes follow-on innovation will defeat its very purpose".[14] Similarly, the response from China to the Questionnaire explained that "scientific and technological innovations are always carried out on the basis of prior art" and therefore, "if use of relevant patents for scientific research and experimental purposes would be only possible with prior consent by the patent right holders, it may hinder the research and development process, and would thus not be conducive to scientific and technological progress, and contrary to the legislative purpose of patent laws." In the response of Brazil, it is explained that, since the patent system aimed at stimulating research and innovation by providing a framework which ensured that the benefits of inventions accrue to society as a whole, the purpose of the research exception is "to limit the rights granted by a patent in order to allow the development of scientific or technological research, thereby striking the right balance between right holders' and third parties' interests while fostering the advancement of the society".[15] Reponses from other countries generally highlight the importance of freedom of research without fear of patent infringement.[16]

10. Some countries, which include teaching within the scope of the research exemption, note that the exception also promotes education and enhanced the level of teaching.[17]

---

10 J. C. Lai et all "Intellectual Property and Access to Im/material Goods", 2016, p. 103.

11 Professor L. Bently et all. "Exclusions from Patentability and Exceptions and Limitations to Patentee's' Rights, SCP/15/3, p.59.

12 For example, see the responses to the Questionnaire on exceptions and limitations to patent rights from Algeria, Austria, Bhutan, Brazil, Germany, Honduras, Hungary, Italy, Japan, the Netherlands, Poland, Portugal, Republic of Korea, Serbia, Spain, Sweden, Switzerland, Uganda, Ukraine, the United Kingdom and Zimbabwe. In this regard, the response from Norway stated that "the exclusive right conferred by a patent right is only meant to include the commercial value of the invention", but not "the use of the invention as a knowledge basis for further research and development". The response form Germany stated " that the research exception "[…] limits patent protection and facilitates the development of new technologies on the basis of patented inventions."

13 In the response of the Republic of Korea to the Questionnaire.

14 See, e.g., Correa, C., 'The International Dimension of the Research Exception'. AAAS/SIPPI Paper, January 2004, p.16.

15 See also the responses from Canada, Kyrgyz Republic, the Russian Federation, Sri Lanka and the United States of America to the Questionnaire on exceptions and limitations to patent rights, available at: http://www.wipo.int/scp/en/exceptions/.

16 See, e.g, the responses to the Questionnaire from Austria, Switzerland and the Russian Federation.

17 See, e.g., the responses to the Questionnaire from Indonesia and Honduras.

Box 3. Policy objectives of the exception in Costa Rica

"Perhaps the main challenge is precisely to implement this academic exception such that the patent document serves as a useful instrument in the teaching and learning process and as a source of inspiration and creativity for generating new knowledge. This in turn requires an effort to educate faculty and staff so that patents become resources used above all in classrooms and laboratories"[18]

3. Research Exception and International Legal Framework

11. No international treaty expressly addresses the research exception. However, Article 30 of the TRIPS Agreement lays down general principles regarding the exceptions and limitations to the rights which may be provided by the WTO Members. Since Articles 30 is a permissive ("may") provision, Members are permitted, but not obliged, to provide those limited exceptions to the rights. The provision states:

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

12. The WTO Dispute Settlement Panel in *Canada - Patent Protection of Pharmaceutical Product* case[19] has referred to the research exception in conjunction with its ruling on Article 30 of the TRIPS Agreement. Specifically, the Panel stated:

> "We may take as an illustration one of the most widely adopted Article 30-type exceptions in national patent laws - the exception under which use of the patented product for scientific experimentation, during the term of the patent and without consent, is not an infringement. It is often argued that this exception is based on the notion that a key public policy purpose underlying patent laws is to facilitate the dissemination and advancement of technical knowledge and that allowing the patent owner to prevent experimental use during the term of the patent would frustrate part of the purpose of the requirement that the nature of the invention be disclosed to the public. To the contrary, the argument concludes, under the policy of the patent laws, both society and the scientist have a "legitimate interest" in using the patent disclosure to support the advance of science and technology. While the Panel draws no conclusion about the correctness of any such national exceptions in terms of Article 30 of the TRIPS Agreement, it does adopt the general meaning of the term "legitimate interests" contained in legal analysis of this type."[20]

---

18 Juan Carlos Carvajal M., Technological Institute of Costa Rica (ITCR), cited in the submission of Costa Rica.
19 WTO document WT/DS114/R. For the summary of the case, see document SCP/13/3, pp. 21 and 22.
20 WTO document WT/DS114/R, para 7.69.

13. While the Panel did not draw a clear conclusion about the consistency of the research exception with Article 30 of the TRIPS Agreement, many commentators believe that, the Panel infers such an exception would be regarded as "limited exception" within the meaning of that provision.[21]

14. Relatedly, in the negotiating records of the TRIPS Agreement, the first drafts of the provision that was to become Article 30 contemplated to include an illustrative list of exceptions including a "scientific use" exception. Ultimately, the illustrative list approach was abandoned in favor of a more general wording as provided in current Article 30 of the TRIPS Agreement and the negotiating records of the TRIPS Agreement provided no explanation of the reason for this decision.[22]

4. Research Exception in the Regional Instruments

15. Several regional instruments regulate, *inter alia*, the research exception. These are: Decision № 486 establishing the Common Industrial Property Regime for the Andean Community (hereafter "Andean Community Decision № 486"); Agreement Revising the Bangui Agreement of March 2, 1977, on the Creation of an African Intellectual Property Organization (1999) (hereafter "Bangui Agreement",); Patent Regulation of the Cooperation Council for the Arab States of the Gulf; Patent Regulations under the Eurasian Patent Convention; and North American Free Trade Agreement.[23]

16. The wording of the relevant provisions differs under these instruments and no further interpretive guidelines and jurisprudence has been found in relation to any of those provisions delineating the potential scope of those exceptions under the relevant regional instruments.[24]

---

21 E.g., see Professor L. Bently et all. ": Exclusions from Patentability and Exceptions and Limitations to Patentee's' Rights, SCP/15/3, Annex I, p. 39, available at: http://www.wipo.int/edocs/mdocs/scp/en/scp_15/scp_15_3-annex1.pdf; or Correa, C., 'The International Dimension of the Research Exception'. AAAS/SIPPI Paper, January 2004, p.19.

22 WTO document WT/DS114/R, para 7.70.

23 As regards Europe, Article 27 of the Agreement relating to Community patents (89/695/EEC) (adopted 15 December 1989) provided for a research exception. Although the Agreement has not entered into force, some contracting states have brought their national laws in line with the Agreement. Further harmonizing effect is expected from the Agreement on a Unified Patent Court (UPC) which will, *inter alia*, harmonize substantive patent law relating to the scope and limitations of the rights conferred as well as the remedies in cases of infringement as regards the European patents and European patents with unitary effect. As regards the research exception, Article 27 of Chapter V of the UPC Agreement states: "The rights conferred by a patent shall not extend to any of the following: "[…] (b) acts done for experimental purposes relating to the subject matter of the patented invention; […]". As of November 25, 2018, the UPC has not entered into force.

24 However, at least in relation to the Bangui Agreement, UNCTAD – ICTSD Policy Brief stated that, in the absence of any further qualifying language, the language contained in this legal instrument would provide a safe harbor against patent infringement for practically all scientific and technological research activities. UNCTAD – ICTSD Policy Brief N7, March 2010. The Research and Experimentation Exceptions in Patent Law: Jurisdictional Variations and the WIPO Development Agenda.

Table 1. REGIONAL INSTRUMENTS	
Andean Community Decision № 486[25]	Article 53: "The owner of the patent may not exercise the right referred to in the foregoing Article in relation to the following acts: [...] (b) acts performed for exclusively experimental purposes on the subject matter of the patented invention; (c) acts performed solely for the purposes of teaching or scientific or academic research;
Patent Regulation of the Cooperation Council for the Arab States of the Gulf [26]	Article 14(1): "The rights under the patent shall not extend to: 1) Acts done particularly for scientific research purposes."
Bangui Agreement [27]	Article 8(1)(c): "(1) The rights deriving from the patent shall not extend [...] (c) to acts in relation to a patented invention that are carried out for experimental purposes in the course of scientific and technical research;"
Patent Regulation of the Eurasian Patent Convention[28]	Rule 19: "The following cases of the use of the patented invention shall not constitute an infringement of the Eurasian patent: [...] - use for scientific research and experimental purposes;"

25 Andean Community comprises Bolivia, Colombia, Ecuador and Peru.

26 The Cooperation Council for the Arab States of the Gulf comprises the State of the United Arab Emirates, the State of Bahrain, the Kingdom of Saudi Arabia, the Sultanate of Oman, the State of Qatar, and the State of Kuwait.

27 Agreement Revising the Bangui Agreement of March 2, 1977, on the Creation of an African Intellectual Property Organization, 1999. Member States of OAPI are Benin, Burkina Faso, Cameroon, Central African Republic, Chad, Congo, Ivory Coast, Equatorial Guinea, Gabon, Guinea, Guinea-Bissau, Mali, Mauritania, Niger, Senegal, Togo and Comoros.

28 Member States of the EAPO are Turkmenistan, the Republic of Belarus, the Republic of Tajikistan, Russian Federation, the Republic of Azerbaijan, the Republic of Kazakhstan, Kyrgyzstan and Armenia.

5. National Implementation of the Research Exception

5.1 Legal framework regulating the research exception

17. In total, 113 countries have been identified to provide for the research exception under their respective legal frameworks. In most of those countries, there is a specific statutory provision on this exception within respective IP or patent legislation. In common law countries, the research exception is provided through case law, and in some of those countries, the exception has been also codified in the statutory law.[29] Appendix to this document contains provisions of national and regional laws on the research exception.

Table 2. List of countries which provide for research exception
Albania, Algeria, Andorra, Antigua and Barbuda, Argentina, Armenia, Australia, Azerbaijan, Barbados, Belarus, Belgium, Belize, Bhutan, Bolivia, Bosnia and Herzegovina, Botswana, Brazil, Bulgaria, Burkina Faso, Canada, China, Hong Kong (China), Colombia, Costa Rica, Croatia, Cuba, Cyprus, Czech Republic, Democratic People's Republic of Korea, Denmark, Dominica, Dominican Republic, Ecuador, Egypt, El Salvador, Estonia, Ethiopia, Finland, France, Germany, Ghana, Greece, Guatemala, Honduras, Hungary, Iceland, India, Indonesia, Ireland, Israel, Italy, Japan, Jordan, Kazakhstan, Kenya, Kyrgyzstan, Latvia, Lebanon, Liberia, Lithuania, Luxembourg, Malaysia, Malta, Mauritius, Mexico, Mongolia, Morocco, Mozambique, Namibia, Netherlands, New Zealand, Nicaragua, Norway, Oman, Pakistan, Panama, Papua New Guinea, Paraguay, Peru, Philippines, Poland, Portugal, Republic of Korea, Republic of Moldova, Romania, Russian Federation, Saint Lucia, Sao Tome and Principe, Saudi Arabia, Serbia, Singapore, Slovakia, Slovenia, Spain, Sri Lanka, Sweden, Switzerland, Tajikistan, Thailand, The Former Yugoslav Republic of Macedonia, Tonga, Trinidad and Tobago, Tunisia, Turkey, Uganda, Ukraine, United Kingdom, United States of America, United Republic of Tanzania, Uruguay, Uzbekistan, Viet Nam and Zambia.

18. While in most of the countries listed in Table 2, there is a separate provision on the research exception, in some countries, it is combined with the regulatory review exception into a single provision.[30]

19. In some other countries the text of the relevant law does not contain the specific provision on the research exception. However, it should not necessarily infer that the use of the patented invention for research and experimental purposes in those countries would necessarily infringe the patent. To achieve the same policy goal, the scope of exclusive rights can be limited to acts carried out for commercial purposes, i.e., there is only infringement where the use is commercial.[31] Thus, legal framework regulating the research exception varies among countries reflecting different legal tradition.

---

29 These common law countries include: Australia, Canada, and New Zealand.

30 These countries are: Bosnia and Herzegovina, Croatia, Czech Republic, Hungary, Iceland, Portugal, Republic of Korea, Serbia, Slovakia, Slovenia, The Former Yugoslav Republic of Macedonia, and Uruguay and Viet Nam. For further information on the regulatory review exception, see document SCP/28/3.

