

## Standing Committee on the Law of Patents

Twentieth Session  
Geneva, January 27 to 31, 2014

### EXCEPTIONS AND LIMITATIONS TO PATENT RIGHTS: EXPERIMENTAL USE AND/OR SCIENTIFIC RESEARCH

*Document prepared by the Secretariat*

#### INTRODUCTION

1. At its nineteenth session, held from February 25 to 28, 2013, the Standing Committee on the Law of Patents (SCP) agreed that, in relation to the topic “exceptions and limitations to patent rights”, the Secretariat would prepare, *inter alia*, a document, based on input received from Member States, on how the following five exceptions and limitations were implemented in Member States, without evaluating the effectiveness of those exceptions and limitations: private and/or non-commercial use; experimental use and/or scientific research; preparation of medicines; prior use; and use of articles on foreign vessels, aircrafts and land vehicles. The document should also cover practical challenges encountered by Member States in implementing them.
2. Pursuant to the above decision, the Secretariat invited, through Note C.8261, Member States and Regional Patent Offices to submit information to the International Bureau additional to, or updating, the information contained in their responses to the questionnaire on exceptions and limitations to patent rights (hereafter “the questionnaire”) on the above five exceptions and limitations. In addition, Member States and Regional Patent Offices that had not yet submitted their responses to the questionnaire were invited to do so.
3. Accordingly, this document provides information on how exceptions and limitations relating to experimental use and/or scientific research have been implemented in Member States. The document aims at providing the comprehensive and comparative overview of the implementation of an exception and/or limitation related to this subject under the applicable laws of Member States. Reference is made to the original responses submitted by the above Member States and a regional patent office to clarify the scope of the exception in a particular jurisdiction. The questionnaire as well as the responses received from Member States are

available in full on the website of the SCP electronic forum at:

<http://www.wipo.int/scp/en/exceptions>.

4. This document consists of three Sections: (i) Public Policy Objectives for Providing the Exception; (ii) The Applicable Law and the Scope of the Exception; and (iii) Implementation Challenges.

5. The following Member States and patent Offices indicated that their applicable laws provided for exceptions and/or limitations related to the experimental use and/or scientific research: Albania, Algeria, Armenia, Australia, Austria, Azerbaijan, Bhutan, Bosnia and Herzegovina, Brazil, Bulgaria, Burkina Faso, Canada, China, Congo, Costa Rica, Croatia, Cyprus, Czech Republic, Democratic People's Republic of Korea, Denmark, Dominican Republic, El Salvador, Finland, France, Germany, Greece, Honduras, Hong Kong (China), Hungary, Indonesia, Israel, Italy, Japan, Jordan, Kenya, Kyrgyzstan, Latvia, Lithuania, Mauritius, Mexico, Morocco, Netherlands, New Zealand, Norway, Oman, Pakistan, Peru, Philippines, Poland, Portugal, Qatar, Republic of Korea, Republic of Moldova, Romania, Russian Federation, Sao Tome and Principe, Serbia, Slovakia, Spain, Sri Lanka, Sweden, Switzerland, Tajikistan, Thailand, Turkey, Uganda, Ukraine, United Kingdom, United Republic of Tanzania, United States of America, Viet Nam, Zimbabwe and the Eurasian Patent Office (EAPO) (73 in total).

## **PUBLIC POLICY OBJECTIVES FOR PROVIDING THE EXCEPTION**

6. In many Member States, one of the public policy objectives for the provision of the experimental use and/or research exception is to promote scientific research and technological progress and to encourage inventive activities.<sup>1</sup> While a small number of countries stated that the objective was to promote scientific research, most of the countries referred to the promotion of basic and applied research as well as technological development in general. The importance of the freedom of research was highlighted in the responses from Austria, Switzerland and the Russian Federation. According to the response from Australia, the recent introduction of a statutory provision regarding the experimental use exception aimed at drawing a clear line between research and commercial activities, leaving researchers free to conduct their experiments without fear of patent infringement.

7. Some countries include teaching within the scope of the research exemption, noting that the exception also promoted education and enhanced the level of teaching.<sup>2</sup> The response from Norway clarified 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”.

