



**Asia-Pacific  
Economic Cooperation**

**Advancing** Free Trade  
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# Patent Linkage System for Intellectual Property Rights and Public Health Harmonisation

**APEC Intellectual Property Rights Experts Group**

July 2023





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Economic Cooperation**

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# 1. Background

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.

However, APEC has remained in sharing policy experiences and conducting research on the current status, failing to advance a binding regional regime on intellectual property due to non-binding decision-making, voluntary implementation principles, and gaps in regional economic development and intellectual property infrastructure, etc.

Due to the absence of the regional intellectual property regime, APEC relies only on the TRIPS Agreement for intellectual property standards. Recently, with the participation of many APEC members in the mega-FTAs signed in the Asia-Pacific region, such as RCEP and CPTPP, the gap in APEC's intellectual property system is likely to deepen as these members accept the intellectual property regulations under the mega-FTAs.

Therefore, in order to achieve gradual harmonization of intellectual property systems in the region, APEC needs to identify intellectual property issues that are likely to further drift apart due to the reorganization of the international trade order, and to strengthen its members' capabilities and create an appropriate infrastructure. In this context, this paper examines the status of the introduction of the patent linkage system for pharmaceutical patents in APEC.

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. Patent linkage could encourage investment in relation to the referred rights by enhancing transparency and predictability for all stakeholders. It also acts to ensure that regulatory approvals do not 'unduly promote patent infringement.'

The system is important in inducing innovation in the development of new drugs, but APEC member economies differ in their perception of the system's efficacy to ensure public access to drugs and reduce prices. Some economies have introduced a patent linkage system when needed, while others have introduced a system after signing trade agreements. Depending on how the system was introduced in each economy and on the status of the local pharmaceutical industry, the impact of the patent linkage system will inevitably be different.

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 are stark differences in the evaluation of the efficacy of patent linkage that result from the different variations of the policies that are implemented in different economies. The following items should be investigated and identified for the purpose of comparing and understanding each APEC member economies: Law and regulatory agency, IND (type of IND, procedure, documentation, review time), NDA (procedure, documentation, review time based on classification of pharmaceutical products), other regulatory requirements.

As of May 2021, there are 12 APEC member economies that practice patent linkage policies. A number of trade agreements include patent linkage commitments, such as the Comprehensive and Progress Agreement for Trans-Pacific Partnership (CPTPP) and other Trade Related Intellectual Property Rights (TRIPS)-Plus trade agreements, to implement a policy. If not bound by trade policies, they show a positive trend to implement such legislation. The growing global trend of incorporating some forms of patent linkage policies will necessitate policy makers and businesses to be better informed on policies ratified within the APEC bloc.

## 2. Objectives of the project

The purpose of this project is to assist in improving adequate capacity of policy makers, as well as various stakeholders, to develop and operate a desirable patent linkage system within their respective economies. This project also aims to promote a better understanding of negotiators and policy makers in negotiating or implementing international trade agreements that concern patent linkage.

Accordingly, primary objective of this project is to share knowledge and experiences of respective APEC economies in implementing or operating patent linkage system. By reviewing and comparing various cases of other member economies, this project might afford an opportunity for policy makers to establish a patent linkage system that is best suited to their citizens and pharmaceutical industries in harmonizing intellectual property rights (IPR) and public health. Expected effects to be achieved through this project are as follows:

- Member economies that have already implemented patent linkage system will be able to compare their systems with others, while taking into consideration existing trade policies and obligations;
- Member economies that are not familiar with patent linkage system because they have not yet considered policies relating to patent linkage, will be able to more easily understand how an optimal system may be customized to their needs; and
- Other stakeholders, such as researchers and investors engaged in the development of pharmaceuticals, will be able to establish marketing strategies by referencing this project's results.

This project shall ultimately identify various legal mechanisms adopted by APEC economies to develop their patent linkage system and determine current issues faced by economies that have introduced patent linkage systems in various economic situations and industrial structures. And then, as an efficient platform, seminar and workshop will be organized for policy makers in APEC economies to share their knowledge and experiences with regard to patent linkage.