31 Article 30.1. of ORDINANCE No. 89-019 of July 31, 1989 introducing a regime for the protection of industrial property in the Democratic Republic of Madagascar states that "[t]he rights stemming from the patent or the invention author's certificate shall extend only to acts performed for industrial and commercial purposes."

5.2 Scope of the research exception

20. Although the general policy objectives of the research exemption under national laws are more or less in line with the description above, the texts of those provisions are not always exactly the same. For example, the following national provisions can be indicative of the texts variations:

- "Exempted from the provisions as referred to in paragraph (1) and paragraph (2) if the use of said Patent is for the sake of education, research, experiment, or analysis, as long as it does not harm the normal interest of the Patent holder."[32];

- "The rights of the patentee shall not extend to:
  [...]
  b) the use of the patented invention solely for the purposes of scientific research & experimentation;"[33]

- "The grant of a patent under this Act shall be subject to the condition that –
  [...]
  (3) any 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;"[34]

- "The exclusive right shall not apply to:
  [...]
  (3) use in experiments relating to the invention as such;"[35]

21. Thus while there are common components of the research exception among national laws, the differences among those provisions in terms of their expression can result in different interpretation and coverage of the exception.

22. In general, the analysis of laws and jurisprudence indicates that there are certain characteristics that define the scope of the exception in various countries. Specifically, the scope of the exception can be defined through the following:

- the purpose of the research or experiment;
- whether it allows an experiment or research with a commercial intent; and/or
- how the experimental act relates to the patented invention (i.e., whether it allows for experiment or research *with* or *on* a patented invention)

23. The rest of this Section will describe those characteristics that define the scope of the research exception in various countries.

The purpose of the research or experiment

---

32 Article 16 (3) of the Patent Law №. 14 of 1 August 2001 of Indonesia.
33 Section 25 (1) (b) of the Industrial Property Law (Proclamation) № 123 of 10/05/1995 of Ethiopia.
34 Section 47 of the Patent Act № 39 of 20 April 1970 of India (as last amended in 2005).
35 Section 3 (2) of the Patents Act (Act № 1967/550 of 15 December1967 of Finland (as amended up to Act № 2013/101 of 31 January 2013).

24. In many countries, where the experimental use and/or research exception is contained in statutory laws, the relevant provision generally states that the right conferred by a patent does not extend to, for example: activities for "experimental or research purposes"[36], acts for "scientific research or experiment"[37], use for "scientific research and experimental purposes",[38] acts performed for "experimental purposes"[39], acts for "scientific research purposes"[40], acts carried out for "experimental purposes, in connection with scientific or technological studies or researches"[41] or "using inventions for the purposes of evaluation, analysis, research, teaching, testing and trial production".[42]

25. In addition, some countries' provisions state that the activities are only exempted if their purpose is "exclusively" experimental or "only" for research purposes. The provisions found in national laws include, for example, "exclusively for trial or experimental purposes"[43], "solely serving for research on the patented subject matter, including the product obtained directly as a result of using the patented process"[44] or "done only for research and experimental purposes relating to a patented invention."[45], activities for "making or using for purely experimental purposes or for scientific research"[46], acts "performed merely for experimental purposes relating to the subject matter of the invention"[47], activities "only for experimental purposes"[48], acts done merely for the purpose of scientific research[49] and "acts done only for the purposes of scientific research".[50]

26. While the words "research" and "experiment" are commonly used in various laws, in majority of jurisdictions, no further substantive guidance was provided on how these terms would be defined under the relevant laws. Nevertheless, in some jurisdiction, such guidance can be found in the statutory or case law. For example, Section 119C of the Patents Act[51] of Australia provides that acts done for experimental purposes relating to the subject matter of the invention are exempted from infringement, whereas "experimental purposes" include, but not limited to:

(a) determining the properties of the invention;
(b) determining the scope of a claim relating to the invention;
(c) improving or modifying the invention;
(d) determining the validity of the patent or of a claim relating to the invention;

---

36 See Article 69(1) of the Japanese Patent Act and Article 20(2) of the Law on Patents and Utility Models Registration of Bulgaria.
37 See Article 17(2) of the Law on Inventions, Utility Models and Industrial Designs of Armenia, Article 33-b of the Invention Law of the Democratic People's Republic of Korea, Article 13 of the Patent Law of the Kyrgyz Republic, Article 1359(2) of the Civil Code of the Russian Federation.
38 Article 31(2) of the Law of Ukraine "On the Protection of Rights to Inventions and Utility Models" and Rule 19 of the Patent Regulations under the Eurasian Patent Convention.
39 See Section 119C of the Patents Act of Australia, Section 3(3)(iii) of the Consolidated Patents Act of Denmark; Article L613-5 of the Intellectual Property Code of France, Section 11(2) of the Patent Act of Germany, Article 68(1)(a) of the Industrial Property Code of Italy, Section 11(a)(4)(iii) of the Industrial Property Law of Oman, Article 22 of Law 50/2008 on the Protection of Inventions of the Republic of Moldova and Article 75(b) of the Turkish Patent Decree Law.
40 See Section 58 of the Industrial Property Act 2008 of Kenya and Article 8.4(c) of Law 4/2001 of Sao Tome and Principe.
41 See Article 43, paragraph II of Law n.9.279 of Brazil.
42 Article 125(2) of the Law on Intellectual Property 2005, amended and supplemented in 2009, of Viet Nam.
43 Article 102 of the Industrial Property Code (CPI) of Portugal.
44 Article 53(3) of the Patent Act of the Netherlands.
45 Section 21(4)(d) of Patents, Industrial Designs and Trademarks Act 2002 of Mauritius.
46 Section 27(3)(iii) of the Patent Act of Cyprus.
47 Article 38(b) of Law 9947 "On Industrial Property" of Albania.
48 Section 13(4) of the Industrial Property Act of Bhutan and Section 31(5)(c) od Patents Ordinance 2000 of Pakistan.
49 Article 12(1) of the Ordinance No. 03-07 of July 19, 2003 on Patents of Algeria.
50 Section 86(1)(i) of the Intellectual Property Act No.36 of 2003 of Sri Lanka.
51 Section 119C of the Patents Act 1990.

(e) determining whether the patent for the invention would be, or has been, infringed by the doing of an act.

27. Similarly, in New Zealand, the Patents Act provides an experimental use exception in Section 143, which provides non-exhaustive list of acts that are considered to have the experimental purpose.[52]

28. In the United Kingdom, guidance on the interpretation of the term "experimental purposes" is provided by case law.[53] In *Monsanto Co v Stauffer Chemical Co and Another*[54], it was held that only experiments which generate genuinely new information are covered by the exemption, for example, trials carried out in order to discover something unknown or to test a hypothesis. The exemption does not extend to experiments which are designed to verify existing knowledge (for example, to demonstrate to a third party that a product works as claimed), and consequently, clinical trials to obtain regulatory approval are not acts done for experimental purposes. However, in *CoreValve v Edwards Lifesciences*[55], where "a patented pharmaceutically active substance is used in clinical trials with the aim of finding whether and, where appropriate, in what form the active substance is suitable for curing or alleviating certain *other* human diseases" (i.e second indication), it is considered as a legitimate act for experimental purposes. Further, in another case[56], it was held that "experiments for the purposes of litigation are exempted [...] if they relate to the subject matter of the invention found in the claims of the patent alleged to be infringed, in the sense of having a real and direct connection with it."

Box 4. Monsanto Co. *v.* Stauffer Chemical Co. and Another

"Trials carried out in order to discover something unknown, or to test a hypothesis, or in order to find out whether something which is known to work in specific conditions will work in different conditions [...] can fairly be regarded as experiments". But 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 body such as the PSPS or ACAS, that the product works as its maker claims were not to be regarded as acts done "for experimental purposes".[57]

29. In Germany, Section 11(2) German Patent Act provides for experimental use exemption.[58] Two decisions of the Federal Court of Justice, *Clinical Trial I*[59]and *Clinical Trial II,*[60] clarified the scope of the exception in that country. In *Clinical Trial I*, the Court stated that "any systematic procedure aimed at obtaining new information is considered an experiment". According to the Court, the term must be interpreted broadly and, as a rule, covers all experimental acts, irrespective of the motivation and the

52 Section 143(2) of the Patents Act 2013 of New Zealand reads as follows: "((1) It is not an infringement of a patent for a person to do an act for experimental purposes relating to the subject matter of an invention. (2) In this section, act for experimental purposes relating to the subject matter of an invention includes an act for the purpose of—(a) determining how the invention works: (b) determining the scope of the invention: (c) determining the validity of the claims: (d) seeking an improvement of the invention (for example, determining new properties, or new uses, of the invention)."

53 Section 60(5)(b) of the Patents Act of the United Kingdom states "60(5) An act which, apart from this subsection, would constitute an infringement of a patent for an invention shall not do so if – (b) it is done for experimental purposes relating to the subject-matter of the invention;"

54 Monsanto Co v Stauffer Chemical Co and Another [1985] RPC 515.

55 CoreValve v Edwards Lifesciences [2009] EWHC 6 Pat Ct.

56 Smith Kline & French Laboratories Ltd vs Attorney General (1991) 4 TCLR 199.

57 Monsanto Co v Stauffer Chemical Co and Another [1985] RPC 515, p. 517.

58 Section 11 (2) of the German Patent Act states "11. The effect of a patent shall not extend to: [...] 2. acts done for experimental purposes relating to the subject-matter of the patented invention;"

59 BGH, judgement of 11 July 1995 – X ZR 99/92 – *Klinische Versuche I*.

60 BGH, judgement of 17 April 1997 – X ZR 68/94 – *Klinische Versuche II*.

purpose for which the knowledge gained is ultimately intended.[61] Therefore, experiments, tests or trials, etc. aimed at removing an existing uncertainty (e.g. by finding something unknown or testing a hypothesis) may be considered.[62]

30. In the Netherlands, in accordance with the case law, the research exception applies if it is justified by the aim of the research.[63] Aims qualifying as justification are genuine scientific research on the invention and aims that follow from the objectives of the Netherlands Patent Act, such as investigating whether the invention can be put into practice or investigating whether the invention can be improved (realizing technical progress). In the accompanying parliamentary papers for the introduction of the research exception, "research was explained to include scientific research, also in or for the business".

31. According to the Spanish legal doctrine[64] and case law[65], the purpose of the exception is to establish rules that strike a balance between conflicting interests, limiting or restricting the subjective rights, and therefore to be interpreted in a restrictive manner. Consequently, the exception must be understood as imposing two requirements: (i) acts must be carried out for the purposes of experimentation or trial and must be of an exclusively technical or scientific nature; and (ii) they must relate to the subject matter of the patented invention, i.e., they must be carried out "on", and not just "with", the invention itself. Accordingly, experimental acts that do not have the exclusive purpose of improving or consolidating technical aspects relating to inventions *per se* must be excluded from the scope of the exception.

32. In Japan, one generally accepted theory is that "experiments or research" that are exceptions to the patent rights should be limited to experiments and research conducted for the purpose of "advancing the technology", i.e. limited to activities such as patentability searches, function searches, and experiments for the purpose of achieving improvements and developments.[66]

33. In the Russian Federation, the exception applies to acts for conducting scientific research or experiment. The term "scientific (research) activity" is defined in the national law[67] as an "activity aimed at obtaining and applying new knowledge", including both "fundamental scientific knowledge" and "applied scientific knowledge". Further, the term "experimental and development works" is defined as an "activity based on knowledge acquired as a result of conducting scientific research or derived from practical experience, and aimed at preserving life and human health, creating new materials, products, processes, devices, services, systems or methods, and developing them further". While that law does not provide a legal definition of the term "scientific experiment", it is considered to be meant a "method of learning which can help in investigating real phenomena under controlled and managed conditions". In accordance with the response from the Russian Federation, "the distinction between scientific research and experimentation is that with research, study is undertaken of the subject matter in its pure form (without any additional influence thereon), whereas with experimentation, the subject being studied is placed under certain conditions, i.e., under a certain influence from external forces."