8. In Mexico, it was considered that “purely experimental, scientific or technological research, testing or teaching activities, involving the manufacture or use of a patented product or a process, within the private or academic sphere and for non-commercial purposes, are activities which promote and foster inventive industrially applicable activity, technical improvements and the dissemination of technological knowledge within the industry and academic sectors”. It therefore touched upon the public policy regarding further sharing and dissemination of technological knowledge generated from R&D activities conducted by third parties under the research exemption.

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<sup>1</sup> For example, see the responses from Algeria, Austria, Bhutan, Brazil, Germany, Honduras, Hungary, Italy, Japan, the Netherlands, Poland, Portugal, Serbia, Spain, Sweden, Switzerland, Uganda, Ukraine, the United Kingdom and Zimbabwe.

<sup>2</sup> See, for example, the responses from Indonesia and Honduras.

9. The response from the Russian Federation stated that the experimental use and scientific research exception was reasonable in view of the fact that any person, prior to taking a decision on requesting a patent holder to assign or license his patent, should have the opportunity to satisfy himself that the relevant subject matter possessed the characteristics in which he had been interested. The response from the Republic of Korea also highlighted that aspect by stating that a third party should be allowed to work the invention in order to better understand the contents and effects of a patented invention.

10. For the purpose of serving the public interest as a whole, many countries highlighted the purpose of patent law and the necessity of providing an appropriate balance of patent rights, considering the rights of patent holders, the interests of users of the patented technology and the public at large so as to maximize the social benefits.<sup>3</sup> For example, with reference to that balance, it was explained in the response from China 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 Brazil, 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 was “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”. The response from Canada explained that since inventors agreed to the public disclosure of their inventions when submitting a patent application, as part of the balance of rights and obligations under the patent system, “an experimental use exception permits other individuals to investigate that invention, making use of that disclosure.” The response of the Republic of Korea noted that while working of a patented invention permitted under the research exception contributed greatly to the advancement of technologies, “as long as a product developed through such working of the invention is not put on the market, the patentee does not suffer a direct loss”.

11. Reflecting the fact that, in some countries, the scope of the research exception covers the use of patented products or processes for the purpose of obtaining regulatory approval, some countries noted the policy interest in enabling generic medicines to enter the market in due time, in order to “provide patients with quality medicines at reasonable price, and decrease the costs related to the financing of medicines covered by the health scheme” of the country concerned.<sup>4</sup>

12. Some Member States referred to alignments with regional or international treaties with respect to the public policy objective. For example, the responses from Albania, Latvia, Portugal, Spain and the United Kingdom referred to the legislation of the European Union (for example, Article 31 of the Community Patent Convention 1975 and Article 27(b) of the Agreement on Community Patents (1989))<sup>5</sup>. The Dominican Republic and Pakistan referred to the Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS Agreement). In the response from Hong Kong, China, reference was made to the laws of other jurisdictions, in particular, Section 42 of the Irish Patent Act 1992.

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<sup>3</sup> See, for example, the responses from Brazil, Canada, China, the Kyrgyz Republic, the Russian Federation, Sri Lanka and the United States of America.

<sup>4</sup> See the response from Hungary. The response from Israel also indicated the similar policy objective.

<sup>5</sup> Further, Article 27(b) of the Agreement on a Unified Patent Court states that the right conferred by a patent shall not extend to acts done for experimental purposes relating to the subject matter of the patented invention.

## THE APPLICABLE LAW AND THE SCOPE OF THE EXCEPTION

13. 73 responses indicated that their statutory laws provided for exceptions and limitations related to experimental use and/or scientific research. Two Members States do not provide for such a statutory exception, but exclude experimental use and/or scientific research activities from enforcement of patent rights by common law.

14. In line with the above policy objectives, in general, the experimental use and/or scientific research exception allows third parties, without asking consents of patentees, to: (i) examine the stated effects or utilisability of the patent inventions in order to, for example, acquire knowledge, facilitate licensing or challenge the validity of patents; and (ii) improve and further develop the patented invention. However, the provisions regarding this exception in the national laws and the interpretation of those provisions as well as case law developed in some countries show certain differences.

