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DRAFT REFERENCE DOCUMENT ON THE EXCEPTION REGARDING COMPULSORY LICENSING

Standing Committee on the Law of Patents (SCP)
Thirtieth session (June 24 to 27, 2019)

Presentation by the Secretariat

SCP/30/3: Background

At SCP 29 (December 3 to 6, 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 exception regarding compulsory licensing to SCP/30
  - Invite Member States to send any additional inputs for the preparation of the draft reference document (Note C. 8828, dated January 7, 2019)

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- Annex I to document SCP/30/3 contains the draft reference on the exception regarding compulsory licensing

- The Secretariat made use of information submitted by the Member States, as well as other information collected though 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.

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APPENDIX

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1. Compulsory Licensing - Overview of the Exception

- Rights conferred by a patent:
  - Right to prevent a third party from commercial exploitation of the patented invention; and right to assign and conclude licensing contracts - “voluntary” licenses.
- “Compulsory” or “non-voluntary” license granted by a competent national authority to a third party allowing the exploitation of the patented invention during the patent term without the authorization of the patentee.
- “Government use” - authorization granted to a government agency or to a third party authorized to act on behalf of the government.
- International treaties provide conditions to be respected for the grant of such licenses. In general, no international treaty restricts a freedom of countries to determine the grounds upon which compulsory licenses are granted.

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2. Objectives and Goals of the Compulsory Licensing

The policy objectives of compulsory licensing provisions may vary depending on the grounds available under the relevant laws

- Promoting the interest of the general public
  - to safeguard the interest of the general public, including health, defense and development of the economy
- Balancing of interests
  - to strike a balance between the interests of patentees and of third parties and/or public interest and/or society
- Preventing abuses of rights
  - non-working or insufficient working of a patent
- Specific public policy objectives on public health

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3. Compulsory licensing and International Legal Framework

- 3.1 Paris Convention for the Protection of Industrial Property
- 3.2 Agreement on Trade-Related Aspects of the Intellectual Property Rights (TRIPS Agreement)

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4. Compulsory Licensing Provisions in the Regional Instruments

Table 1. REGIONAL INSTRUMENTS	
Andean Community	- Chapter VII of Decision № 486 establishing the Common Industrial Property Regime for the Andean Community
Cooperation Council for the Arab States of the Gulf	- Articles 19 to 22 of the Patent Regulation of the Cooperation Council for the Arab States of the Gulf
African Intellectual Property Organization (OAPI)	- Articles 46 to 56 of Annex I of the Agreement Revising the Bangui Agreement of March 2, 1977, on the Creation of an African Intellectual Property Organization (Bangui (Central African Republic), February 24, 1999)
European Union	- Directive 98/44/EC of the European Parliament and of the Council of July 6, 1998, on the legal protection of biotechnological inventions - Regulation (EC) No. 816/2006 of the European Parliament and of the Council of May 17, 2006, on compulsory licensing of patents relating to the manufacture of pharmaceutical products for export to countries with public health problems

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5. National Implementation of the Exception Regarding Compulsory Licensing

Table 2. List of countries/territories which provide for exception regarding compulsory licensing
Albania, Algeria, Andorra, Antigua and Barbuda, Argentina, Armenia, Australia, Austria, Azerbaijan, Bahrain, Bangladesh, Barbados, Belarus, Belgium, Belize, Benin*, Bhutan, Plurinational State of Bolivia, Bosnia and Herzegovina, Botswana, Brazil, Brunei Darussalam, Bulgaria, Burkina Faso*, Burundi, Cabo Verde, Cambodia, Cameroon*, Canada, the Central African Republic*, Chad*, Chile, China, Hong Kong (China), Colombia, Comoros*, Congo,* Costa Rica, Côte d'Ivoire,* Croatia, Cuba, Cyprus, Czech Republic, Democratic People's Republic of Korea, Denmark, Djibouti, Dominica, Dominican Republic, Ecuador, Egypt, El Salvador, Equatorial Guinea*, Estonia, Eswatini, Ethiopia, Finland, France, Gabon*, Gambia, Georgia, Germany, Ghana, Greece, Grenada, Guatemala, Guinea*, Guinea-Bissau*, Honduras, Hungary, Iceland, India, Indonesia, Iran, Iraq, Ireland, Israel, Italy, Japan, Jordan, Kazakhstan, Kenya, Kyrgyz Republic, Lao People's Democratic Republic, Latvia, Lebanon, Libya, Liechtenstein, Lithuania, Luxembourg, Madagascar, Malaysia, Mali,* Malta, Mauritania,* Mauritius, Mexico, Monaco, Mongolia, Montenegro, Morocco, Mozambique, Namibia, Netherlands, New Zealand, Nicaragua, Niger,* Nigeria, North Macedonia, Norway, Oman, Pakistan, Papua New Guinea, Paraguay, Peru, Philippines, Poland, Portugal, Qatar, Republic of Korea, Republic of Moldova, Romania, Russian Federation, Saint Lucia, Sao Tome and Principe, Saudi Arabia, Senegal,* Serbia, Singapore, Slovak Republic, Slovenia, South Africa, Spain, Sri Lanka, Sudan, Sweden, Switzerland, Syrian Arab Republic, Tajikistan, Thailand, Togo*, Tonga, Trinidad and Tobago, Tunisia, Turkey, Turkmenistan, Uganda, Ukraine, United Arab Emirates, United Kingdom, United Republic of Tanzania, United States of America, Uruguay, Uzbekistan, Viet Nam, Zambia, and Zimbabwe (total: 156).