---

61 BGH, *Klinische Versuche I and II*.

62 Scharen, loc.cit., Sec.11 marginal no. 6. See also the submission of Germany to the SCP/28, available at: http://www.wipo.int/scp/en/meetings/session_29/comments_received.html. For further findings of the Court in *Clinical Trial I* and *Clinical Trial II*, see paragraph 42 of this paper.

63 Supreme Court, 18 December 1992, BIE 1993/81 (ICI/Medicopharma).

64 Fernández-Nóvoa, C.; Otero Lastres, O.L.; y Botana Agra, M.: Manual de la Propiedad Industrial, Marcial Pons, 2009, p.168.

65 *Passim*, Supreme Court Ruling No. 39/2012 (Civil Chamber, Division No.1) of February 10, 2012.

66 See the submission of Japan to the SCP/29, available at: http://www.wipo.int/scp/en/meetings/session_29/comments_received.html.

67 Article 2 of Federal Law No. 127-FZ of August 23, 1996, "On Science and State Science and Technology Policy".

34. The research exception provision in Swiss law also states that the exception covers acts undertaken for research or experimental purposes "in order to obtain knowledge on the subject-matter of the invention including its possible uses; in particular, any scientific research concerning the subject-matter of the invention" is permitted.[68] The Patent Law of Israel states that an "an experimental act in connection with the invention, the objective of which is to improve the invention or to develop another invention" does not constitute "exploitation of an invention". The District Court of Tel Aviv ruled that the law permitted experimental operations, which used existing and patent protected procedures or products in order to improve the process or product, or in order to develop another process or product.[69] In some other countries, the purpose of the research is not determinative of the scope of the relevant exception. For example, in Slovenia, acts done for research and experimental purposes of any kind relating to the subject matter of the patent "irrespective of their final purpose" is permitted under the exception.[70]

Table 3. Different laws provide different purposes for conducting research under the exception:
- Determine how the patented invention works
- Determine the scope of the patented invention
- Determine the validity of the claims
- Seek an improvement to the patented invention
- Invent around the patented invention
- Investigate unknown effects or new uses of the patented invention
- Obtain clinical trial data for marketing authorization

Commercial and/or non-commercial propose of the research or experiment

35. Another important criteria delineating the scope of the research exception is whether it covers experimental acts undertaken for a commercial purpose.

36. In some countries, the text of the research exemption explicitly states that the exemption is applicable when the experiment was made without commercial or gainful intent. For example, Article 36(a) of the Law on Patents and Utility Models of Argentina states that the right conferred by a patent shall not have any effect against:

> " (a) a third party who, in the private or academic sphere and for *non-commercial purposes*, engages in scientific or technological research for purely experimental, testing or teaching purposes, and to that end manufactures or uses a product or a process identical to the one patented." (emphasis added)

37. Another example is found in Article 34 of the Patent Law of Romania:

> "The following acts shall not constitute infringements of the rights provided in Art. 32 and Art. 33:

---

68 Article 9(1)(b) of the Federal Act of 25 June 1954 on Patents for Inventions (status as of 1 January 2017).
69 M.C.P. 19682/05, Transkaryotic Therapies INC vs. Genzyme Corporation (2006) Nevo.
70 Article 19 b) of the Industrial Property Act (ZIL-1-UPB3) of Slovenia (as amended up to 6 December 2013).

e) use of the subject-matter of the patented invention for exclusively *non-commercial experimental purposes*" (emphasis added)

38. In some other countries, the provision explicitly states that the research exemption is applicable also for acts anticipating a future commercial exploitation. For instance, Section 44 (a) of the Industrial Property Act of Uganda states:

"It is not an infringement of a patent to use the patented invention without the authorization of the patent holder in any of the following circumstances:
[...]
(a) to carry out any acts related to experimental use or research on the patented invention, *whether for scientific or commercial purposes*;" (emphasis added)

39. Similarly, Section 12 (4)(a) (iii) of the Zanzibar Industrial Property Act states that the

"The rights under the patent shall extend:
[...]
(iii) to acts done relating to experimental use on or relating to the patented invention, *whether for scientific or commercial purposes*;" (emphasis added)

40. In many other countries, however, the provisions do not expressly specify whether activities undertaken with commercial intent are encompassed within the exception. In that regard, courts in some countries provided some guidance. In the United Kingdom, the court in *Monsanto Co v Stauffer Chemical Co* case held that the exception could cover experimental work having a commercial purpose, but not all trials for a commercial purpose fall within the exception.[71] Further, in CoreValve v Edwards Lifesciences it was held that the exception under Section 60(5)(b) of the Patents Act did not apply to the clinical trials in question since one of the purposes of those experiments was to "generate immediate revenue of a substantial character". It follows that commercial factors must be considered in determining whether the exception applies.[72]

41. In Germany, in its decision *Clinical Trial I,* the Federal Court of Justice also affirmed the applicability of Section 11(2) of the Patent Act also for experiments on humans which are conducted with the intention to find out whether a patented drug is suitable for curing or alleviating other diseases (second indication).[73] The exemption provision is even applicable if the nature of experiments goes beyond pure research and economic interests are also pursued. This broad interpretation of the exception was confirmed by the Federal Court of Justice in 1997 in *Clinical Trial II*. According to the Court, Section 11(2) of the Patent Act was also applicable if the trials served the purpose of obtaining data for gaining authorization to put medicinal products on the market in respect of a pharmaceutical composition. Specifically, the Court stated that an activity "oriented towards clearing up uncertainties with regard to the object of the patented invention or bringing out new discoveries about said object" qualifies as experimental use under the exception, provided that these activities with research purposes relate to the object of the patented invention, and that clinical trials conducted for the same indication as that of the patented invention can be covered under the experimental use exemption. In this context, the Federal Court of Justice adhered to its view that economic interests, as a rule, did not conflict with the application of Section 11(2) of the Patent Act. However, the court specified that the exception provision did not

---

71 Monsanto Co v Stauffer Chemical Co and Another [1985] RPC 515., see paragraph 29 of this paper.
72 CoreValve v Edwards Lifesciences [2009] EWHC 6 Pat Ct.
73 Specifically, the Courts stated that It does not 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." The experimental use may be conducted in order to "discover the effects of a substance or possible new uses hitherto unknown." BGH, *Klinische Versuche I.*

apply to experiments which only served to clarify commercial factors, such as market needs, price acceptability and distribution options.[74]

42. In New Zealand, in *Smith Kline & French Laboratories Ltd vs Attorney General*, the Judge acknowledged the fine line between "commercial" and "non-commercial" research[75].

Box 5. New Zealand: Smith Kline & French Laboratories Ltd vs Attorney General

In this case, the Judge stated: "Doubtless experimentation will usually have an ultimate commercial objective; where it ends and infringement begins must often be a matter of degree. If the person concerned keeps his activities to himself, and does no more than further his own knowledge or skill, even though commercial advantage may be his final goal, he does not infringe. But if he goes beyond that, and uses the invention or makes it available to others, in a way that serves to advance in the actual market place, then he infringes".[76]

43. In Australia, as regards Section 119C of the Patents Act, it was explained that the exception did not apply where the main purpose of activities was to commercialize the invention, or to manufacture it for the purpose of sale or use for commercial purposes. Additionally, 'market research' on a patented invention (e.g. making and using the invention to test the likely commercial demand for a product) was not exempt, as that too had a predominantly commercial purpose.[77]

44. In addition, in some other countries the scope of the research exception, as provided under their respective laws, covered only activities relating to non-commercial purposes.[78] For example, in France, the research exception should be "assessed strictly and may apply only to the experimental acts, the aim of which is to participate in the verification of the technical interest of the invention or its development in order to advance knowledge, and not to commercially-oriented acts." [79]

45. In the United States of America, there is no statutory research exception provision, but a "truly narrow" exception exists with respect to experimental activities developed by case law.[80] Specifically, in *Madley v. Duke* case[81], the concept was defined as "any use which has the slightest commercial implication or is in keeping with the legitimate business of the alleged infringer" cannot qualify for the experimental use defense. The Court did not apply the experimental use exception to the Duke University's activities, since those research activities unmistakably furthered the institution's legitimate business objectives, including educating and enlightening students and the faculty participating in these projects.[82]

---

74 BGH, *Klinische Versuche II*.

75 *Smith Kline & French Laboratories Ltd vs Attorney General* (1991) 4 TCLR 199.

76 Commenting on this case, the submission from New Zealand explained "It would appear from this decision that it is the ultimate objective of the research which determines whether or not the use of a patented invention for research or experimental purposes infringes a patent. "Non-commercial" research would not infringe, while "commercial" research would. It is not clear though, just where the boundary between "commercial" and "non-commercial" research lies." See response of New Zealand to the Questionnaire.

77 See the submission of Australia to SCP/29.

78 See, e.g.,the responses to the Questionnaire from Costa Rica, Dominican Republic, El Salvador, Honduras, Mexico, Republic of Moldova, Romania, Turkey, and the United States of America. See also UNCTAD submission in paragraph 7 of document SCP/25/3.

79 See response of France to the Questionnaire in relation to Article L613-5 (b) of the Intellectual Property Code of France (consolidated version of 7 September 2018).

80 Roche Prods., Inc v. Bolar Pharm. Co., 773 F.2d 858, 863 (Fed. Cir.1984).

81 Madley v. Duke, 307 F. 3d 1351 (Fed. Cir. 2002).

82 Ibid.

Box 6. The Research Exception in the United States of America

In 1813, in *Whittemore v. Cutter* case, the Supreme Court stated that it could never have been the intention of the legislature to punish a man who constructed such a machine merely for philosophical experiments or for the purpose of ascertaining the sufficiency of the machine to produce its described effects.[83] In *Sawin v. Guild*, the Supreme Court distinguished between the making with an intent to use for profit and for the mere purpose of philosophical experiment or to ascertain the verity and exactness of the specification.[84] Consequently, acts with an intent to use the invention for profit or for commercial purposes are considered not to be covered by the case law exception.

In *Madey v. Duke*, the issue was whether research activities in non-State universities fall under the exception.[85] The Court concluded that, as long as the act was in furtherance of the alleged infringer's legitimate business and was not solely for amusement, to satisfy idle curiosity, or for strictly philosophical inquiry, the act did not qualify for the very narrow and strictly limited experimental use defense.[86]

46. As regards the scope of the exception in developing countries specifically, the UNCTAD submission to the SCP noted many developing countries limited the scope of this exception to research done solely for non-commercial purposes. It further notes that: "[t]his is not in line with economic realities, where research undertaken for scientific purposes may at the same time be used for commercial purposes. Developing countries that recently amended their patent laws often reflect this reality by allowing research on the patented substance to enable the generation of new knowledge, even where there may be a distant commercial purpose."[87]

Relation of the experimental act to the patented invention (experiment or research "with" or "on" a patented invention)

47. In many countries, the relevant provision specify that experimental act must relate to the subject matter of the patented invention. For example, Section 30(5) of the Patents Ordinance of Pakistan states:

> "The rights under the patent shall not extend to: [...] acts done only for experimental purposes relating to a patented invention;"

48. Similarly, Article 20(2) of the Law on Patents and Utility Models Registration of Bulgaria states:

> "The effect of a patent shall not extend to: [...] use of the invention for experimental or research purposes relating to the subject matter of the patented invention;[88]

49. While the exact scope of the expression "relating to the subject matter of the patented invention" is determined by the relevant jurisdiction, it appears to indicate that third parties may only experiment *on*

---

83 Whittemore v. Cutter, 29 Fed Cas. 1120 (C.C.D. Mass. 1813).
84 Sawin v. Guild, 21 F. Cas. 554 (C.C.D. Mass. 1813).
85 State universities and its employees acting in their official capacity have immunity from patent infringement on the ground of the Eleventh Amendment. See a presentation by Prof. Sean O'Conner at the "WIPO Colloquia on Selected Patent Issues: Research Exemption".
86 Madey v. Duke University, 307 F.3d. 1351 (Fed. Cir. 2002).
87 See document SCP/25/3, p.2.
88 See also the relevant provisions of Albania, Andorra, Antigua and Barbuda, Belize, Bhutan, Botswana, Croatia, Denmark, Dominica, El Salvador, Finland, Germany, Ghana, Hungary, Liberia, Luxembourg, Mauritius, Mozambique, New Zealand, Norway, Papua New Guinea, Republic of Moldova, Saint Lucia, Serbia, Singapore, Slovenia, Tonga, Trinidad and Tobago, United Kingdom and United Republic of Tanzania.

or *into* a patented invention, for example, working *on* the patented invention in order to explore unknown effects or further develop the invention.