### *Scope of the statutory exception*

15. In most countries where the experimental use and/or research exception is contained in statutory laws, the relevant provision states that the right conferred by a patent does not extend to, for example, activities for “experimental or research purposes”<sup>6</sup>, acts for “scientific experiment or scientific research”<sup>7</sup>, “scientific research or experiment”<sup>8</sup>, acts performed for “experimental purposes”<sup>9</sup>, acts for “scientific research purposes”<sup>10</sup>, acts “carried out for experimental purposes in the course of scientific and technical research”<sup>11</sup> or “using inventions for the purposes of evaluation, analysis, research, teaching, testing and trial production”<sup>12</sup>. The law of Switzerland states that the exception covers “acts undertaken for research or experimental purposes in order to obtain knowledge about the subject-matter of the invention including its uses; in particular, any scientific research concerning the subject-matter of the invention is permitted”. The relevant provisions under the national/regional laws commonly use the terms “scientific research”, “research” or “experiment”, but in general, they are not further defined in the laws. Interpretation of those terms will be discussed later in this document.

16. The provisions of the patent laws of some countries 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”<sup>13</sup>, “solely serving for research on the patented subject matter, including the product obtained directly as a result of using the patented process”<sup>14</sup> or “done only for research and

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<sup>6</sup> See Article 69 of the Patent Law of China, Article 69(1) of the Japanese Patent Act and Section 20.2 of the Patent Law of Latvia.

<sup>7</sup> See Article 17(2) of the Law on Inventions, Utility Models and Industrial Designs of Armenia.

<sup>8</sup> See 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 35 of the Patent Law of Lithuania, Article 1359(2) of the Civil Code of the Russian Federation, 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.

<sup>9</sup> 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, Section 1 of the Patent Law of Israel, Article 68(1)(a) of the Industrial Property Code of Italy, Section 3(3)-3 of the Patent Act of Norway, 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.

<sup>10</sup> See Section 58 of the Industrial Property Act 2008 of Kenya, Article 8.4(c) of Law 4/2001 of Sao Tome and Principe and Section 38 of the Patent Act of Tanzania.

<sup>11</sup> See Article 8(1)(c) of the Bangui Agreement. A similar provision is found in Article 43, paragraph II of Law n.9.279 of Brazil.

<sup>12</sup> Article 125(2) of the Law on Intellectual Property 2005, amended and supplemented in 2009, of Viet Nam.

<sup>13</sup> Article 102 of the Industrial Property Code (CPI) of Portugal.

<sup>14</sup> Article 53(3) of the Patent Act of the Netherlands.

experimental purposes relating to a patented invention.”<sup>15</sup>, activities for “making or using for purely experimental purposes or for scientific research”<sup>16</sup>, acts “performed merely for experimental purposes relating to the subject matter of the invention”<sup>17</sup>, activities “only for experimental purposes”<sup>18</sup>, acts done merely for the purpose of scientific research<sup>19</sup> and “acts done only for the purposes of scientific research”<sup>20</sup>

17. In the patent laws of some countries, activities regarding education and academic teaching are also explicitly excluded from acts infringing patent rights in the context of research and/or experimental use. For example, Article 18 of the Law of Industrial Property of Honduras provides that patent rights may not be enforced against acts exclusively for the purposes of “experimentation, scientific research or teaching”, and Article 22 of the Industrial Property Law of Mexico states that right conferred by a patent shall not produce any effect against a third party who, in the private or academic sphere and for non-commercial purposes, carries out “purely experimental scientific or technological research, testing or teaching activities”. Some other countries also provide similar provisions in their patent laws, such as acts for “research and experimental purposes, for the evaluation thereof, analysis or teaching”<sup>21</sup>, “exclusively for experimental use of the invention for scientific purposes or educational purposes and such other activities directly related to such scientific or educational experimental use”<sup>22</sup>, acts exclusively performed for experimental purposes and “for the purposes of teaching or scientific or academic research”<sup>23</sup> and acts for the purposes of “study, research, experimentation or analysis”<sup>24</sup>.