5. National Implementation of the Exception Regarding Compulsory Licensing

5.1 Legal framework regulating the exception regarding compulsory licensing

- In most countries, a specific statutory provision in IP or patent legislation
- In some countries, no provision on this exception, however, the provisions on compulsory licenses are applied through the membership in a regional agreement
- In some countries, a compulsory license to remedy an anti-competitive practice engaged in by the patentee is prescribed in the patent law and/or in the competition (antitrust) law

5. National Implementation of the Exception Regarding Compulsory Licensing

5.2 Scope of the compulsory licensing exception

a) Nature of the license, its duration and the general licensing terms
b) Prior efforts to obtain authorization on “reasonable terms and conditions” and within a “reasonable period of time”
c) Remuneration of the right holder
d) Judicial or similar review
e) Grounds for the grant of a compulsory license

5. National Implementation of the Exception Regarding Compulsory Licensing

Grounds for the grant of a compulsory license

Table 3. National laws provide different grounds for applying for a compulsory license, for example:
- Exercise of rights in abusive manner
- Non-working or insufficient working of the patented invention
- Dependent patents
- Anti-competitive practices and/or unfair competition
- National emergency or circumstances of extreme urgency
- Public interest
- Public non-commercial use
- Failure to meet market demand on reasonable terms
- The reasonable requirements of the public are not satisfied
- Compulsory licenses for patented pharmaceutical products for manufacture and export to countries with insufficient or no manufacturing capacities in the pharmaceutical sector
- Compulsory cross-licensing in case of interdependence between plant varieties and patented inventions

5. National Implementation of the Exception Regarding Compulsory Licensing

- Grounds for the grant of a compulsory license

  "development of other vital sectors of the national economy", "needs of national economy", "public necessity", "serious public interest menace", "non-exploitation of the patent for failure to manufacture or incomplete manufacture of the product […] or commercialization that does not satisfy the needs of the market", "the patented invention is not available to the public at a reasonably affordable price", "sold at unreasonably high prices or not meet the public demand without any legitimate reason", "where patent has not been exploited in a manner which contributes to the promotion of technological innovation and to the transfer and dissemination of technology", "protection of natural environment" or "the establishment or development of industrial and commercial activities is unfairly prejudiced".

5. National Implementation of the Exception Regarding Compulsory Licensing

Grounds found frequently in national laws are analyzed:

(a) Non-working or insufficient working
(b) The reasonable requirements of the public are not satisfied
(c) Failure to meet market demand on reasonable terms
(d) Compulsory license on the ground of anti-competitive practices
(e) Grant of compulsory licenses on the ground of dependent patents
(f) Grant of compulsory licenses on the ground of public interest / national emergency or circumstances of extreme urgency / public non-commercial use / Government use

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6. Challenges Faced by the Member States in Implementing the Exception Regarding the Compulsory Licensing

- Challenges may be of dual nature:
  i. Difficulties encountered by the governments in the implementation or transposition of international law at the national level; and
  ii. Challenges faced by individual stakeholders in using the national legal framework, resulting from the government's enactment of the national law.

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i. Difficulties encountered by the governments in the implementation or transposition of international law at the national level:

- *Constructive ambiguity of international treaties;*
- *Complexity of practical implementation of the Special Compulsory Licensing System;*
- *Operation of law and administrative framework*
- *Institutional capacity;*
- *National governance and internal coordination; and*
- *Extrinsic influences.*

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II. Difficulties faced by various stakeholders in using a national legal framework

- *Ambiguity and uncertainty of national law*
- *Technical capacity*
- *Identifying relevant patents and their status*

- *Other aspects that affect the use of compulsory licenses*
  - No patents
  - No need to resort to a compulsory license

- *Other challenges where use of compulsory licensing provisions may not lead to intended policy outcomes*
  - lack of technological capacity
  - economic factors might affect business decisions of generic producers (i.e., economies of scale and associated marketing costs)
  - difficulties in meeting quality standards
  - test data protection

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7. Results of Implementation of the Exception Regarding the Compulsory Licensing

- Mechanism has been rarely used, considering the total number of patent grants.
- However, requests to issue a compulsory license and grants are not necessarily limited to a specific technology area in few jurisdictions.
- During the last decade, the use of compulsory licenses has been more frequent in relation to pharmaceutical patents.
- Where compulsory licenses have been granted in the area of pharmaceuticals, in many instances, they have been reported to have resulted in substantial reduced prices.
- The argument on the side of the research-based pharmaceutical companies is that the grant of a compulsory license can have a chilling effect on R&D, potentially hurting patients who may require new and innovative life-saving therapies.
- The economic studies on the relationship between compulsory licensing and welfare in general or specifically in relation to the changes in pharmaceutical R&D are limited.
- Result achieved by each compulsory license may need to be analyzed against the backdrop of each case, avoiding the generalization of the effects that compulsory licenses might bring.

Thank you.

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