Overall, this project could help promote domestic policies and programs in APEC economies, and broader regional efforts for harmonization of patent linkage regimes in the APEC region, from the perspective of health and access to medical services.

### 3. Concept and Structure of Patent Linkage Systems

#### (1) Concept and Characteristics of Patent Linkage Systems

A patent linkage system refers to the system that operates the patent system in conjunction with the approval system for drugs.

- In principle, marketing approval of drugs and patent protection are governed by different agencies under separate legal frameworks. The drug authority examines the safety and effectiveness of drugs according to the application for marketing approval of drugs, and determines whether to grant an approval, while the patent authority examines the novelty and inventiveness of drugs once a patent application is filed for drugs, and determines whether to grant a patent.
- Therefore, even if a generic drug infringes a patent, it is not a matter of consideration for the drug authority so that the drug can be granted an approval. If the patentee of a drug patent becomes aware of the infringement, he or she can confront the marketing of the generic drug through a patent infringement lawsuit.
- However, under a patent linkage system, if there is an application for marketing approval of a generic drug relying on the data of a drug that was previously approved, the drug authority must take measures to prevent patent infringement in the marketing approval process in consideration of the patent infringement of the generic drug.

A patent linkage system contributes to early settlement of potential drug patent disputes before marketing of generic drugs, and improvement of access to drugs by the public.

- Where patent-related clarification, prohibition of marketing, and notification procedures to the patentee, etc. are required of generic drugs applied for approval, the patent linkage system might serve as a safeguard against infringement of original drugs' patents and motivate the development of a new drug from the perspective of the patentee.
- On the other hand, granting a certain exclusive marketing approval to a generic drug and allowing a license to use the patent inventions for the purpose of collecting data necessary for approval of drugs, etc. might serve as a useful complement to a patent linkage system for achieving public health goals by facilitating generic drugs to enter the market from the perspective of generic drug sellers.
- However, if a patent linkage system is abused, there is a possibility that it will delay generic drugs' entry into the market and rather hinder technology competition.
- On the other hand, there are concerns that if a patent linkage system grants an exclusive marketing approval to generic drugs applications that meet only procedural requirements without substantial and reasonable patent invalidity or non-infringement claims, it may lead to an increase in patent trials and lawsuits, wasting costs and hindering sound business activities.<sup>1</sup>

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<sup>1</sup> With the full-fledged implementation of the patent linkage system in Republic of Korea in March 2015, the number of petitions for trial in 2015 alone recorded 1,957, indicating a surge in patent disputes in the pharmaceutical industry. Among them, 703 petitions were withdrawn. This suggests that a number of petitions for trial were indiscriminately made in the early stage of the enforcement of the patent linkage system. Shin Hye-eun, Jeong Yong-ik, Park Jong-hyuk, "Explanation of the Patent Linkage System", Korea Institute of Intellectual Property, Intellectual Property Research Series-13, SECHANG PUBLISH (2018), p.172.

Therefore, a patent linkage system needs to be designed in consideration of an appropriate balance between original and generic drugs, and it is desirable to upgrade it step by step according to the economy's current state of the pharmaceutical industry, public health level, and patent system development, etc.

## **(2) Proliferation of Patent Linkage Systems**

### **1) Bilateral and Multilateral FTAs of the United States**

A patent linkage system, which originated in the United States, has spread to other economies as it is included in the bilateral free trade agreement signed by the United States.

- Article 16.8(4)(c) of the FTA with Singapore and Article 17.10(2)(c) of the FTA with Chile signed by the United States in 2003 stipulate a patent linkage system as an obligation stating, “[each] Party shall not grant marketing approval to any third party prior to the expiration of the patent term, unless by consent or [with the] acquiescence of the patent owner”
- The FTAs signed by the United States since 2004 obligate each Party to “implement measures in its marketing approval process to prevent such other persons from marketing a product without the consent or acquiescence of the patent owner during the term of a patent,” as in Article 18.9 (5)(b) of the FTA with Republic of Korea signed in 2007.
- United States-Mexico-Canada Agreement (USMCA), which took effect in July 2020 through renegotiation of NAFTA, has stipulated patent linkage through a notification system and procedures to assert patent rights or to challenge a patent's validity.
- The previous NAFTA did not provide for a patent linkage system, but the USMCA obligates a patent linkage system in Article 20.50, which requires the parties to provide “a system to provide notice to a patent holder,” “adequate time and sufficient opportunity for such a patent holder to seek...available remedies,” and “procedures, such as judicial or administrative proceedings,...for the timely resolution of disputes concerning the validity or infringement of an applicable patent.”