18. Some other countries’ laws explicitly indicate the aspect of technological development in research by exempting “research and development activities and for experiments relating to the subject matter”<sup>25</sup>. 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 protected procedures or products in order to improve the process or product, or in order to develop another process or product.<sup>26</sup>

19. Other Member States explicitly include, in their provisions regarding the experimental use exception, acts for validation of studies or trials, in particular, the use of patented subject matter for obtaining marketing authorization or for other administrative processes. For example, the patent laws of the Czech Republic, Hungary, Portugal and Spain state that the exclusive patent rights do not extend to acts done for experimental purposes relating to the subject matter of the invention, including experiments and tests necessary for the marketing authorization of the patented product or process. Similar provisions are found in the laws of, for example, Azerbaijan, the Republic of Korea, Serbia and Slovakia. In Germany and Japan, the courts have established that the term “experimental use” in their laws covers clinical trials conducted

<sup>15</sup> Section 21(4)(d) of Patents, Industrial Designs and Trademarks Act 2002 of Mauritius.

<sup>16</sup> Section 27(3)(iii) of the Patent Act of Cyprus.

<sup>17</sup> Article 38(b) of Law 9947 “On Industrial Property” of Albania.

<sup>18</sup> Section 13(4) of the Industrial Property Act of Bhutan and Section 31(5)(c) of Patents Ordinance 2000 of Pakistan.

<sup>19</sup> Article 12(1) of the Ordinance No. 03-07 of July 19, 2003 on Patents of Algeria.

<sup>20</sup> Section 86(1)(i) of the Intellectual Property Act No.36 of 2003 of Sri Lanka.

<sup>21</sup> Article 69(1)(iii) of the Industrial Property Law of Poland.

<sup>22</sup> Section 72.3 of the Republic Act 8293, as amended by the Republic Act 9502, of the Philippines.

<sup>23</sup> Article 16(2) of the Law on Patents, Industrial Designs and Utility Models of Costa Rica, Article 30 of Law No. 20-00 on Industrial Property of the Dominican Republic and Article 126(c) of the Law on Intellectual Property of El Salvador.

<sup>24</sup> Section 36(2) of the Patent Act B.E. 2522, as amended by the Patent Act (no.2) B.E.2535 and the Patent Act (No.3) B.E. 2542 of Thailand.

<sup>25</sup> Article 73(b) of the Patent Law of Bosnia and Herzegovina, Article 20(1) of the Law on Patents and Utility Models Registration No.27/2 of Bulgaria, Article 63(2) of the Patent Act of Croatia and Article 59(2) of the Patent Law of Serbia.

<sup>26</sup> M.C.P. 19682/05, Transkaryotic Therapies INC vs. Genzyme Corporation (2006) Nevo.

for the same indication as that of the patented invention. However, the case law of the United Kingdom established that acts carried out for the purpose of obtaining regulatory approval (clinical trials) are not covered by the experimental use exception under Section 60(5)(b) of the Patents Act<sup>27</sup>. Similarly, in the Netherlands, the research exception does not cover research for commercial purposes such as clinical trials.<sup>28</sup> Further details concerning the so-called Bolar exception will be addressed in a document to be submitted to the 21<sup>st</sup> session of the SCP.

20. In some Member States, their national laws explicitly require that the research exception shall not violate the legitimate interests of the patent holder by stating that, for example, the exception shall not “conflict with a normal exploitation of the patent” and shall not “unreasonably prejudice the legitimate interests of the patent holder”<sup>29</sup>. Similarly, Article 16 of the Patent Law of Indonesia states that the patent rights do not extend to the use of a patent for the purposes of education, research, experiment, or analysis “as long as it does not harm the normal interest of the patent holder”.

21. In Australia, an explicit experimental use exception<sup>30</sup> was introduced in 2012 in order to draw a clear line between research and experimental activities relating to patented inventions, which are exempt from infringement, and commercial activities. Thus, the provision contains a non-exhaustive list of “experimental purposes relating to the subject matter of the invention” as follows: “(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”. Similarly, in New Zealand, while case law had established that “non-commercial” research would not infringe a patent, while “commercial” research would<sup>31</sup>, there was considerable uncertainty as to what does or does not constitute experimental use. Consequently, the Patents Act 2013 provides an explicit experimental use exception in Section 143, which includes an exhaustive list of acts that are considered to have the experimental purpose.<sup>32</sup>

22. Two Member States already exclude experimental use or scientific research from the scope of the right conferred by a patent, for example, by providing that the “exploitation by experiment relating to the subject matter of the invention for experimental purposes shall remain outside the scope of rights conferred by the patent”<sup>33</sup>

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<sup>27</sup> Monsanto Co v Stauffer Chemical Co and another [1985] RPC 515. However, Section 60(5)(i) of the Patents Act exempts trials and studies carried out on generic medicines from patent infringement.

