

# REFERENCE DOCUMENT ON EXCEPTION REGARDING ACTS FOR OBTAINING REGULATORY APPROVAL FROM AUTHORITIES (SECOND DRAFT)

Standing Committee on the Law of Patents (SCP)  
Twenty- eighth session (July 9 to 12, 2018)

Presentation by the Secretariat

# SCP/28/3: Background

At SCP 27 (December 11 to 15, 2018), the Committee agreed that:

- The Secretariat would
  - Continue working on a draft reference document on exceptions and limitations
  - In particular, submit **a second draft reference document on exception regarding acts for obtaining regulatory approval from authorities** to SCP/28
    - First draft reference document (SCP/27/3) was submitted to SCP 27
  - Invite Member States to send any additional inputs with respect to, for example, challenges faced by Member States in implementing the exception and results of the national/regional implementation (Note C. 8728, dated February 9, 2018)

# SCP/28/3: Second Draft Reference Document

- Annex I to document SCP/28/3 contains the second draft reference document
- 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.

# SCP/28/3: Second Draft Reference Document

- Improved layout
- Improved structure and content : new data/information and new sections
- Recourse to boxes, figures and tables to illustrate data and to help the comprehension of concepts
- New additions to Appendix containing national/regional provisions

# SCP/28/3: Second Draft Reference Document

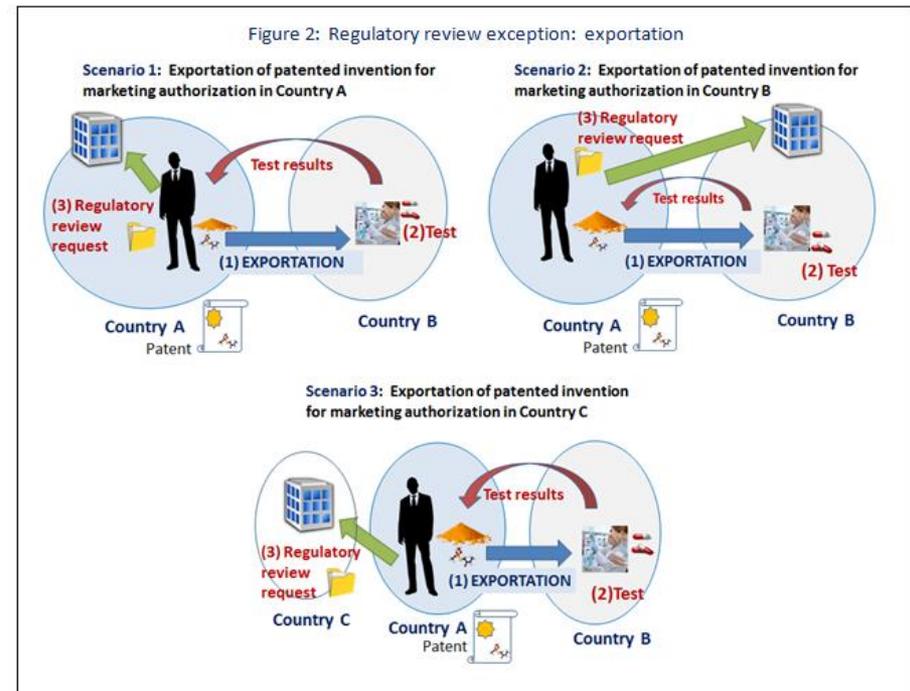
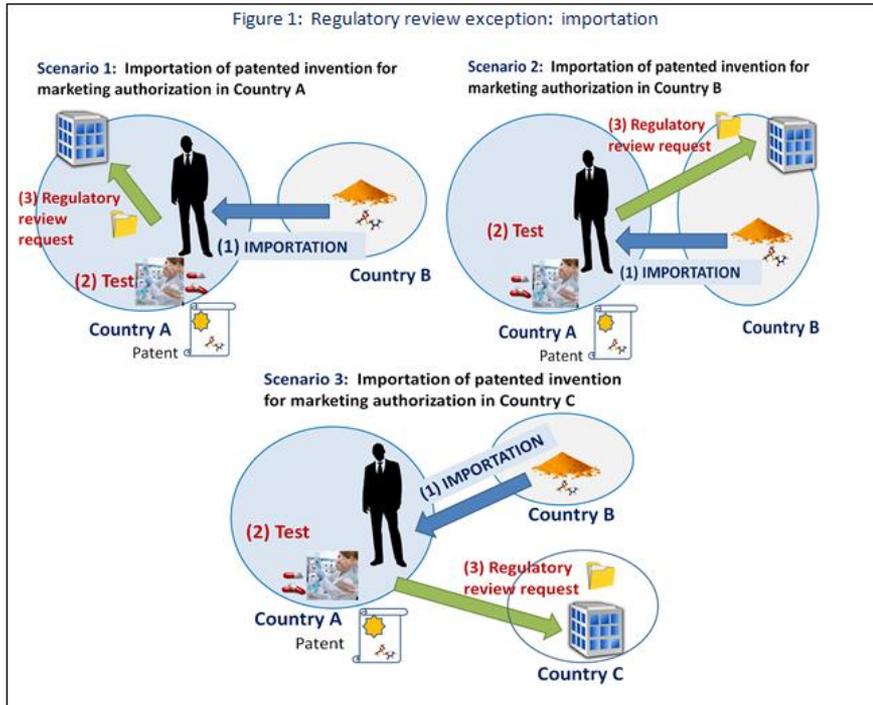
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## APPENDIX

# 5.2 Permitted acts under the regulatory review exception

## Importing and exporting



Thank you.