### **2) Regional Comprehensive Economic Partnership (RCEP)**

The RCEP Agreement, which entered into force in January 2022, is the world's largest free trade agreement with approximately 31.9% of global trade as of 2020, involving 15 economies in total, including 10 ASEAN economies and Australia; China; Japan; Republic of Korea and New Zealand.

- Among APEC members, 12 economies participated in RCEP, including Brunei Darussalam; China; Republic of Korea; Malaysia; Singapore; Thailand and Viet Nam, which are more than half of all APEC members, and as of April 2022, the Philippines and Indonesia have yet to ratify the Agreement.

The RCEP Agreement stipulates provisions on intellectual property in Articles 11.1 through 11.83, in Chapters 11, but there are no provisions regarding a patent linkage system, so the parties are not obligated to introduce it.

- During the negotiations of the Agreement, Japan and Republic of Korea proposed to include TRIPS-plus provisions in the intellectual property chapter, such as extending the duration of drug patents and linking patents in the licensing process of drugs,<sup>2</sup> but this was not finally reflected in the Agreement.

### 3) Comprehensive and Progressive Agreement for Trans-Pacific Partnership (CPTPP)

The CPTPP Agreement, which entered into force in December 2018, is a multilateral free trade agreement with approximately 15.2% of global trade as of 2019, involving 11 economies including Australia; Brunei Darussalam; Canada; Chile; Japan; Malaysia; Mexico; New Zealand; Peru; Singapore and Viet Nam.

- All the economies participating in the CPTPP are APEC members, which are more than half of all APEC members, just like RCEP. As of April 2022, Brunei Darussalam; Chile and Malaysia have yet to ratify the Agreement, and Republic of Korea is seeking to join the Agreement.

The Comprehensive and Progressive Trans-Pacific Partnership (CPTPP) is an agreement based on the Trans-Pacific Partnership (TPP), and the two agreements stipulate exactly the same for a patent linkage system in Article 18.53 of Chapter 18.

- The Agreement requires to notify the patentee of an application for marketing approval of drugs relying on drug patent data in subparagraph (1)(a) of Article 18.53, and subparagraphs (b) and (c) obligate to prevent the marketing of drugs infringing patents and prepare sufficient remedies to resolve a dispute.
- The Agreement also stipulates to prepare procedures in paragraph 2 of Article 18.53 to prevent a third party from obtaining the marketing approval of a drug using a patent without the consent of the patentee through a list of drug patents or cooperation between the patent authority and the drug authority.

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<sup>2</sup> Belinda Townsend, "Defending access to medicines in regional trade agreements: lessons from the Regional Comprehensive Economic Partnership - a qualitative study of policy actors' views", *Globalization and Health*, Vol.17 (2021), p.3. Belinda Townsend et al., "The Regional Comprehensive Economic Partnership, Intellectual Property Protection, and Access to Medicines", *Asia Pacific Journal of Public Health*, Vol.28, No.8 (2016), p.686.

**Table 3-(2)-1. Provisions related to the patent linkage system under the Comprehensive and Progressive Trans-Pacific Partnership (CPTPP)**

**Article 18.53: Measures Relating to the Marketing of Certain Pharmaceutical Products**

1. If a Party permits, as a condition of approving the marketing of a pharmaceutical product, persons, other than the person originally submitting the safety and efficacy information, to rely on evidence or information concerning the safety and efficacy of a product that was previously approved, such as evidence of prior marketing approval by the Party or in another territory, that Party shall provide:

- (a) a system to provide notice to a patent holder or to allow for a patent holder to be notified prior to the marketing of such a pharmaceutical product, that such other person is seeking to market that product during the term of an applicable patent claiming the approved product or its approved method of use;
- (b) adequate time and opportunity for such a patent holder to seek, prior to the marketing of an allegedly infringing product, available remedies in subparagraph (c); and
- (c) procedures, such as judicial or administrative proceedings, and expeditious remedies, such as preliminary injunctions or equivalent effective provisional measures, for the timely resolution of disputes concerning the validity or infringement of an applicable patent claiming an approved pharmaceutical product or its approved method of use.