<sup>28</sup> Supreme Court, 23 June 1995, NJ 1996, 463 or BIE 1995/33 (ARS/Organon): The research exception under Article 53(3) NPA 1995 is not meant for research for commercial purposes such as clinical trials, but is allowable for a commercial company.

<sup>29</sup> Article 26 of the Patent Law of Lithuania and Section 36(2) of the Patent Act of Thailand.

<sup>30</sup> Section 119C of the Patents Act 1990.

<sup>31</sup> For example, Smith Kline & French Laboratories Ltd vs Attorney General (1991) 4 TCLR 199. “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”.

<sup>32</sup> Section 143(2) of the Patents Act 2013 of New Zealand reads as follows: “(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).”

<sup>33</sup> Article 75(b) of the Turkish Patent Decree Law. Similarly, in Sri Lanka, the patent rights extend only to acts done for industrial or commercial purposes and therefore, they “in particular do not extend to acts done only for the purpose of scientific research”.

### *Common law exceptions*

23. In Canada, several court cases<sup>34</sup>, taken together, have been considered to demonstrate that there is a judicially recognized research exception, but no case to date has clearly set out the scope of this exception.

24. Similarly, the experimental use exception is found in the United States of America through case law<sup>35</sup>, although its scope is restricted in a way that “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.”

### *Entitlement to the exception*

25. Most of the Member States stated that they did not distinguish the nature of third parties conducting experimentation or research for the purposes of applying the exception. In other words, whether an entity conducting research or experiment is a commercial entity, non-commercial entity, university or public research institute is not relevant for the applicability of the exception.

26. In that regard, many countries clarified that the nature of the experimental or research activity, and not the nature of the entity which conducts research, is relevant to the determination of the exception. For example, the response from Canada clarified that it was the “nature of the activity” which was relevant to the applicability of the exception. The response of Germany stated that limitation to the patent rights for acts done for experimental purposes applied to “all experiments relating to the subject matter of the patented invention, irrespective of the aim of the experiment, and of the person or organization conducting the experiment”. Further, the response from Mexico noted that Article 22 of its law referred only to “a third party”, without specifying what the nature of that third party should be, but did state that such a party might carry out experimental, testing or teaching activities with a patented product or process, only in the “private or academic” sphere and for “non-commercial purposes”.

27. In Tajikistan, its law<sup>36</sup> limits the nature of the organization conducting the experiments or research to academic, educational and research institutions. Further, certain activities covered by the exception in some jurisdictions<sup>37</sup>, such as academic research or teaching, may predetermine the nature of the entities covered by the exception (for example, academic institutions).

### *Interpretation of the terms “experiment” and “research”*

28. In the vast majority of Member States, the concepts of experimental use and/or scientific research are not defined by the law. The notable exceptions are the patent laws of Australia and New Zealand<sup>38</sup>. The response from Hong Kong, China, stated that its court would determine whether a particular act fell within the scope of the exception, based on the facts and circumstances of each case. The Republic of Moldova, in its response, highlighted that in the absence of the definition in the national legislation, “general principles contained in international treaties”, such as the TRIPS Agreement and the Paris Convention for the Protection of Industrial Property, would be applied by its courts.

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<sup>34</sup> See, for example, *Micro Chemicals Ltd. v. Smith Kline & French Inter-American Corp.* (1971), 2 C.P.R.(2d) 193 (S.C.C.), *Cochlear Corp. v. Cosem Neurostim Ltée* (1995), 64 C.P.R.(3d) 10 (F.C.T.D.), *Dableh v. Ontario Hydro* (1996), 68 C.P.R.(3d) 129, at 145 (F.C.A.).

<sup>35</sup> *Madley v. Duke*, 307 F. 3d 1351 (Fed. Cir. 2002).