50. However, there are also cases where research is conducted *with* or *using* the patented invention. For instance, a patented invention may be used on another invention for research purposes in order to, for example, explore more about such other invention.

51. The question as to whether the experimental use exemption covers this latter case has been particularly discussed in the context of research in the biotechnological area. It was observed that, in the area of genetic research, in particular, patents granted on up-stream research results could impede the down-stream innovation, since the use of the research tools could be crucial for the development of downstream innovation (such as pharmaceutical applications) and, in many cases, there was no way to invent around the patented research tools. In this regard, commentators note that "[s]ome of the most important genetic research tools are fundamental research platforms that open up new and uncharted areas of investigation"[89]. In this case, the downstream researchers are not conducting research *on* the research tool patents, but rather conducting research *with* the research tool patents.

52. From the policy perspective, first, an appropriate balance should be found between the incentives for innovators to further develop innovative research tools and the interests of other researchers to use those research tools, and second, a balance between the legitimate rights of up-stream researchers (including the exclusive patent rights holders) and access to the results of up-stream research by others with a view to promote the follow-on research. It is often argued that allowing third parties to use research tools without payment under the research exception would likely undermine any incentive to invest in the creation of the research tools themselves.[90] Therefore, a cautious approach has been suggested by some experts, particularly on the definition of the appropriate scope of the exception, to avoid inconsistency with Article 30 of the TRIPS Agreement, in so far as any exception must not "unreasonably conflict with the normal exploitation of the patent".[91]

53. The analysis of national legislations indicate, in this regard, that many legal systems seek to limit the operation of the research exemption to cover research "on" the invention rather than "with" the invention.[92] While the question of access to research tools may not appear to be clearly settled everywhere, in Switzerland, access to research tools is guaranteed through the right to a non-exclusive license.[93]

---

89 E. Richard Gold, Yann Joly & Timothy Caulfield, "Genetic Research Tools, the Research Exception and Open Science" (2005) 3:2 *GenEdit,* 1-8. Noting the importance of research tools for further research, Dreyfuss, R. notes: "any scientists that would like to study the genetics of breast cancer needs to utilize the [patented] BRCA 1 test". 'Protecting the Public Domain of Science: Has the time of an experimental use defense arrive?' 46 *Arizona Law Review* (2004), 457.

90 See, e.g., Professor L. Bently et all. "Exclusions from Patentability and Exceptions and Limitations to Patentees' Rights, SCP/15/3, Annex I, p. 57, and Richard Gold and Yann Joly, Annex VI, p.41.

91 Correa, C., 'The International Dimension of the Research Exception'. AAAS/SIPPI Paper, January 2004.

92 See responses to question 17 of the Questionnaire from the following countries which explicitly indicate that the relevant provisions only allowed research "on" or relating to the patented invention: Albania, Dominican Republic, Germany, Hong Kong (China), Kyrgyz Republic, Netherlands, Norway, Russian Federation, Switzerland and Tajikistan.

93 The effect of Article 40e of the Patents Act of Switzerland is that in cases where the patented biotechnological invention is used as a research tool, in particular, for the purposes of carrying out tests or developing a new pharmaceutical product, the interested person shall first seek a voluntary licence from the patent holder, and if the latter refuses, the interested person may apply to the court for the grant of a licence to use the invention in question (See submission of Switzerland in document SCP/23/3, p.6).

Box 7. Research "on" or "with" patented invention: responses from Australia and the Russian Federation

In Australia, the exception contained in Section 119C of the Patents Act 1990 does not apply to the "use of patented 'research tools'. A 'research tool' is something that is used to facilitate an experiment, rather than something that is the subject of the experiment. For example, a researcher testing the effect of a particular herbicide on different plants might use a patented wetting agent to facilitate uptake of the herbicide. Here use of the wetting agent should not be exempt from infringement, as it is being used as a tool and the experiments do not relate to it."[94]

The response from the Russian Federation to the Questionnaire explained that, in accordance with Article 1359 of the Civil Code, the exception applies to "an experiment or scientific research conducted in relation to the patented product or process itself, and not to using them as a means of conducting experiment or research, for example, in measuring instruments or in other equipment facilitating the performance of an experiment or research."[95]

54. In Germany, according to *Clinical Trial I* decision, the experimental act is related to the subject matter of the patented invention if the technical teaching of the patent claim is the object of the experimental act.[96] This criterion is used by the Federal Court of Justice to limit the broad scope of application of the term "experiment". In its *Clinical Trial II* decision, the court made it clear that the experimental act and the subject matter of the patented invention are not related if the experiment is performed on such a large scale that it is no longer justifiable by the experimental purpose. If the sole purpose of the experiment is to lastingly disrupt the sale of another person's patented product, there is no relation to the subject matter of the patented invention. If a patented subject matter is only used as a tool within the scope of the experiment, there is no relation either. The same applies to bioequivalence studies, which merely aim to establish that medicinal products with the same active substance that are manufactured in different ways can be substituted for each other without putting the patient at risk.[97]

55. However, in some other countries, it is not clear from the texts of the relevant provisions whether they apply research "on" and/or "with" criteria in determining the scope of the exception.[98] At least in one country, Belgium, the text of the research exception provision expressly states that exception applies to "acts accomplished for scientific purposes *on* and/or *with* the subject matter of the patented invention".[99]

---

94 See the submission of Australia to SCP/28, available at: http://www.wipo.int/scp/en/meetings/session_29/comments_received.html.

95 See the response from the Russian Federation to the Questionnaire, available at: http://www.wipo.int/scp/en/exceptions/replies/russia.html#Q3

96 BGH, *Klinische Versuche I and II*; Rinken, loc. cit., Sec.11 marginal no. 10.

97 However, bioequivalence studies may be covered by the exemption provision of Section 11(2)(b) of the Patent Act (referred to as *Bolar exception*). See submission of Germany to the SCP/29.

98 See, e.g, the research exception provisions of China, India, Thailand, Ukraine, Uruguay, and Viet Nam.

99 Article XI.34. § 1er. of the Law of 19 April 2014 of Belgium.

6. Challenges Faced by Member States in Implementing the Research Exception

56. The analysis of the legislation of WIPO Member States indicates that the research exemption, while widely varies in scope, is "one of the most widely adopted Article 30-type exceptions in national patent laws", as stated by the WTO Dispute Settlement Panel.[100] As regards the challenges related to a practical implementation of this exception at the national level, most of the Member States reported that no particular challenge had been encountered in their respective countries.[101] In addition, most of the Member States responded that the national legal framework was adequate to meet the objective of the research exception, and no change in their laws in this regard had been envisaged.[102]

57. However, referring to challenges, some Member States noted that there was an uncertainty over the scope of the experimental use exception in their countries. For example, the submission from Tanzania explains that Section 38 of its law provides that the exclusive patent rights extend only to acts done for industrial or commercial purposes and in particular not acts done for scientific research. Since there has not been any court decision which would demonstrate the demarcation line between the scientific research for industrial or commercial purposes, the scope of this provision is considered uncertain.[103,104] In some countries such uncertainty in scope had resulted in a legislative change and provision of the explicit research exception in the respective statutes.[105] For example, in Switzerland, the Swiss legislator introduced a statutory research exemption in Article 9(1)(b) of the Patents Act as a consequence of the survey where participants expressed difficulties with DNA patents and their impact on research and further development.[106] In Australia, the Patents Act was amended "to draw a line between research and commercial activities. [...] The intent was to give broad and clear protection to research and experimental activities in order to maximise the potential for research in Australia".[107]

---

100 *Canada - Patent Protection of Pharmaceutical Product* case. WTO document WT/DS114/R.

101 For example, the response from Pakistan highlighted that the experimental use exception had never been an issue. See also the responses submitted by Member States to SCP/28 as well as the responses to the Questionnaire from the following Member States : Algeria, Australia, Bosnia and Herzegovina, Canada, China, Costa Rica, Croatia, Denmark, the Dominican Republic, El Salvador, Honduras, Hungary, Latvia, the Netherland, Pakistan, Peru, Portugal, the Republic of Moldova, the Russian Federation, Sao Tome and Principe, Turkey and the United States of America.

102 See the responses from Algeria, Bosnia and Herzegovina, Canada, China, Costa Rica, Croatia, Cyprus, Denmark, the Dominican Republic, France, Honduras, Hong Kong (China), Hungary, Japan, Kenya, Latvia, Mexico, Moldova, the Netherlands, Norway, Peru, Poland, Portugal, the Russian Federation, Sao Tome and Principe, Spain, Sweden, Switzerland and Turkey.

103 See submission of United Republic of Tanzania in document SCP/23/3.

104 See also the submission by UNCTAD in document SCP/25/3: "It may be stated that patent exceptions and limitations, while available in domestic law, are often unclear in scope and therefore difficult to make operational."

105 For example, the legislative amendments as regards the research exception were made to the laws of Australia, Canada, Switzerland, Uganda and Zambia.

106 See the submission of Switzerland in document SCP/23/3.

107 See the response of Australia to the Questionnaire.

7. Results of Implementation of the Research Exception

58. While there are numerous literature discussing the optimal scope of the research exception in specific countries from the legal perspective, the economic data empirically testing the effect of the implementation of the research exception on research and innovation is limited. While the research exception should, in general, promote the research use of patented inventions by third parties, information on whether the third parties indeed rely on the exception in conducting their research is not necessarily documented and/or publicly available or countable. Since activities that benefit from such exception take place in research laboratories, there are inherent difficulties in collecting information about the use of the exception by individual stakeholders.[108]

59. Few countries reported on the effect of the exception on research in response to the Questionnaire carried out within the SCP: the submission from Australia stated that an infringement exemption introduced in Section 119C of the Patents Act was "to give broad and clear protection to research and experimental activities in order to maximize the potential for research and innovation in Australia" and that the provision "has given certainty and clarity to researchers".[109] In the United Kingdom, the experimental use exception was a subject of a consultation by the UK Intellectual Property Office in response to a number of reports that had concluded that clarification or restructuring of the research exception was needed. In particular, it was noted that the lack of case law might lead to uncertainty over the scope of the experimental use exception. However, no conclusive evidence was provided in the consultation responses to indicate that the existing experimental use exception was restricting research, and the absence of clear evidence did not support a change in legislation.[110]

60. With regard to the academic literature on the subject, some academics opposing to the notion of a research exemption argue that patents do not prohibit research on the invention: they merely add to the costs of doing research, since the researcher must pay monopoly prices in order to use the patented invention. In essence, they argue that an efficient allocation of resources – which provides the appropriate level of investment incentives for *all* research – requires researchers to pay the full costs of any inputs they use. If they use knowledge created by another researcher, they should pay for both the fixed costs of discovery as well as the on-going marginal costs. Thus, they argue that the existence of a research exemption would have an adverse effect on innovation.[111]

61. The argument continues that university researchers have a choice about whether to pay a license fee, to invent around the patent, or work on another problem. If they choose to obtain a license from the right holder they must pay the patent holder for any inputs they use. In order to do so, the researchers need to attract higher levels of funding, often from the government. It is argued that this has the effect of supporting incentives for the upstream researcher as well as concentrating research funds on projects which are judged to have the best potential. Hence, licensing without research exception provides an efficient way to balance investment incentives with appropriate spill-overs.[112]

---

108 Nevertheless, the indication of the patented invention in the state of the art part of the patent application, so long as that patent is enforceable, could serve as an indication that the use of the research exception took place. See the submission of El Salvador in document SCP/23/3.

109 See the response of Australia to the Questionnaire.

110 See the response of the United Kingdom to the Questionnaire.

111 Gans, J. (2005), 'The dynamic effects of intellectual property practices' *Intellectual Property Research Institute of Australia*, cited in "Research use of patented knowledge: a review", STI working paper 2006/2, OECD.

