

DRAFT REFERENCE DOCUMENT ON RESEARCH EXCEPTION

Standing Committee on the Law of Patents (SCP)
Twenty- ninth session (December 3 to 6, 2018)

Presentation by the Secretariat

SCP/29/3: Background

At SCP 28 (July 9 to 12, 2018), the Committee agreed that:

- The Secretariat would
 - Continue working on a draft reference document on exceptions and limitations
 - In particular, submit a draft reference document on **the research exception** to SCP/29
 - the same style and structure as the draft reference document SCP/28/3
 - Invite Member States to send any additional inputs for the preparation of the draft reference document (Note C. 8787, dated July 31, 2018)

SCP/29/3: Draft Reference Document

- Annex I to document SCP/29/3 contains the draft reference document on research exception
- The Secretariat made use of information submitted by the Member States, as well as other information collected through the SCP activities, as indicated in document SCP/27/3, e.g.:
 - Reports of the various SCP sessions; Responses to the Questionnaire on Exceptions and Limitations to Patent Rights; Seminars and Sharing Sessions on the topic of Patents and Health; Experts' Study on Exclusions from Patentable Subject Matter and Exceptions and Limitations to the Rights (SCP/15/3); SCP documents produced by the Secretariat; and other sources of literature.
- The document follows the style and structure of the draft reference document on the exception regarding acts for obtaining the regulatory approval from authorities (SCP/28/3)

SCP/29/3: Draft Reference Document

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APPENDIX

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1. Overview of the Research Exception

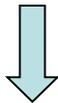
- Patent system provides incentives for investment in innovative activities and dissemination of innovative knowledge
- However, in economic term, exclusive rights conferred by the patent, creates deadweight losses
- A number of mechanisms are provided in the patent system to correct potential inefficiencies of the market power created by exclusive rights, e.g.: **exceptions and limitations to the rights**

Balance between patentee's rights
and public interest

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1. Overview of the Research Exception

- **Research exception / experimental use exception** is one of the most widely provided exceptions in patent systems
- In general, the research exception enables researchers to examine the stated effects of patented inventions and improve them without having to fear infringing the patent



- Positive environment for research activities facilitates the dissemination and advancement of technical knowledge and add to the development of technologies, thereby contributing to the objectives of the patent system

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2. Objectives and Goals of the Research Exception

- Disclosure requirement → the research exception is implicit in the patent system's *quid pro quo*
- Third parties should be allowed to work the invention in order to:
 - verify the veracity of the patent disclosure;
 - investigate the contents and the stated effects of a patented invention;
 - facilitate licensing or challenge the validity of patents.
- To achieve a right balance between the interest of the right holders and the users of those rights and protection of public interests
 - To promote scientific research and technological progress
 - To promote education and teaching

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3. Research Exception and International Legal Framework

■ **Article 30 of the TRIPS Agreement** (*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.

■ *Canada - Patent Protection of Pharmaceutical Product* – Panel provided no clear conclusion about the consistency of the research exception with Article 30 of the TRIPS Agreement.

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4. Research Exception in the Regional Instruments

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

5. National Implementation of the Research Exception

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 (113).

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5. National Implementation of the Research Exception

5.1 Legal framework regulating the research exception

- Research exception in
 - a specific statutory provision in patent law
 - case law
- In some laws, a single provision for the research exception and the regulatory review exception
- In some other countries, no provision on research exception, however the scope of exclusive rights can be limited to acts carried out for commercial purposes

5. National Implementation of the Research Exception

5.2 Scope of the research exception

- The texts of the provisions on the research exception differs
- 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 *on* or *with* a patented invention)

5. National Implementation of the Research Exception

The purpose of the research or experiment

- In many countries, right conferred by a patent does not extend to, e.g.: activities for “experimental or research purposes”/ use for “scientific research and experimental purposes”/ acts performed for “experimental purposes” / “exclusively” or “only” for trial or experimental purposes
- In general, the terms “experiments” and “research” are **not defined by the laws.**
- However, in some jurisdiction, **guidance on the interpretation can be found in the statutory or case law**

5. National Implementation of the Research Exception

The purpose of the research or experiment

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

5. National Implementation of the Research Exception

Commercial/non-commercial aspects

- In some countries, the exemption is applicable when the experiment was made **without commercial or gainful intent**
- In some other countries, the exception applies to **both commercial and non-commercial** research
- In some other countries, the relevant texts are silent as regards the commercial aspects
 - Courts in some countries provided some guidance
 - whether the “immediate purpose” of the act is “to generate revenue” or not (UK)
 - “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 (US).

5. National Implementation of the Research Exception

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

Research on or into a patented invention

= working on the patented invention for improvement etc.

Research with (using) a patented invention

= using the patented invention for working on another invention

- In many countries experimental act must relate to the subject matter of the patented invention
- In some other countries, it is not clear whether they apply research “on” and/or “with” criteria
- In Belgium, the exception applies to “acts accomplished for scientific purposes *on* and/or *with* the subject matter of the patented invention”

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

Implementation Challenges

- Most Member States responded:
 - No challenges in relation to the practical implementation of the exception.
 - The legal framework of the exception was adequate to meet the objectives sought.
- In some Member States an uncertainty over the scope of the experimental use exception.

7. Results of Implementation of the Research Exception

- The economic data empirically testing the effect of the implementation of the research exception on research and innovation is limited
 - Few countries reported on the effect of the exception
 - AU- the provision “has given certainty and clarity to researchers”
 - Inherent difficulties in collecting information about the use of the exception by individual stakeholders (information is not necessarily documented and/or publicly available or countable)
- Conclusion:
 - Further economic analysis are needed to ascertain the effect of the research exemptions on scientific inquiry
 - The optimal research exception should provide incentive to invest while not limiting knowledge spill-overs which would only have a small effect on the incentive to invest
 - Any research exception must comply with the requirements of international legal obligations, in particular, the TRIPS Agreement
 - Clarity in the scope of the research exception at the national level

Thank you.