<sup>36</sup> Article 30 of the Law of the Republic of Tajikistan “On inventions”.

<sup>37</sup> See the responses from Costa Rica and Pakistan.

<sup>38</sup> See paragraph 21 of this document.

29. In the Netherlands, in accordance with the case law, the research exception applies if it is justified by the aim of the research.<sup>39</sup> 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".

30. According to the Spanish legal doctrine<sup>40</sup> and case law<sup>41</sup>, 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.

31. 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<sup>42</sup> 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."

32. In the United Kingdom, case law provides guidance on the interpretation of the term "experimental purposes". In *Monsanto Co v Stauffer Chemical Co and another*<sup>43</sup>, it was held that "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". However, trials carried out in order to demonstrate to a third party that a product works or in order to amass information to satisfy a third party are not to be regarded as acts done "for experimental purposes". In *CoreValve v Edwards Lifesciences*<sup>44</sup>, 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", it is considered as a legitimate act for experimental purposes. The court, however, considered that "there must be an outward limit to that principle", and held that the application of the principle should involve the consideration of whether the immediate purpose of the transaction was to generate revenue. The clinical trials in question were not considered to be exempted [...] since one of the purposes

<sup>39</sup> Supreme Court, 18 December 1992, BIE 1993/81 (ICI/Medicopharma).

<sup>40</sup> Fernández-Nóvoa, C.; Otero Lastres, O.L.; y Botana Agra, M.: Manual de la Propiedad Industrial, Marcial Pons, 2009, p.168.

<sup>41</sup> *Passim*, Supreme Court Ruling No. 39/2012 (Civil Chamber, Division No.1) of February 10, 2012.

<sup>42</sup> Article 2 of Federal Law No. 127-FZ of August 23, 1996, "On Science and State Science and Technology Policy".

<sup>43</sup> See footnote 27.

<sup>44</sup> *CoreValve v Edwards Lifesciences* [2009] EWHC 6 Pat Ct.

of the trials was to 'generate immediate revenue of a substantial character'. It follows that commercial factors must be considered in determining whether the exception applies". Further, in another case<sup>45</sup>, 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."

33. In the United States of America, according to its case law, "regardless of whether a particular institution or entity is engaged in an endeavor for commercial gain, so long as the act is in furtherance of the alleged infringer's legitimate business and is not solely for amusement, to satisfy idle curiosity, or for strictly philosophical inquiry, the act does not qualify for the very narrow and strictly limited experimental use defense".

34. In the questionnaire, countries were asked to indicate purposes of experimentation and/or research, if such purposes are relevant to the determination of the exception. They were requested to choose applicable purposes from the five purposes already enumerated in the questionnaire and specify any other purposes, where applicable. The five specified purposes of the exception were: (i) to determine how the patented invention works; (ii) to determine the scope of the patented invention; (iii) to determine the validity of the claims; (iv) to seek an improvement to the patented invention; and (v) to invent around the patented invention. Not many countries replied to this particular question, and some countries pointed out the practical difficulties in answering this question. Among those countries that answered the question most of them indicated that all, or almost all, of the five purposes are relevant. Some Member States referred to other purposes, such as "academic or teaching" purposes or "improvement of the patented invention or developing a new one". In Turkey, the exception aims to cover "non-commercial experimental purposes" with a "very broad definition without any restriction".

35. Finally, as indicated in paragraphs 19 and 32, above, one of the aspects where the interpretation of the exception differs among countries is whether the experimental use and research exception *per se* applies to studies and tests carried out to obtain authorization for generic medicines.

#### *Research on and/or with a patented invention*

36. Research or experiment may be conducted on or into a patented invention, for example, working on the patented invention in order to explore unknown effects or further develop the invention. However, it may be conducted with or using the patented invention by, for example, using a patented invention on another invention in order to explore more about such other invention. For the determination of the scope of the experimental use/research exception, a question as to whether the experimentation must be conducted on the patented invention or conducted with the patented invention was asked in the questionnaire. None of those criteria, however, was determinative in many Member States, since, for example, beyond the requirement that the act must be done for experimental purposes "relating to the subject matter of the invention", the law "contains no requirement to consider the above criteria in determining the scope of the exception".<sup>46</sup>

37. In some Member States, both criteria, i.e., "research on" and "research with" the patented invention, are applied for the determination of the scope of the exception.<sup>47</sup> In Costa Rica, this interpretation is based on Article 16.2(b) and (c) of its law which refers to acts performed for

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<sup>45</sup> Smith Kline & French Laboratories Ltd vs Attorney General (1991) 4 TCLR 199.