112 Ibid.

62. Focusing on the deadweight losses, transaction costs and fundamental uncertainty, sSome other academics, advocates of the research exception, argue that the exceptions provide relief from imposition of monopoly prices.[113] Specifically, they state that since much research is cumulative in nature, negotiating and concluding multiple patent licenses before any actual research takes place could involve significant transaction costs. Further, it is alleged that, most research, by its very nature, is subject to fundamental uncertainty and since it cannot be known at the outset which research line will be successful, the greater the possibility of using the reservoir of existing knowledge is, the greater the possibility is to achieve a breakthrough.[114]

63. Furthermore, numerous academics papers exist discussing the narrow experimental use defence operating in the United States of America and suggesting various measures to be undertaken in that country.[115]

64. To conclude, it appears further economic analysis are needed to ascertain the effect of the research exemptions on scientific inquiry. What is certain is that, innovation policies should be designed to balance the incentives to invest in innovative activity with the promotion of spill-overs. The optimal research exception should provide incentive to invest while not limiting those knowledge spill-overs which would only have a small effect on this incentive to invest.[116]

65. In addition, from the legal perspective, any research exception must comply with the requirements of international legal obligations, in particular, the TRIPS Agreement. Further, in order to achieve its policy goal, at the national level, clarity in the scope of the research exception should be provided. That would ensure legal certainty and predictability for both patentees and third parties relying on the exception in conducting research.

[Appendix follows]

---

113 For general discussion on economic rational of the patent system, see Chapter II of the Report on International Patent System (SCP/12/3 Rev. 2).

114 "Research use of patented knowledge: a review", STI working paper 2006/2, OECD. See also prof. L. Bently stating that "[...] non-commercial uses can, in general, be thought of as uses which are unlikely to add much, if anything, to the "incentive" provided by the patent monopoly. At the same time, allowing patents to cover such activities would impose significant costs: most obviously, there would be the transactions costs of policing and licensing such uses." He further concludes that, the reasoning based on market failure might justify some narrow forms of the "experimental use" exception. Professor L. Bently et all. "Exclusions from Patentability and Exceptions and Limitations to Patentees' Rights", SCP/15/3, p.57. See also Correa stating that narrow research exceptions may slow down important research by restricting or delaying access to patented technologies that may be necessary and for which licences are sometimes not available or are too expensive to obtain. Correa, C., 'The International Dimension of the Research Exception'. AAAS/SIPPI Paper, January 2004.

115 Professor L. Bently provides a thorough overview of papers as regards the experimental use defence operating in the United States of America: "According to some, the notoriously narrow experimental use defence operating in the US has not caused significant difficulties (yet).[...] Yet there is widespread dissatisfaction amongst academics, at least, with the current state of US law. Ever since Professor Eisenberg published her ground-breaking article on the topic in 1989,[...] one scholar after another have stepped up to propose some sort of reform to provide the defence with greater flexibility.[...] In 2000, Professor Maureen O'Rourke, proposed the adoption of a "fair use" exception to patent infringement. Three years later, Professor Rochelle Dreyfuss, perhaps inspired by the viral licences utilised in the GPL and by Creative Commons, proposed that public institutions are able to use patented inventions in experiment so long as they undertake that any products of such research are themselves placed into the public domain.[...] The following year, Richard Nelson proposed a similar scheme, instead conditioning the exception for the non-profit institution on an undertaking to license on a non-exclusive basis and for a reasonable royalty any patented outcome of the research.[...] Professor Katherine Strandburg has proposed a combination of an exception for "experimenting on" (such as that which operates in Germany and the United Kingdom) with a compulsory licence for "experimenting with" a patented invention." See "Exclusions from Patentability and Exceptions and Limitations to Patentees' Rights", SCP/15/3.

116 "Research use of patented knowledge: a review", STI working paper 2006/2, OECD.

COMPILATION OF VARIOUS LEGAL PROVISIONS ON THE RESEARCH EXCEPTION

COMPILATION DE DIVERSES DISPOSITIONS JURIDIQUES CONCERNANT L'EXCEPTION EN FAVEUR DE LA RECHERCHE

COMPILACIÓN DE LAS DIFERENTES DISPOSICIONES LEGALES SOBRE LA EXCEPCIÓN CON FINES DE INVESTIGACIÓN

تجميع لمختلف الأحكام القانونية بشأن الاستثناء لأغراض البحث

研究例外不同法律规定汇编

КОМПИЛЯЦИЯ РАЗЛИЧНЫХ ПРАВОВЫХ ПОЛОЖЕНИЙ ОБ ИСКЛЮЧЕНИИ ДЛЯ НАУЧНО-ИССЛЕДОВАТЕЛЬСКИХ ЦЕЛЕЙ

TABLE OF CONTENTS

ALBANIA

Article 38 (1) b) of the Patent Law № 9947 of 7 July 2008 (as amended up to Law № 55/2014 of 29 May 2014)

38. Limitation of the Effects of the Patent.

The rights conferred by the patent shall not extend to:

[...]

b) acts performed merely for experimental purposes relating to the subject matter of the invention.

ALGERIA

Article 12 (1) n. 1 of the Ordinance № 03-07 of 19 Joumada El Oula 1424 corresponding to July 19, 2003 on Patents

12. Les droits découlant d'un brevet d'invention ne s'étendent qu'aux actes accomplis à des fins industrielles ou commerciales.

Les droits découlant d'un brevet d'invention ne s'étendent qu'aux actes accomplis à des fins industrielles ou commerciales.
Ces droits ne s'étendent pas:
1°) aux actes accomplis aux seules fins de la recherche scientifique;

[...]

ANDORRA

Article 23 (4) of the Patent Act of 10 June 1999

23. Rights conferred by a patent.

[...]

(4) The rights conferred by a patent shall not extend to:
(c) acts done for experimental purposes relating to the subject-matter of the patented invention;

[...]

ANTIGUA AND BARBUDA

Section 11 (4) (c) of the Patent Act № 23 of 23 December 2003

11 (4) (1) (c) The rights under the patent shall not extend:

[...]

(c) to acts done only for experimental purposes relating to a patented invention;

[...]

ARGENTINA

Article 36 (a) of the Law № 24.481 of 30 March 1995 on Patents and Utility Models (as amended up to Decree № 27/2018 of 10 January 2018)

36. El derecho que confiere una patente no producirá efecto alguno contra:

a) Un tercero que, en el ámbito privado o académico y con fines no comerciales, realice actividades de investigación científica o tecnológica puramente experimentales, de ensayo o de enseñanza, y para ello fabrique o utilice un producto o use un proceso igual al patentado.

[...]

ARMENIA

Article 17 (2) of the Law of the Republic of Armenia of June 10, 2008, on Inventions, Utility Models and Industrial Designs

17. Acts not Recognized as Infringements on the Exclusive Right Conferred by Patent.

The use of patented invention, utility model shall not constitute an infringement of the exclusive rights of the patent owner under Article 16 of this Law if used:

[...]

(2) as a subject of scientific research or scientific experiment;

[...]

AUSTRALIA

Section 119C of the Patents Act 1990 (consolidated as of 24 February 2017)

119C Infringement exemptions: acts for experimental purposes.

(1) A person may, without infringing a patent for an invention, do an act that would infringe the patent apart from this subsection, if the act is done for experimental purposes relating to the subject matter of the invention.

(2) For the purposes of this section, experimental purposes relating to the subject matter of the invention include, but are not limited to, the following:

(a) determining the properties of the invention;

(b) determining the scope of a claim relating to the invention;
(c) improving or modifying the invention;
(d) determining the validity of the patent or of a claim relating to the invention;
(e) determining whether the patent for the invention would be, or has been, infringed by the doing of an act.

[...]

AZERBAIJAN

Article 23 of the Law of the Republic of Azerbaijan on Patents 1997

23. Acts not constituting infringement of the exclusive rights of patent owners.

The following shall not be deemed as infringements of the exclusive rights of the patent owner:

[...]

- the use of product containing a patented subject matter of industrial property for the scientific experiments or research purposes, as well as in the testing of a patented subject matter of industrial property;

[...]

BARBADOS

Article 6 (1) of the Patents Act 2001 (Cap. 314) (as amended by Act № 2 of 2006)

6 (1): The rights vested in the owner of a patent by section 5 in respect of any invention do not apply to:
(a) the use of the invention for scientific research only;

[...]

BELARUS

Article 10 of the Law of the Republic of Belarus № 160-Z of 16 December 2002 on Patents for Inventions, Utility Models, Industrial Designs (as amended up Law № 328-Z of 22 December 2011)

10. Actions Not Recognized as Violation of the Exclusive Right of the Patent-Holder.

[...]

conducting the scientific research or experiment on the method in which the invention, industrial model or industrial design protected by the patent are used;

[...]

BELGIUM

Article XI.34. § 1er. of the Law of 19 April 2014, inserting Book XI 'Intellectual Property' to the Code of Economic Law, and specific provisions to the Book XI in Books I, XV and XVII of the Code

XI.34. § 1er. Les droits conférés par le brevet ne s'étendent pas:

[…]

b) aux actes accomplis à des fins scientifiques sur et/ou avec l'objet de l'invention brevetée;

[…]

BELIZE

Article 33 (4) (c) of the Patents Act (Cap. 253, Revised version 2000)

33 (4): The rights under the patent shall not extend to:

[…]

(c) acts done only for experimental purposes relating to a patented invention;

[…]

BHUTAN

Section 13 (4) a) of the Industrial Property Act of the Kingdom of Bhutan 2001

13 (4) (a): The rights under the patent shall not extend:

[…]

(iii) to acts done only for experimental purposes relating to a patented invention;

[…]

BOLIVIA

Article 53 (b) of the decision № 486 of 14 September 2000 of the Commission of the Andean Community

53. The owner of the patent may not exercise the right referred to in the foregoing Article in relation to the following acts:

[…]

(b) acts performed for exclusively experimental purposes on the subject matter of the patented invention;

[...]

BOSNIA AND HERZEGOVINA

Section 73 (b) of the Law on Patents as of 28 May 2010

73. Exceptions from the Exclusive Rights.

The patent holder's exclusive right shall not apply to:

[...]

b) acts performed for research and development purposes, and for experiments relating to the subject matter of the protected invention, including the acts necessary for obtaining registration or marketing authorization for the product which is a medicine intended for humans or animals or a medicinal product;

[...]

BOTSWANA

Section 25 (1) (c) of the Industrial Property Act 2010 (Act № 8 of 2010)

25. (1) The rights conferred by a patent shall not extend to –

[...]

(c) acts done only for experimental purposes relating to the subject-matter of the patented invention;

[...]

BRAZIL

Article 43 II of the Patent Law № 9.279 of 14 May 1996 as last amended by Law № 10.196 of 14 February 2001

43: The provisions of the previous Article do not apply:

[...]

(II) to acts carried out by unauthorized third parties for experimental purposes, in connection with scientific or technological studies or researches;

[...]

BULGARIA

Article 20 (2) of the Law on Patents and Utility Models Registration of 9 November 2006 as last amended by Law of 18 May 2012

20. The effect of a patent shall not extend to:

[...]

2. use of the invention for experimental or research purposes relating to the subject matter of the patented invention;

[...]

BURKINA FASO

Article 8 (1) (c) of the Agreement Revising the Bangui Agreement of 2 March 1977 on the Creation of an African Intellectual Property Organization (Bangui (Central African Republic), 24 February 1999)

8. Limitation of the Rights Conferred by the Patent:

(1) The rights deriving from the patent shall not extend

[...]

(c) to acts in relation to a patented invention that are carried out for experimental purposes in the course of scientific and technical research;

[...]

CANADA

Section 55.2. (1), (6) of the Patent Act (R.S.C., 1985, c. P-4) (status as of 21 June 2016)

55.2 (1) Exception.

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.

[...]

(6) For greater certainty, subsection (1) does not affect any exception to the exclusive property or privilege granted by a patent that exists at law in respect of acts done privately and on a non-commercial scale or for a non-commercial purpose or in respect of any use, manufacture,

construction or sale of the patented invention solely for the purpose of experiments that relate to the subject-matter of the patent.

CHINA

Article 69 (4) of the Patent Law of the People's Republic of China (as amended up to the Decision of 27 December 2008 regarding the Revision of the Patent Law of the People's Republic of China)

69. The following shall not be deemed to be patent right infringement:

[...]

(4) Any person uses the relevant patent specially for the purpose of scientific research and experimentation;

[...]

