
Purpose: Information
Submitted by: Korea
Background and objectives of the project under IPEG 04 2021T
1. Background and Objective

Background of the project

◆ APEC is pursuing gradual trade liberalization in the region with an aim to create a regional free trade zone in the long run. As one of the key issues of trade liberalization, it focuses on harmonizing the intellectual property regimes in the region and developing the regional intellectual property system.

◆ With regard to the key issues of trade liberalization, it focuses on harmonizing the intellectual property regimes in the region and developing the regional intellectual property system together.
Meanwhile, A patent linkage system might be defined as a system for checking the existence of a patent when a drug/pharmaceutical is approved by competent authorities.

With COVID-19 making a devastating impact on the global economy, APEC member economies are in need of policies that will facilitate the development of innovative drugs and expedite the trade of pharmaceutical products.

However, there would be differences in the evaluation of the efficacy of patent linkage that result from the different variations of the policies in each economy.
1. Background and Objective

Objective of the project

◆ Afford an opportunity for member economies to their systems with others for taking into consideration existing trade policies and obligations.

◆ Promote a better understanding of negotiators and policy makers in negotiating or implementing international trade agreements that concern patent linkage.

◆ Create a foundation for promoting domestic policies & programs in APEC economies and broader regional efforts for harmonization of patent linkage regimes in APEC region, from the perspective of health and access of medical services.
2. Patent Linkage System

Outline of patent linkage system

◆ Since marketing approval of drugs and examination/granting of patents are usually regulated by different authorities based on separate laws, the drug authority examines the safety and effectiveness of generic drugs regardless of patent infringement.

◆ Therefore, even if a generic drug infringes a patent, it is not considered by the drug authority and the drug may be licensed. Thus, the patentee of the patented drug has to address the marketing of the generic drug through a patent infringement lawsuit if he or she becomes aware of the infringement.
Outline of patent linkage system

However, under the patent linkage system, which operates the drug licensing system in conjunction with the patent system, the drug authority must take measures to prevent patent infringement in the marketing approval process of drugs in consideration of patent infringement.

Meanwhile, in making decisions on the management of drug patent lists, marketing bans, and generic exclusivity, etc. in the patent linkage procedure, the competent authority must consider the decisions of the patent authority regarding the validity, extension of the duration, and scope of patent rights, etc.
Diversity of patent linkage system

◆ As for the purpose and operating principle of the patent linkage system, and the operational status of each economy that introduced the system, there is a difference in detail.

◆ Nevertheless, patent linkage system generally consists of the common key procedures.
2. Patent Linkage System

Key procedures of patent linkage system

◆ Registration of drug patents
◆ Notification of application for marketing approval
◆ Measures to prohibit marketing
◆ Generic exclusivity (exclusive marketing approval)
Survey in progress

◆ Design of a questionnaire to survey details on legislations, policies and programs for patent linkage in APEC economies (27 June 2022)

◆ Survey questionnaire was circulated by APEC secretariat (28 June 2022)

  ✓ Response was requested by 25 July 2022

  ✓ So far, 11 out of 21 economies have responded to the survey

◆ Collecting and analyzing of answers submitted by APEC economies for the above questionnaire is still in progress.
3. Survey on Patent Linkage System

Survey questionnaire

- Whether to introduce Patent Linkage System
- Structure and Key Components of Patent Linkage System of each Economy
- Difficulties and obstacles in introducing patent linkage system
Analysis on survey response

- Conducting a post-workshop survey to evaluate results from the workshop.

- Completion of a final report including survey results, feedback during the workshop, and recommendations to help APEC economies make informed and effective policy decisions.
Timeline

- Started the Project: 2022 Mar.
- Completed Preliminary Report: 2022 May
Thank you