<sup>46</sup> See the response from the United Kingdom. The responses from El Salvador and Zimbabwe noted that their laws were silent in that regard.

<sup>47</sup> Azerbaijan, Bosnia and Herzegovina, Costa Rica, Croatia, Denmark, Finland, Honduras, Mexico, Oman, Pakistan, Peru, Poland, Republic of Korea, Romania, Serbia, Sweden, Turkey, Uganda, Ukraine, Viet Nam and Zimbabwe.

experimental purposes relating to the subject matter of the patented invention.<sup>48</sup> The responses from Poland and the Republic of Korea stated that the phrases found in the relevant national laws, i.e., “employing of an invention” and “working of inventions”, respectively, indicated the applicability of the both criteria. In the response from Uganda, the phrase “acts done in pursuance of scientific research” in Section 28(a) of the Patents Act was cited as the basis of the interpretation.

38. Some other Member States only applied the research exemption to “research on” the patented invention.<sup>49</sup> For example, in the Russian Federation, 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. Similarly, the response from Tajikistan indicated that the “research on” criterion derived from its law<sup>50</sup>, which stated that scientific research or experiments “involving devices incorporating patented inventions” was covered by the exception. The responses from the Kyrgyz Republic and the Netherlands stated that their applicable laws provided that the exception applied to “research on the patented subject matter”.

39. Some countries took the view that their national laws applied the “research on” criterion, since their provisions specified that experimentation was “with respect to the patented invention”<sup>51</sup> or for the “experimental purposes relating to the subject matter of the patented invention”<sup>52</sup>.

40. No Member State used the criterion of “research with” as a single criterion for the determination of the scope of the experimental use/research exception.

#### *Commercial and/or non-commercial purposes*

41. With respect to the relevance of the commercial or non-commercial intention of the experimentation and/or research to the determination of the scope of the exception, among those Member States that provided information, most stated that the commercial intention of the experimentation and/or research was not relevant or both commercial and non-commercial activities were covered by the exception.<sup>53</sup>

42. In the United Kingdom, the court held that the exception could cover experimental work having a commercial purpose, but not all trials for a commercial purpose fell within the exception.<sup>54</sup> Further, in *CoreValve v Edwards Lifesciences*, it was held that the exception did not apply, since one of the purposes of the experiments was to “generate immediate revenue of a substantial character”.<sup>55</sup> In the Netherlands, according to its case law, the exception applies to “research on a patented invention for licensing purposes”. The response from France clarified that the 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.”

<sup>48</sup> Similar explanations were given in the responses from Finland, Germany, Hong Kong (China), Romania and Sweden.

<sup>49</sup> Albania, Australia, Dominican Republic, Germany, Hong Kong (China), Kyrgyz Republic, Netherlands, Norway, Russian Federation, Switzerland and Tajikistan.

<sup>50</sup> Article 30 of the Law of the Republic of Tajikistan “On inventions”.

<sup>51</sup> Article 30(b) of Law No. 20-00 of the Dominican Republic.

<sup>52</sup> Section 11(2) of the Patent Act of Germany and Section 75(b) of Patents Ordinance of Hong Kong (China).

<sup>53</sup> Algeria, Azerbaijan, Brazil, China, Croatia, Cyprus, Denmark, Finland, France, Germany, Hong Kong (China), Hungary, Israel, Mauritius, Netherlands, Norway, Pakistan, Portugal, Sao Tome and Principe, Serbia, Spain, Sri Lanka, United Kingdom and Viet Nam.

<sup>54</sup> *Monsanto Co v Stauffer Chemical Co and another* [1985] RPC 515.

<sup>55</sup> *CoreValve v Edwards Lifesciences* [2009] EWHC 6 Pat Ct

43. Some Member States only cover activities relating to non-commercial purposes.<sup>56</sup> For example, in Romania, the statutory provision provides that the exception is applicable exclusively for the non-commercial experimental purposes.