HONG KONG, CHINA

Article 75 (b) of the Patents Ordinance 2017 (Chapter 514)

75. Limitation of effect of patent:

The rights conferred by a patent shall not extend to-

[...]

(b) acts done for experimental purposes relating to the subject-matter of the relevant patented invention;

[...]

COLOMBIA

Article 53 (b) of the decision № 486 of 14 September 2000 of the Commission of the Andean Community

53. The owner of the patent may not exercise the right referred to in the foregoing Article in relation to the following acts:

[...]

(b) acts performed for exclusively experimental purposes on the subject matter of the patented invention;

[...]

COSTA RICA

Article 16 (2) (b) and (c) of the Law № 6867 of 25 April 1983 on Patents, Industrial Designs and Utility Models (as amended up to Law №. 8686 of 21 November 2008)

16. Rights conferred by patents. Limitations.

Provided that the following exceptions do not unjustifiably affect the normal working of the patent or result in unreasonable prejudice to the legitimate interests of the owner or his licensee, the rights conferred by the patent shall not extend to:

[...]

(b) acts performed for experimental purposes which are related to the subject matter of the patented invention;

(c) acts done exclusively for the purpose of teaching or scientific or academic research in respect of the subject matter of the patented invention;

[...]

CROATIA

Article 63 (2) of the Patent Act and Acts on Amendments to the Patent Act № 173/2003 of 1 January 2004, as amended by Act № 76/2013 of 29 June 2013

63. Exceptions from the exclusive rights.

The patent owner's exclusive right of exploitation of the invention shall not apply to:

[...]

2. acts done for the purposes of research and development and for experiments relating to the subject-matter of the protected invention, including where such acts are necessary for obtaining registration or authorization for putting on the market a product comprising a medicine intended for people or animals, or a medicinal product;

[...]

CUBA

Article 47 (a), (c) of Decree-Law № 290 of 20 November 2011 on Inventions and Industrial Designs and Models

47. Los derechos conferidos por la patente no se extienden a:

a) los actos realizados exclusivamente con fines de enseñanza o de investigación científica o tecnológica;

[...]

c) los actos realizados con fines experimentales que se refieran al objeto de la invención patentada;

[...]

CYPRUS

Article 27 (3) (ii) and (iii) of the Patent Law of 1998 (amended in 2000,2002 and 2006)

27. Rights conferred by a patent.

[...]

(3) Notwithstanding paragraphs (1) and (2) of this section, the owner of a patent shall have no right to prevent third parties from performing, without his authorization, the acts referred to in subsections (1) and (2) of this section in the following circumstances:

[...]

(ii) Where the act is done privately and on a non-commercial scale, provided that it does not significantly prejudice the economic interests of the proprietor of the patent;

(iii) Where the act consists of making or using for purely experimental purposes or for scientific research;

[...]

CZECH REPUBLIC

Section 18 (d), (e) of the Act № 527 / 1990 Coll. on Inventions and Rationalisation Proposals, as follows from amendments implemented by Act № 519/1991 Coll., Act № 116/2000 Coll. and Act № 207/2000 Coll.

18. The rights of the proprietor of the patent shall not be infringed by use of the protected invention:

[...]

d) in acts done for non-commercial purposes;

e) in act relating to the subject-matter of the invention done for experimental purposes, including experiments and tests necessary under special legal regulations3a) prior to being placed on the market.

DEMOCRATIC PEOPLE'S REPUBLIC OF KOREA

Article 33 (2) 3 (3) (iii) of the Invention Law of the Democratic People's Republic of Korea (amended by Decree № 597 of 11 March 1999 of the Presidium of the Supreme People's Assembly)

33. Use of patented science and technology without permission

A patented science and technology may be used without the consent of the patent owner if:
[...]

2. it is used for scientific research and experiment;

[...]

DENMARK

Section 3 (3) (iii) of the Consolidate Patents Act (Consolidate Act № 221 of 26 February 2017)

3. (3) The exclusive right shall not extend to:

[...]

(iii) acts done for experimental purposes relating to the subject-matter of the patented invention;

[...]

DOMINICA

Article 33 (4) c) of the Patents Act № 8 of 7 October 1999

33. Rights of owner of patent.

[...]

(4) The rights under the patent shall not extend to:

[...]

c) acts done only for experimental purposes relating to a patented invention;

[...]

DOMINICAN REPUBLIC

Article 30 (b) and (c) of the Law on Industrial Property № 20-00 of 8 May 2000

30. Limitation and Extent of the Rights of the Patent.

The patent does not give the right to prevent:

[...]

b) Actions carried out exclusively for purposes of experimentation with regard to the patented invention.

c) Actions carried out exclusively for purposes of teaching or of scientific or academic research.

[...]

ECUADOR

Article 53 (b) of the decision № 486 of 14 September 2000 of the Commission of the Andean Community

53. The owner of the patent may not exercise the right referred to in the foregoing Article in relation to the following acts:

[...]

(b) acts performed for exclusively experimental purposes on the subject matter of the patented invention;

[...]

EGYPT

Article 10 of the Law № 82 of 3 June 2002 on the Protection of Intellectual Property Rights

10.

[...]

The following shall not be considered as infringements of that right when carried out by third parties:

(1) Activities carried out for scientific research purposes.

[...]

EL SALVADOR

Article 61 (c) of the Legislative Decree № 912 of 14 December 2005 on Amendments to the Law on the Promotion and Protection of Intellectual Property

61. Letters (a), (b) and (c) of the first subparagraph of Art. 116 are hereby amended and letter (e) added, as follows:

[...]

(c) To a third party that, without commercial purposes, carries out acts of manufacture or use of the invention for experimental purposes relating to the subject of the patented invention or for the

purposes of scientific, academic or teaching research, provided that this does not unjustifiably infringe upon the normal exploitation of the invention that the holder may or does carry out;

[...]

ESTONIA

Paragraph 16 (3) of the Patents Act of 1 January 2015 (consolidated text of 1 January 2015)

§ 16. Acts which do not constitute infringement of exclusive right of proprietor of patent.

The following acts do not constitute infringement of the exclusive right of the proprietor of a patent:

[...]

3) the use of the patented invention in testing related to the invention itself, including the use of a medicinal product containing the patented invention in clinical trials of the medicinal product;

[...]

ETHIOPIA

Section 25 (1) (b) of the Industrial Property Law (Proclamation) № 123 of 10 May 1995

25. Limitations of Rights.

1. The rights of the patentee shall not extend to:

[...]

b) the use of the patented invention solely for the purposes of scientific research & experimentation;

[...]

FINLAND

Section 3 (2) of the Patents Act (Act № 1967/550 of 15 December1967, as amended up to Act № 2013/101 of 31 January 2013)

3.

[...]

The exclusive right shall not apply to:

[...]

(3) use in experiments relating to the invention as such;

[...]

FRANCE

Article L613-5 (b) of the Intellectual Property Code (consolidated version of 7 September 2018)

Article L613-5

Les droits conférés par le brevet ne s'étendent pas:

[...]

b) Aux actes accomplis à titre expérimental qui portent sur l'objet de l'invention brevetée;

[...]

GERMANY

Section 11 (2) of the Patent Act (as amended up to Act of 8 October 2017)

11. The effect of a patent shall not extend to:

[...]

2. acts done for experimental purposes relating to the subject-matter of the patented invention;

[...]

GHANA

Section 11 (4) (c) of the Patent Act of 31 December 2003 (Act 657)

11. Rights Conferred by Patent.

[...]

(4) The rights under the patent shall not extend to:

[...]

(c) acts done only for experimental purposes relating to a patent invention; or

[...]

GREECE

Article 10 (2) a) of the Law 1733/87 of 22 September 1987 on Technology Transfer, Inventions and Technological Innovation

10. Contents of the right.

[...]

2. The owner of the patent may not forbid, in the meaning of the preceding paragraph, the following activities:

a. The use of the invention for nonprofessional or research purposes;

[...]

GUATEMALA

Article 130 (b) and (c) of the Industrial Property Law, Decree № 57-2000 of 18 September 2000

130. La patente no dará el derecho a su titular de impedir:

[...]

b) Actos realizados exclusivamente con fines de experimentación respecto al objeto de la invención patentada;

c) Actos realizados exclusivamente con fines de enseñanza o investigación científica o académica, sin propósitos comerciales, respecto al objeto de la investigación patentada;

[...]

HONDURAS

Article 18 of the Law on Industrial Property (approved by Decree Law № 12-99-E of 30 December 1999)

18. Los derechos conferidos por la patente sólo podrán hacerse valer contra actos realizados por terceros con fines industriales o comerciales. En particular, tales derechos no podrán hacerse valer contra actos realizados exclusivamente en el ámbito privado y con fines no comerciales, o con fines de experimentación, investigación científica o enseñanza relativos al objeto de la invención patentada.

HUNGARY

Article 19 (6) b) of the Act № XXXIII of 1995 on the Protection of Inventions by Patents (consolidated text of 17 June 2017)

19.

[...]

(6) The exclusive right of exploitation shall not extend to:

[...]

(b) acts done for experimental purposes relating to the subject matter of the invention, including experiments and tests necessary for the marketing authorisation of the product constituting the subject matter of the invention or the product obtained through the process constituting the subject matter of the invention;

[...]

ICELAND

Article 3 (3) of the Patents Act № 17/1991 (as amended up to Act № 126/2011)

3.
[...]

The following are excepted from the exclusive right:

[...]

(3) use of the invention for experiments which relate to the invention itself, [i.a. studies and trials and other related procedures that are necessary to make possible an application for marketing authorization for e.g. a generic medicinal product and an improved pharmaceutical form;]

[...]

INDIA

Section 47 of the Patent Act № 39 of 20 April 1970 (as last amended in 2005)

47. Grant of patents to be subject to certain conditions. - The grant of a patent under this Act shall be subject to the condition that –

[...]

(3) any 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;

[...]

INDONESIA

Article 16 (3) of the Patent Law №. 14 of 1 August 2001

16.

[…]

(3) Exempted from the provisions as referred to in paragraph (1) and paragraph (2) if the use of said Patent is for the sake of education, research, experiment, or analysis, as long as it does not harm the normal interest of the Patent holder.

IRELAND

Section 42 (b) of the Patents Act № 1 of 27 February 1992 (as last amended by Intellectual Property (Miscellaneous Provisions) Act № 36 of 2014)

42. The rights conferred by a patent shall not extend to-

[…]

(b) acts done in conducting studies, tests, experiments and trials (including clinical trials and field trials) with a view to satisfying the application requirements for a marketing authorisation or similar instrument (howsoever described) that is required by the law of the State or of any other state in order to sell or supply or offer to sell or supply-
(I) a medicinal product for human use, within the meaning of subsection (2), or
(II) a - veterinary medicinal product, within the meaning of subsection (2),
or

[…]

ISRAEL

Section 1 of the Patent Law, 5727-1967 (consolidated version of 2014)

[…]

"exploitation of an invention" –

(1) In respect of an invention that is a product – any act that is one of the following: production, use, offer for sale, sale, or import for purposes of one of the enumerated acts;

[…]

but excluding any of the following:

[…]

(2) any experimental act in connection with the invention, the objective of which is to improve the invention or to develop another invention;

[...]

ITALY

Article 68 (1) of the Industrial Property Code (Legislative Decree № 30 of 10 February 2005, as amended up to Legislative Decree № 63 of 11 May, 2018)

68. Limitations on patent rights.

1. Whatever the object of the invention may be, the exclusive authority attributed by patent rights does not extend to the following:

a) actions carried out in the private sphere and for non-commercial purposes, or as experimentation;

[...]

JAPAN

Article 69 (1) of the Patent Act № 121 of 13 April 1959, as amended up to Act № 55 of 10 July 2015)

69. Limitations of patent right.

(1) A patent right shall not be effective against the working of the patented invention for experimental or research purposes.

[...]

JORDAN

Article 21 C of the Patent Act 1999 № 32 of 1 December 1999

21. Rights of the Patentee.

C. Notwithstanding the provisions of this Law or any other legislation, carrying out research and development, and submitting applications for obtaining approvals to market a product prior to the expiry date of the patent protection shall not be considered an act of civil or criminal infringement.

