

## Standing Committee on the Law of Patents

**Twenty-Seventh Session**  
**Geneva, December 11 to 15, 2017**

**SUMMARY: DRAFT REFERENCE DOCUMENT ON EXCEPTION REGARDING  
ACTS FOR OBTAINING REGULATORY APPROVAL FROM AUTHORITIES**

*Document prepared by the Secretariat*

### INTRODUCTION

1. Pursuant to the decision of the Standing Committee on the Law of Patents (SCP) at its twenty-sixth session, held in Geneva from July 3 to 6, 2017, document SCP/27/3 entitled “Draft reference document on exception regarding acts for obtaining regulatory approval from authorities” is prepared by the Secretariat.
2. The primary source of information for the preparation of the reference document was information collected through the SCP activities. Since 2009, a substantive amount of information has been collected on the subject of exceptions and limitation to patent rights. In preparation of this document, the Secretariat consulted and made use of, among others: (i) Reports of the various SCP sessions; (ii) Experts’ Study on Exclusions from Patentable Subject Matter and Exceptions and Limitations to the Rights (SCP/15/3); (iii) Responses to the Questionnaire on Exceptions and Limitations to Patent Rights, submitted by the Member States and regional patent offices; (iv) Seminar on the Relationship between Patent Systems and the Availability of Medicines in Developing Countries and Least Developed Countries (SCP/23); (v) Sharing Session on Countries’ Use of Health-Related Patent Flexibilities (SCP/20); (vi) 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).

3. In addition, pursuant to the decision made at the twenty-sixth session of the SCP, the Secretariat made use of additional inputs provided by the Member States and the regional patent offices during the intersessional period between the twenty-sixth session and the twenty-seventh session of the SCP. Further, reflecting the discussions at the twenty-sixth session of the SCP, the Secretariat also consulted other sources for supplementary information.

4. The reference document contains the following sections: (i) description of the regulatory review exception; (ii) objectives and goals; (iii) the regulatory review exception and the TRIPS Agreement; (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.

## DESCRIPTION OF THE EXCEPTION

5. This section of the reference document provides the general overview of the regulatory review exception.

6. Some products, typically pharmaceutical products, cannot be marketed without obtaining marketing authorization from a competent regulatory authority. In general, in order to obtain such authorization, an applicant is required to submit certain amount of information on the product that typically requires the production and testing of some of its samples. Such production and use may be considered an infringement of the patent, if the applicant is not a patentee.

7. Because marketing authorization process may take several years, the inability to use the patented invention during the approval process, prior to the expiration of the patent, would delay market entry of competitive products, such as generics. To mitigate this situation, many patent laws provide for the regulatory review exception which, in general, entitles a third party to use a patented invention, before the end of the patent protection, without the consent of the patent holder for the purposes of developing information to obtain a marketing approval.

## OBJECTIVES AND GOALS

8. This section illustrates the policy objectives and goals of the regulatory review exception. The responses to the Questionnaire on Exceptions and Limitations to Patent Rights, submitted by Member States and regional patent offices, are used as a primary source of information in this regard. In general, the regulatory review exception in many countries aims at avoiding a *de facto* extension of patent protection due to a lengthy regulatory approval process, and thus facilitating market entry of competitive products immediately after the expiration of a patent. In the area of pharmaceuticals, since competition often lowers prices, this exception is considered to promote the affordability of off-patent medicines and reduction of the cost of treatments.

## REGULATORY REVIEW EXCEPTION AND THE TRIPS AGREEMENT

9. This section provides an overview of the WTO Dispute Settlement Panel Report regarding the *Canada – Patent Protection of Pharmaceutical Products* case<sup>1</sup>, in which the regulatory review exception and the “stockpiling” exception contained in the Patent Act of Canada were examined. The Panel found that Canada’s regulatory review exception provision was justified under Article 30 of the TRIPS Agreement by meeting all three cumulative criteria under that Article. As regards the stockpiling exception provision which allowed producers of generic drugs to make the drugs and begin stockpiling them six months prior to the expiration of the patent, the Panel found that the measure was not justified under Article 30, since it is not “limited” as required by that provision.

## NATIONAL AND REGIONAL IMPLEMENTATION

10. This section provides information on how the exception related to acts for obtaining regulatory approval from authorities has been implemented in various national/regional laws. The exception is found in the applicable laws of more than 65 countries. In general, countries take different approaches in implementing this exception at the national level. The section analyses the relevant provisions of the national/regional laws as regards to: (i) the source of law; (ii) who is entitled to the regulatory review exception; (iii) which products are covered by the exception; (iv) what kind of acts are permitted by the exception; (v) whether a regulatory review request shall be filed within a specific time period or not in order to enjoy the exception.

## CHALLENGES FACED BY MEMBER STATES IN IMPLEMENTATION OF THE EXCEPTION

11. This section reviews various challenges encountered by the Member States in implementing the regulatory review exception at the national level. Some Member States have reported that such challenges were uncertainty about the scope of the exception in the national laws and lack of awareness about this exception among potential users who might benefit from it.

12. In addition, some other issues that might affect the use of the regulatory review exception as well as general challenges with respect to national law implementation are reported in this section.

## RESULTS OF IMPLEMENTATION OF THE EXCEPTION

13. This section reports on the impact of the implementation of the regulatory review exception in national/regional laws. In general, some Member States have reported a positive effect of the implementation of the regulatory review exception in the national law on the timely regulatory registration and entry of generic versions of medicines into the market. While some empirical studies suggest that competition with generic manufacturers reduce the price of originator products in the pharmaceutical sector, these findings were not specifically attributed to the regulatory review exception.

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<sup>1</sup> WTO document WT/DS114/R.

## APPENDIX

14. The draft reference document contains, in its Appendix, a compilation of national/regional legal provisions that address the regulatory review exception. The Appendix updates and supplements the information contained in a similar compilation found in document CDIP/5/4, Annex I.

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