44. Among those Member States that cover experiments and research for non-commercial purposes only, most of them do not provide for definitions that distinguish commercial and non-commercial purposes. The response from Honduras stated that there was no distinction or definition of the term ‘non-commercial purposes’, but it was interpreted “according to the economic sphere” and a “perception of a gain”. Accordingly, “when economic remuneration is not received,” the activity is considered to be in the “non-commercial sphere” required by the law of Honduras. In the Republic of Moldova, the definition of the term “non-commercial purposes” was considered unnecessary, since the commonly accepted meaning of the term would apply.

45. In the United States of America, the concept is defined by case law 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.<sup>57</sup>

## IMPLEMENTATION CHALLENGES

46. For most of the Member States, the applicable legal framework is adequate to meet the objective of the experimental use and/or scientific research exception, and no change in their laws in this regard has been envisaged.<sup>58</sup> The response from Pakistan highlighted that the experimental use exception had never been an issue. The response from the United States of America noted that a recent major reform of its patent law, Leahy-Smith America Invents Act (AIA), had made any further amendment in its patent law during the remainder of that Congressional Term quite improbable.

47. In the United Kingdom, the experimental use exception was the subject of a 2008 consultation by the UK Intellectual Property Office (UKIPO). The purpose of that consultation was to seek evidence on the effect of the patent research exception and to identify the extent of stakeholder concerns on that aspect of the UK patent law. The consultation was held 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. Following the consultation, two areas which do not strictly concern the experimental use exception, namely, the risk of patent infringement during clinical trials and the use of patented plant material by plant variety breeders, are the subject of further investigation and monitoring in the United Kingdom.

48. Similarly, in Canada, while commentators had expressed concerns that the lack of case law might lead to uncertainty, and had called for legislative change, no problem with the practical implementation of the exception had been found.

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<sup>56</sup> Costa Rica, Dominican Republic, El Salvador, Honduras, Mexico, New Zealand (response submitted prior to the enactment of the Patents Act 2013), Republic of Moldova, Romania, Turkey, Tanzania, Uganda, United States of America and Zimbabwe.

<sup>57</sup> *Madley v. Duke*, 307 F. 3d 1351 (Fed. Cir. 2002)

<sup>58</sup> 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, Turkey and the EAPO.

49. In Uganda, amendments regarding the scientific research exception have been proposed in the Industrial Property Bill. Section 28(a) of the Patent Act as it stands states that patent rights shall not be considered infringed by acts done in pursuance of scientific research, and it is limited to a non-commercial purpose. The amendment has been proposed so that the exception would cover experimentation for both scientific and commercial purposes.

50. In Zambia, a Bill introducing an explicit provision on an experimental use and research exception in its law has been proposed.<sup>59</sup>

51. The Brazilian Government has been carrying out an evaluation on the implementation of the exception with a view to assessing its usefulness in light of the objective of ensuring a balanced patent system. The response from El Salvador stated that it intended to revise the law in the medium term.

52. Most Member States indicated that they had encountered no challenges in relation to the practical implementation of this exception<sup>60</sup>, or did not provide any answer. Referring to challenges, the response from France noted that the Law of February 26, 2007 had introduced a specific exception for bioequivalence tests in the field of medicines with a view to promoting generic medicines.<sup>61</sup>

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<sup>59</sup> The relevant section in the proposed Bill reads as follows: "It shall not be an infringement of a patent to use the patented invention without the authorization of the patent holder in any of the following circumstances: (a) carrying out acts related to the experimental use of the patented invention, whether for scientific or commercial purposes; (b) to make use of the patented invention for teaching purposes; [...]". In addition, the proposed Bill also contains the so-called Bolar exception.

<sup>60</sup> See the responses from Algeria, Bosnia and Herzegovina, China, Costa Rica, Croatia, Denmark, the Dominican Republic, El Salvador, Honduras, Hungary, Latvia, the Netherlands, Pakistan, Peru, Portugal, the Republic of Moldova, the Russian Federation, Sao Tome and Principe, Turkey and the United States of America.

<sup>61</sup> Article L613-5(d) of the Intellectual Property Code of France.