KAZAKHSTAN

Article 12 (2) of the Law on Patents of the Republic of Kazakhstan № 427-I of 16 July 1999 (as amended up to Law of the Republic of Kazakhstan № 378-V of 31 October 2015)

12. Acts which are not Recognised as Violation of Exclusive Right of Patentee.
The following shall not be recognised as violation of the exclusive right of the patentee:

[...]

2) carrying out scientific research or experiment on means which contain the protected object of industrial property when such research or experiment does not have a commercial purpose;

[...]

KENYA

Section 58 (1) of the Industrial Property Act № 3 of 27 July 2001 (as amended up to Act № 11 of 2017)

58. Limitation of rights.

(1): The rights under the patent shall extend only to acts done for industrial or commercial purposes and in particular not to acts done for scientific research.

[...]

KYRGYZSTAN

Article 13 (2) of the Law of the Kyrgyz Republic №. 8 of 14 January 1998 on Patents (as amended up to Law № 76 of 10 April 2015)

13. Actions Not Considered as an Infringement of the Exclusive Right of the Patent Owner.

The following is not recognized as an infringement of the exclusive right of the patent owner:

[...]

2) conducting scientific research or an experiment with an article containing an object of industrial property;

[...]

LATVIA

Section 20 (2) of the Patent Law of 1 March 2007 (as amended up to 1 January 2012)

20. Limitations of Exclusive Rights Resulting from a Patent.

The exclusive rights resulting from the patent shall not extend to:

[...]

2) experimental or investigative activities;

[...]

LEBANON

Article 42 of the Law № 240 of 14 August 2000

42. - A person infringing the rights of a basically published patent while being aware of such action, shall be penalized by a fine ranging from five to fifty million Lebanese Liras and imprisonment from three months up to three years or by either of the penalties hereinbefore mentioned.

- Exploiting the invention on non-commercial, nonindustrial personal aims or for scientific research reasons shall not be considered counterfeit according to the provisions of the Article herein.

LIBERIA

Paragraph 13.11 (b) (ii) *of the Act to Repeal an Act Adopting a New Copyright Law of the Republic of Liberia approved on 23 July 1997; and the Industrial Property Act of Liberia approved on 20 March 2003, constituting Title 24 of the Liberian Code of Laws Revised, and to enact in their stead a New Title 24 to be known as the "Liberia Intellectual Property Act, 2016"*

§13.11. Rights Conferred by the Patent; Limitations and Exceptions.

[...]

b) The rights under a patent may not be used to prevent:

[...]

ii. acts done for purposes of scientific research in academic, educational or research institutions;

iii. acts done for experimental purposes relating to the subject matter of the patented invention;

[...]

LITHUANIA

Article 26 of the Patent Law № I-372 of 18 January 1994 (as last amended by Act – №. X-1119 of 10 May 2007)

26. Rights of the Owner of a Patent.

[...]

The owner of the patent shall have no right to prevent third parties from performing acts referred to in paragraphs 1 and 2, provided that:

[...]

2) the act is done for experimental purposes or for scientific research, and this does not conflict with a normal exploitation of the patent and does not unreasonably prejudice the legitimate interests of the patent owner;

[...]

LUXEMBOURG

Article 47 (b) of the Law of 20 July 1992 on the Changes in the System for Patents for Invention (as amended by the Law of 24 May 1998)

47. Limitation of the Effects of the Patent.

The rights afforded by the patent shall not extend to:

[...]

(b) acts done for experimental purposes relating to the subject matter of the patented invention;

[...]

MALAYSIA

Section 37 (1) of the Patents Act of 1983 (as amended up to Act A1264)

37. Limitation of rights.

(1) The rights under the patent shall extend only to acts done for industrial or commercial purposes and in particular not to acts done only for scientific research.

[...]

MALTA

Article 27 (6) (b) of the Patents and Designs Act (chapter 417) of 01 June 2002

27.

[...]

(6) Notwithstanding subarticles (1) and (2), the proprietor of a patent shall have no right to prevent third parties from performing the acts referred to in subarticles (1) and (2)(b) in the following circumstances:
[...]

(b) where the act consists of making or using such product for purely experimental purposes or for scientific research;

[...]

MAURITIUS

Section 21(4)(d) of the Patents, Industrial Designs and Trademarks Act of 8 August 2002

21. Rights conferred by patent.

[...]

(4). Any right under the patent shall not extend –

[...]

d) to acts done only for research and experimental purposes relating to a patented invention;

[...]

MEXICO

Article 22 (I) of the Law on Industrial Property (consolidated text published in the Official Journal of the Federation on 18 May 2018)

22. El derecho que confiere una patente no producirá efecto alguno contra:

I.- Un tercero que, en el ámbito privado o académico y con fines no comerciales, realice actividades de investigación científica o tecnológica puramente experimentales, de ensayo o de enseñanza, y para ello fabrique o utilice un producto o use un proceso igual al patentado;

[...]

MONGOLIA

Article 18.2.2. of the Patents Act of 25 June 1993 (as amended up to 1 September 2016)

18. Exploitation of Inventions, Industrial Designs and Utility Models.

[...]

2. The following exploitation of the invention or industrial design protected by the patent or utility model protected by the certificate shall not be regarded as an infringement of the exclusive rights of the patent or certificate owner:
[...]

18.2.2. the use for scientific research, education or experimental purposes;

[...]

MOROCCO

Article 55 (b) of the Law № 17-97 on the Protection of Industrial Property (as amended by Laws № 31-05 and № 23-13)

55. Les droits conférés par le brevet ne s'étendent pas:

[...]

b) aux actes accomplis à titre expérimental qui portent sur l'objet de l'invention brevetée;

[...]

MOZAMBIQUE

Article 75 (a) of the Industrial Property Code (approved by Decree № 47/2015 of 31 December 2015)

75. Limitation of the rights derived from a patent.

The rights of the patent holder shall not extend to the following:

a) Acts relating to a patented invention for the purposes of scientific research;

[...]

NAMIBIA

Section 108 (c) of the Industrial Property Act 2012 (Act № 1 of 2012)

108. Limitations of rights.

The rights of the owner of a registered design do not extend to

[...]

(c) acts related to experimental use of the design or acts done on a noncommercial scale for scientific research;

[...]

NETHERLANDS

Section 53 (3) of the Patent Act 1995 (Act of 15 December 1994 containing Rules Relating to Patents)

53.

[...]

3. The exclusive right shall not extend to acts solely serving for research on the patented subject matter, including the product obtained directly as a result of using the patented process.

[...]

NEW ZEALAND

Section 143 of the Patent Act 2013 as at 16 December 2017

143 No infringement for experimental use.

(1) It is not an infringement of a patent for a person to do an act for experimental purposes relating to the subject matter of an invention.

(2) In this section, act for experimental purposes relating to the subject matter of an invention includes an act for the purpose of-

(a) determining how the invention works:
(b) determining the scope of the invention:
(c) determining the validity of the claims:
(d) seeking an improvement of the invention (for example, determining new properties, or new uses, of the invention).

[...]

NICARAGUA

Article 46 (a) and (b) of the Law on Patents, Utility Models and Industrial Design № 354 of 21 November 2000

46. Limitation of Patent Rights.

A patent shall not confer the right to prohibit the following acts:

a) those conducted in a private circle and for noncommercial purposes, and also those conducted solely for the purposes of experimentation in relation to the subject matter of the patented invention;

b) those performed exclusively for teaching or scientific or academic research purposes in relation to the subject matter of the patented invention, and those referred to in Article 5ter of the Paris Convention for the Protection of Industrial Property;

[...]

NORWAY

Section 3 (3) no. 3 of the Patents Act (Act № 9 of 15 December 1967) (consolidated version of 2018)

3. The exclusive right shall not include:

[...]

3) Exploitation by experiment relating to the subject matter of the invention

[...]

OMAN

Section 11 (4) (C) of the Industrial Property Rights Law (promulgated by the Royal Decree №. 67/2008)

11.

[...]

4 - The rights under the patent shall not extend:

[...]

C) to acts done only for experimental purposes relating to a patented invention;

[...]

PAKISTAN

Section 30 (5) of the Patents Ordinance № LXI of 2 December 2000

30. Rights conferred by patent.

[...]

(5) The rights under the patent shall not extend to:

[...]

c) Acts done only for experimental purposes relating to a patented invention;

[...]

f) Acts done for teaching purposes in educational or research institutions.

[...]

PANAMA

Article 19 (1) of the Law № 61 of 5 October 2012, amending Law № 35 of 10 May 1996 on Industrial Property

19. El derecho que confiere una patente no producirá efecto alguno contra:

1. Un tercero que, en el ámbito privado, realice actos relacionados con la invención patentada a escala no comercial, con fines experimentales, de investigación científica o de enseñanza y con una finalidad no comercial;

[...]

PAPUA NEW GUINEA

Section 29 (4) (c) of the Patent and Industrial Act № 30 of 19 July 2000

29. Rights conferred by a patent.

[...]

(4) The rights of an owner of a patent shall not extend to:

[...]

c) acts done only for experimental purposes relating to a patented invention;

[...]

PARAGUAY

Article 34 (a) and (b) of the Law № 1.630/2000 on Patents (as last amended by Law № 2.593/2005)

34. De las limitaciones al derecho de patente y agotamiento del derecho.

La patente no dará el derecho de impedir:

[...]

a) los actos realizados exclusivamente con fines de experimentación y sin fines comerciales respecto al objeto de la invención patentada;

b) los actos realizados exclusivamente con fines de enseñanza o de investigación científica o académica;

[...]

PERU

Article 53 (b) of the decision № 486 of 14 September 2000 of the Commission of the Andean Community

53. The owner of the patent may not exercise the right referred to in the foregoing Article in relation to the following acts:

[...]

(b) acts performed for exclusively experimental purposes on the subject matter of the patented invention;

[...]

PHILIPPINES

Section 72.3. of the Intellectual Property Rights Code, Act № 8293 of 1 January 1998

72. Limitations of Patent Rights.

The owner of a patent has no right to prevent third parties from performing, without his authorization, the acts referred to in Section 71 hereof in the following circumstances:

[...]

(3) Where the act consists of making or using exclusively for the purpose of experiments that relate to the subject matter of the patented invention;

[...]

POLAND

Article 69 (1), (iii) of the Act of 30 June 2000 on Industrial Property (as amended up to Act of 24 July 2015)

69.

1. The following shall not be considered acts of infringement of a patent:

[...]

(iii) employing of an invention for search and experimental purposes, for the evaluation thereof, analysis or teaching;

[...]

PORTUGAL

Article 102 (c) of the Industrial Property Code (as amended up to Law № 46/2011 of 24 June 2011)

102. Limitation of rights conferred by a patent.

The rights conferred by a patent do not extend to:

[...]

c) Acts performed exclusively for trial or experimental purposes, including experiments for the preparation of the administrative processes required for the approval of products by the competent official bodies, though industrial or commercial exploitation of these products may not commence before expiry of the patent protecting them;

[...]

REPUBLIC OF KOREA

Article 96 (1) of the Patent Act № 950 of 31 December 1961 (as amended up to Act № 14112 of 29 March 2016)

96. Limitations on Effects of Patents.

(1) The effects of a patent shall not extend to the following:

1. Execution of a patented invention for the purpose of research or testing (including research and testing for obtaining permission for items of medicines or reporting items of medicines by under the Pharmaceutical Affairs Act or for registering pesticides under the Pesticide Control Act);

[...]

REPUBLIC OF MOLDOVA

Article 22 (1) (b) of the Law № 50-XVI of 7 March 2008 on the protection of Inventions (as amended up to Law № 101 of 26 May 2016)

22. Limitation of Effects of a Patent.

(1) The rights conferred by a patent shall not extend to:

[...]

b) acts done for experimental purposes relating to the subject-matter of the patented invention;

[…]

ROMANIA

Article 34 (e)of the Patent Law № 64/1991 (as amended up to Law № 28/2007)

34. The following acts shall not constitute infringements of the rights provided in Art. 32 and Art. 33:

[…]

e) use of the subject-matter of the patented invention for exclusively noncommercial experimental purposes;

[…]

RUSSIAN FEDERATION

Article 1359 (2) of the Civil Code of the Russian Federation (Part IV).

