

Document SCP/36/6:

Constraints Faced by Developing Countries and Least Developed Countries (LDCs) in Making Full Use of Patent Flexibilities and their Impacts on Access to Affordable Especially Essential Medicines for Public Health Purposes in Those Countries (Update of Document SCP/26/5)

Presentation by the Secretariat

Standing Committee on the Law of Patents
36th session
October 14-18, 2024



SCP/36/6: Background

At SCP 35 (October 16 to 20, 2024), the Committee agreed that:

- ❑ The Secretariat would
 - Update document SCP/26/5 (Constraints Faced by Developing Countries and LDCs in Making Full Use of Patent Flexibilities and their Impact on the Access to Affordable Especially Essential Medicines for Public Health Purposes in those Countries), based on the information received from Member States, in view of their experiences relating to the COVID-19 pandemic.
- ❑ Member States invited to submit relevant inputs to the Secretariat, through C. 9199.
- ❑ Limited number of inputs received from Member States.
- ❑ The Secretariat utilized information made available from other SCP activities and consulted publicly available literature to obtain supplementary material on the topic.

SCP/36/6: Scope of the update

- ❑ Numerous publications focus
 - ❑ Meaning, scope, and offer general recommendations for effective utilization of flexibilities
 - ❑ Often emphasize the importance of flexibilities in promoting access to medicines, including COVID-19-related technologies, particularly in developing countries and LDCs
 - ❑ Often do not specifically address the constraints to making full use of flexibilities
- ❑ According to the agreed scope of this study, the updated document
 - ❑ does not engage in general discussions on the importance of the flexibilities
 - ❑ it primarily focuses on the constraints to the use of flexibilities and their impacts on access to affordable, essential medicines for public health purposes in developing countries and LDCs
 - ❑ does not aim to discuss solutions or measures to overcome the constraints identified
 - ❑ does not provide an analysis of legal obligations created by the international agreements regarding patents; nor does it enumerate the specific options available for national/regional implementation of these international agreements, or examine how each specific option impacts access to medicines

Structure of document SCP/26/5 (SCP/36/6)

❑ TERMINOLOGIES

- ❑ Patent flexibilities

- ❑ Full use of patent flexibilities

❑ CONSTRAINTS TO THE FULL USE OF PATENT FLEXIBILITIES BY DEVELOPING COUNTRIES AND LDCs

- ❑ Constraints encountered by governments at the stage of national implementation of flexibilities

- ❑ Constraints faced by various stakeholders in using a national legal framework that has implemented policy options

❑ IMPACT OF CONSTRAINTS ON THE ACCESS TO AFFORDABLE ESPECIALLY ESSENTIAL MEDICINES FOR PUBLIC HEALTH PURPOSES IN DEVELOPING COUNTRIES AND LDCs

❑ PRELIMINARY CONCLUSIONS

Constraints to the Full Use of Patent Flexibilities by Developing Countries and LDCs

- ❑ Constraints encountered by governments at the stage of national implementation of flexibilities
 - ❑ *Complexity of practical implementation*
 - ❑ *Institutional challenges, including institutional capacity*
 - ❑ *National governance and internal coordination*
 - ❑ *Extrinsic influences*
- ❑ Constraints faced by various stakeholders in using a national legal framework that has implemented policy options
 - ❑ *Ambiguity and operationability of national law*
 - ❑ *Technical IP capacity*
 - ❑ *Identifying relevant patents and their status*

Other challenges where use of patent flexibilities alone may not achieve intended policy outcomes

- Manufacturing and distribution capacity*
- Trade secrets*
- Test data protection*
- Quality standards*
- Difficulties in conducting public procurement abroad*

Impact of Constraints on the Access to Affordable Especially Essential Medicines for Public Health Purposes in Developing Countries and LDCs

- ❑ None of the Member States' submissions have provided information on impact of constraints on access to affordable especially essential medicines, including COVID-19 technologies, for public health purposes.
- ❑ Furthermore, a literature review has revealed a lack of meaningful empirical studies that would enable credible conclusions on this issue.

Thank you for your attention.

