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SCP 27th DRAFT REFERENCE DOCUMENT ON EXCEPTION REGARDING ACTS FOR OBTAINING REGULATORY APPROVAL FROM AUTHORITIES

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Outline

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- A draft reference document
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The Background

At SCP 26th (July 3 to 6, 2017), the Committee agreed that:

- the Secretariat would prepare a draft reference document on exceptions and limitations to patent rights in conjunction with patent protection;

- the Secretariat would invite Member States to send any additional inputs for the preparation of the draft reference document (Note C. 8687, dated August 21, 2017); and

- The Secretariat make use of all information available from the SCP activities

Source of Information (1)

- Reports of the various SCP sessions;
- Responses to the Questionnaire on Exceptions and Limitations to Patent Rights, submitted by the Member States and regional patent offices;
- Seminar on the Relationship between Patent Systems and the Availability of Medicines in Developing Countries and Least Developed Countries (SCP/23);
- Sharing Session on Countries' Use of Health-Related Patent Flexibilities (SCP/20);
- Experts' Study on Exclusions from Patentable Subject Matter and Exceptions and Limitations to the Rights (SCP/15/3).

Source of Information (2)

SCP documents produced by the Secretariat, including:

- Preliminary Study on the Issue of Exclusions from Patentable Subject Matter and Exceptions and Limitations to the Rights (SCP/13/3);
- Exceptions and Limitations to Patent Rights: Acts for Obtaining Regulatory Approval from Authorities (SCP/21/3); and
- Practical Experiences on the Effectiveness of, and Challenges Associated to, Exceptions and Limitations (SCP/25/3).

A Draft Reference Document

- Use plain and descriptive language.
- Use facts to show tendencies but no recommendations.
- Recourse to boxes and tables to illustrate further data.
- Use of concrete provisions to illustrate certain concepts.
- Addition of an appendix with provisions considered.

The Structure

Contains the following sections:

(i) Description of the regulatory review exception;

(ii) Objectives and goals;

(iii) The multilateral legal framework of the regulatory review exception;

(iv) National/regional implementation;

(v) Challenges faced by Member States in implementing the exception; and

(vi) Results of the national/regional implementation.

In addition, it contains an Appendix, in which national legal provisions on the regulatory review exception are compiled.

The Substance: Description of the Regulatory Review Exception

- Entitles a third party to use a patented invention, without the consent of the patent holder, before the end of the patent protection, if such use is for the purposes of developing information to obtain a marketing approval.
- In order to obtain a marketing approval (authorization), an applicant is required to submit certain amount of information on the product that typically requires the production and testing of its samples. Such production and use of the product for testing may be considered an infringement of the patent, if the applicant is not the patentee.

The Substance: Objectives and Goals

- Aimed at avoiding a *de facto* extension of the patent term due to a lengthy regulatory approval process, and thus facilitating the marketing of generic medicines immediately after the expiration of the patent term.
- Japan (case law), recognized that "if any clinical investigations needed for getting approval of manufacturing generic drugs were not able to be conducted during the time when the patent rights are effective, this would substantially result in third parties not being freely able to use the patented inventions for a considerable length of time, even after the patent rights have expired…" Second Petty Bench of the Supreme Court, April 16, 1999 (Case No.153(ju) of 1998) (Minshu 53 (4) 627).

The Substance: Multilateral Agreements

- WTO Dispute Settlement Panel in *Canada - Patent Protection of Pharmaceutical Products* case.

- The Panel examined whether the regulatory review provision (Section 55.2(1)) and the stockpiling provision (Section 55.2(2)) of the Patent Act of Canada were justified, *inter alia*, under Article 30 of the TRIPS Agreement.

- The Panel held that Canada's regulatory review provision was justified under Article 30 by meeting all these three cumulative criteria.

The Substance: National and Regional Implementation

- The applicable laws of more than 65 countries have been identified to provide for the exception related to acts for obtaining regulatory approval from authorities.
- The regulatory review exception and experimental/scientific research exception are expressly combined into a single provision.
- In few countries, the regulatory review exception is considered by case laws as being covered by a provision regarding experimental use or scientific research exception.
- In few countries, the exception is contained not in the law on patents but in the regulations relating to health and/or pharmacy.

The Substance: Beneficiaries

- General clauses, such: “any person”, “any party”, “any third party” or “any legal person”
- More focused authorizations, such as:

  Thailand: “those who wish to produce, distribute or import the patented pharmaceutical product after the expiration of the patent term”.

  Brazil: “non-authorized third parties […] whose acts aim exclusively producing information […] to obtain regulatory approval”

  United States of America: “those whose actions are “solely for uses reasonably related to the development and submission of information under a Federal Law which regulates the manufacture, use, or sale of drugs or veterinary biological products”.

The Substance: Products Covered

- “any products” that require regulatory approval
- Limited to certain products, such as “pharmaceutical products”, “human or a veterinary drug or a medical products”, “patented drugs or patented medical apparatus and instruments”, “medicines”, “medicaments”, “medicinal products”, “certain medicinal products”, “pharmaceutical and agricultural chemicals”, “certain medicinal and plant protection products”, “allopathic medicines”, “drugs or veterinary biological products”, “medicinal products for human use or medicinal products for veterinary use”, “reference medicine” and “generic medicines”
- Medical devices ?

The Substance: Permitted acts

- “studies”, “trials”, “tests”, “examinations” and/or “experiments”, as well as “consequential practical requirements”, “related practical needs” or “related procedures” necessary for obtaining a marketing “authorization”, “permission”, “registration” or “marketing clearance”.

- Switzerland, the exception applies, *inter alia*, to “experiments and clinical trials in which a pharmaceutical product containing a protected active ingredient is tested to obtain the data required for marketing approval”.

The Substance: Reported Challenges

- Uncertainty about the scope.
- Lack of awareness.
- Absence of production capacity of generic medicines in the territory.

Final Comments

1. Regarding the form of a reference document. The current work is an example of what can be done by the Secretariat and it is an attempt to set the common grounds for any future work if the committee agreed so.
2. Some countries reported that the implementation of the regulatory review exception in the national law has a positive effect on the timely regulatory registration and entry of generic versions of medicines into the market.
3. Several studies have analyzed the effect of generics' entry and have found the reduction of prices of brand-name medicines due to competition from generic manufacturers.

Thank you

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