1359. Acts which Shall Not an Infringement of the Exclusive Right to an Invention, Utility Model, or Industrial Design.

The performance of the following acts shall not constitute an infringement of the exclusive right to an invention, utility model, or industrial design:

[…]

2) scientific research of a product or process incorporating an invention or utility model, or scientific research of a device incorporating an industrial design or the conduct of an experiment with such a product, process, or device;

[…]

SAINT LUCIA

Section 62 (2) (b) of the Patents Act № 16 of 27 August 2001

62. Meaning of infringement.

[…]

(2) An act, which apart from this subsection would constitute an infringement of a patent for an invention shall not do so if:

b) it is done for experimental purposes relating to the subject matter of the invention;

[...]

SAO TOME AND PRINCIPE

Article 8.4 (c) of the Law № 4/2001 of 31 December 2001 on Industrial Property

8. Duration and annual fees.

[...]

4. The rights deriving from the patent do not include:

[...]

c) Acts regarding an Invention patented for scientific research purposes;

[...]

SAUDI ARABIA

Article 47 of the Law of Patents, Layout-Designs of Integrated Circuits, Plant Varieties, and Industrial Designs (promulgated by Royal Decree № M/27 of 29/5/1425H (17 July 2004))

47.

[...]

However, the owner of the protection document's right shall not preclude others from exploiting his invention in non-commercial activities relating to scientific research.

SERBIA

Article 21 (2) of the Law on Patents of 4 January 2012 (Official Gazette of the Republic of Serbia № 99/2011)
21. Exceptions to Exclusive Rights.

The exclusive rights of a right holder referred to in Articles 14 and 15 of this Law shall not apply to:

[...]

2) research and development activities relating to the subject matter of a protected invention, including activities that are necessary for obtaining an authorization from the competent authority for placing on the market a product which is a drug intended for use on humans or animals, or a medicinal product or plant protection products defined by the law regulating plant protection products;

[...]

SINGAPORE

Section 66 (2) b) of the Patent Act (Chapter 221) Revised Edition 2005, as amended up to the Statutes (Miscellaneous Amendments) Act 2014)

Meaning of infringement.

66.

[...]

(2) An act which, apart from this subsection, would constitute an infringement of a patent for an invention shall not be so if —
(b) it is done for experimental purposes relating to the subject-matter of the invention;

[...]

SLOVAKIA

Article 18 (1) (f) of the Act № 435/2001 Coll. on Patents, Supplementary Protection Certificates and on Amendment of Some Acts [Patent Act (as amended up to Act № 125/2016 Coll.)]

18.

(1) Rights of a patent owner shall not be infringed if an invention is exploited:

[...]

f) in activity conducted for experimental purposes which shall also be studies, exams necessary for registration proceedings pursuant to a special regulation.

[...]

SLOVENIA

Article 19 b) of the Industrial Property Act (ZIL-1-UPB3) (as amended up to 6 December 2013)

19. Limitation of rights conferred by a patent.

The rights conferred by a patent within the meaning of Article 18 shall not extend to:

(b) acts done for research and experimental purposes of any kind relating to the subject matter of the patent irrespective of their final purpose;

[...]

SPAIN

Article 61 (1) (b) of the Law № 24/2015 of 24 July 2015 on Patents

61. Límites generales y agotamiento del derecho de patente.

1. Los derechos conferidos por la patente no se extienden:

[...]

b) A los actos realizados con fines experimentales que se refieran al objeto de la invención patentada.

[...]

SRI LANKA

Section 86 (1) (i) of the Intellectual Property Act № 36 of 2003

86. (1) The provisions of section 84 shall:

(i) extend only to acts done for industrial or commercial purposes and in particular shall not extend to acts done only for the purpose of scientific research;

[...]

SWEDEN

Section 3 (3) no. 3 of the Patent Act № 837 of 12 January 1967

3.

The following are excepted from the exclusive right:

[...]

(3) use of the invention for experiments which relate to the invention itself;

[...]

SWITZERLAND

Article 9 (1) (b) of the Federal Act of 25 June 1954 on Patents for Inventions (status as of 1 January 2017)

9. Exceptions aux effets du brevet.

(1) Les effets du brevet ne s'étendent pas:

[...]

b. aux actes accomplis à des fins expérimentales et de recherche servant à obtenir des connaissances sur l'objet de l'invention, y compris sur ses utilisations possibles; est permise notamment toute recherche scientifique portant sur l'objet de l'invention;

[...]

TAJIKISTAN

Section 30 of the Law of the Republic of Tajikistan № 17 of 28 February 2004 on Inventions (as amended up to Law № 956 of 19 March 2013)

30. Acts which shall not an Infringement of the Exclusive Right.

The following actions shall not be deemed infringements of a patent owners' exclusive right:

[...]

- scientific research or experiments in academic, educational and research institutions involving devices incorporating inventions;

[...]

THAILAND

Section 36 (2) no. 1 of the Patent Act B.E. 2522 of 11 March 1979

36.

[...]

(2)

[...]

The preceding paragraph shall not apply to:

(1) any act for the purpose of study, research, experimentation or analysis, provided that it does not unreasonably conflict with a normal exploitation of the patent and do not unreasonably prejudice the legitimate interests of the patent owner;

THE FORMER YUGOSLAV REPUBLIC OF MACEDONIA

Section 91 (2) of the Law on Industrial Property adopted on 12 January 2009

91. Free use.

The right of the patent holder laid down in Article 89 of this Law regarding the exclusive utilisation of the invention shall not relate to:

[...]

2) undertaking activities for research and development of the subject of the protected invention, in particular: manufacture, use, offer for sale, export or import of the protected invention, including also activities for obtaining approval for placing medications for human and veterinary medicine and products for protection of plants on the market;

[...]

TONGA

Section 13 (4) (c) of the Industrial Property Act № 19 of 09 November 1994

13. Rights conferred by patent; exploitation by Government or person thereby authorized.

[...]

(4) The rights under the patent shall not extend:

[...]

(c) to acts done only for experimental purposes relating to a patented invention;

[...]

TRINIDAD AND TOBAGO

Section 42 (b) of the Patent Act № 21 of 1996 (as last amended by the Act № 18 of 2000)

42. Limitation of effect of patent.

The rights conferred by a patent shall not extend to:

[...]

b) acts done for experimental purposes relating to the subject matter of the relevant patented invention;

[...]

TUNISIA

Article 47 (b) of the Patents Law № 2000-84 of 24 August 2000

47. The rights conferred by the patent shall not extend to the following:

[...]

(b) acts performed experimentally that relate to the subject matter of the patented invention;

[...]

TURKEY

Article 75 (b) of the Law № 6769 of 22 December 2016 on Industrial Property

75. Limits of the Scope of Rights Conferred by a Patent.

The following acts shall remain outside the scope of rights conferred by a patent:

[...]

b/ Acts involving, for experimental purposes, the invention, subject matter of a patent;

[...]

UGANDA

Section 44 (a) of the Industrial Property Act of 6 January 2014

44. Exception to exclusive rights.

It is not an infringement of a patent to use the patented invention without the authorization of the patent holder in any of the following circumstances:

[...]

(a) to carry out any acts related to experimental use or research on the patented invention, whether for scientific or commercial purposes;

[...]

UKRAINE

Article 31 (2) of the Law of Ukraine № 3687-XII of 15 December 1993 on Protection of Rights to Inventions and Utility Models (as amended up to 5 December 2012)

31. Acts which Shall Not an Infringement of the Exclusive Right.

[...]

2. The use of the patented invention (utility model) shall not be considered to be the infringement of rights deriving from a patent provided that it is used:

[...]

for scientific or experimental purposes;

[...]

UNITED KINGDOM

Section 60 (5) (b) of the Patents Act of 2004

60. Meaning of infringement.

[...]

(5) An act which, apart from this subsection, would constitute an infringement of a patent for an invention shall not do so if –

[...]

(b) it is done for experimental purposes relating to the subject-matter of the invention;

[...]

UNITED REPUBLIC OF TANZANIA

Section 12 (4)(a) (iii) of the Zanzibar Industrial Property Act 2008 (Act № 4 of 2008)

12. Rights conferred by a patent.

[...]

(4) (a) The rights under the patent shall extend:

[...]

(iii) to acts done relating to experimental use on or relating to the patented invention, whether for scientific or commercial purposes;

[...]

URUGUAY

Article 39 (c) and (d) of the Law № 17.164 of 2 September 1999 regulating Rights and Obligations relating to Patents, Utility Models and Industrial Designs

39. The rights conferred by patents shall not cover the following acts:

[...]

(c) acts carried out solely for experimental purposes, including acts anticipating future commercial exploitation, carried out during the year prior to expiry of the patent;

(d) acts carried out for teaching, scientific or academic research purposes;

[...]

UZBEKISTAN

Section 12 of the Law of the Republic of Uzbekistan № 1062-XII of 6 May 1994 on Inventions, Utility Models and Industrial Designs (as amended up to Law of the Republic of Uzbekistan № ZRU-446 of 14 September 2017)

12. Acts not recognized as an infringement of a patent owner's exclusive right.

The following shall not be recognized as an infringement of a patent owner's exclusive right:

[...]

the conduct of scientific research or an experiment on means containing industrial property subject matter protected by patents;

[...]

VIET NAM

Article 125 (2) a) of the Intellectual Property Law № 50/2005/QH11 of 29 November 2005

125. Right to prevent others from using industrial property objects.

[...]

2. Owners of industrial property objects as well as organizations and individuals granted the right to use or the right to manage geographical indications shall not have the right to prevent others from performing the following acts:

a/ Using inventions, industrial designs or layout-designs in service of their personal needs or for noncommercial purposes, or for purpose of evaluation, analysis, research, teaching, testing, trial

production or information collection for carrying out procedures of application for licenses for production, importation or circulation of products;

[...]

ZAMBIA

Section 75 (1) of the Patents Act 2016 (Act № 40 of 2016)

75. Limitations of patent rights.

(1) Despite any other provision of this Act, rights under a patent shall be limited to industrial or commercial activities and shall not extend to the following:

(a) acts done by any person, involving a patented invention, for scientific research;

[...]

(d) acts related to experimental use of the patented invention;

[...]

(2) Where test batches of a patented product have been produced in terms of subsection (1), the term of the patent of the original product shall not be extended.

ANDEAN COMMUNITY

Article 53 (b) of the decision № 486 of 14 September 2000 of the Commission of the Andean Community

53. The owner of the patent may not exercise the right referred to in the foregoing Article in relation to the following acts:

[...]

(b) acts performed for exclusively experimental purposes on the subject matter of the patented invention;

[...]

EURASIAN PATENT ORGANIZATION

Rule 19 of the Patent Regulations under the Eurasian Patent Convention (adopted by the Administrative Council of the Eurasian Patent Organization (EAPO) at its second (1st ordinary) session on 1 December 1995, with the amendments and additions adopted by the Administrative Council of the EAPO at its thirty second (22st ordinary) EAPO AC session on 1-3 November 2016.

19. Acts not Infringing the Eurasian Patent.

The following cases of the use of the patented invention shall not constitute an infringement of the Eurasian patent:

[...]

use for scientific research and experimental purposes;

[...]

GULF COOPERATION COUNCIL (GCC)

Section 14 (1) of the Patent Regulation for the GCC States was approved by the GCC Supreme Council during its 13th summit held in Abu Dhabi 21-22 September 1992

14: The rights under the patent shall not extend to:
1) Acts done particularly for scientific research purposes.

[...]

ORGANISATION AFRICAINE DE LA PROPRIÈTÈ INTELLECTUELLE (OAPI)

Article 8 (1) c) of the Bangui Agreement of 2 March 1977 on the Creation of an African Intellectual Property Organization (1999)

8 (1): The rights deriving from the patent shall not extend:
(c) to acts in relation to a patented invention that are carried out for experimental purposes in the course of scientific and technical research;

[...]

NORTH AMERICAN FREE TRADE AGREEMENT (NAFTA)

Article 1709 (6) of the North American Free Trade Agreement of 1 January 1994

1709: Patents.

[...]

6. A Party may provide limited exceptions to the exclusive rights conferred by a patent, provided that such exceptions do not unreasonably conflict with a normal exploitation of the patent and do not unreasonably prejudice the legitimate interests of the patent owner, taking into account the legitimate interests of other persons.

[...]

[End of Appendix and of document]