2. As an alternative to paragraph 1, a Party shall instead adopt or maintain a system other than judicial proceedings that precludes, based upon patent-related information submitted to the marketing approval authority by a patent holder or the applicant for marketing approval, or based on direct coordination between the marketing approval authority and the patent office, the issuance of marketing approval to any third person seeking to market a pharmaceutical product subject to a patent claiming that product, unless by consent or acquiescence of the patent holder.

### **(3) Structure of Patent Linkage Systems**

#### **1) Authority that operates patent linkage systems**

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.

However, under a 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.

- Therefore, in general, the authority in charge of product licensing under the pharmaceutical regulations manages the list of drug patents to check the patent relationship of a generic drug applied for marketing approval, supervise the duty of notification, and prohibit the marketing of the generic drug, etc.
- Meanwhile, in making decisions on the management of drug patent lists, marketing bans, and generic exclusivity, etc. in a 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.

## **2) Patent Law Issues related to patent linkage systems**

As for the origin and history of a patent linkage system, and patent laws of economies that introduced those systems, including Canada; Republic of Korea; Singapore; Chinese Taipei; the United States; etc., the details vary by economy, but a patent linkage system closely relates to the following patent law issues:

- ① Extension of the duration of drug patents; and
- ② Exception for the practice of a patented invention for clinical trials, etc. (exception to patent infringement).

### **Extension for the duration of drug patents**

This system means a system that extends the duration of a drug patent for the period in which the patent could not be practiced due to the licensing process in consideration of the characteristics of drugs that require a long period of time in the licensing process.

- The extension of the duration of drug patents serves to strengthen drug patents, just like the purpose of a patent linkage system, and it is also an important consideration for determining the validity of patents and verifying the patent relationships in the operation of a patent linkage system.
- Most economies allow a drug patent to be extended only once within a specified period when extending the duration of the drug patent.

### **Exception for the practice of a patented invention for clinical trials, etc**

Exception for the practice of a patented invention for clinical trials, etc. mean that the act of practicing a patented invention for research or experiments necessary for drug licensing procedures is allowed as an exception that does not constitute patent infringement.

- The exclusion of clinical trials, etc. from patent infringement is for promoting the entry of generic drugs into market under the operation of a patent linkage system by preventing unreasonable extension of the duration of drug patents as a side effect of prohibition of clinical trials, etc.
- Many economies specify in patent law the practice of patented inventions for product licensing of drugs as an exception that does not infringe on patents.

## **3) Components related to patent linkage systems**

As for the purpose and operating principle of a patent linkage system, and the operational status of economies that introduced the system, including Canada; Republic of Korea; Singapore; Chinese Taipei and the United States, the details vary by economy, but a patent linkage system generally consists of the following procedures:

- ① Registration of applicable drug patents,
- ② Notification of application for marketing approval,
- ③ Measures to provide adequate time and opportunity for resolution of patent disputes prior to marketing, and
- ④ Generic exclusivity (exclusive marketing approval).

### **Registration of applicable drug patents**

Registration of drug patents in a patent linkage procedure refers to a procedure in which patent information related to the licensed drug is submitted to the competent authority and recorded in the drug patent list.

- The registration of applicable drug patents serves as a tool for the competent authority to identify the scope of drugs covered by a patent linkage system and to consider patent infringement in the licensing process of generic drugs.

### **Notification of the application for marketing approval of drugs**

A notification in a patent linkage procedure is a procedure in which a person applying for marketing approval for a generic drug notifies the patentee of a registered drug related to the applied drug of the application for marketing approval.

- This notification is the most essential element of a patent linkage system as a basis for the patentee to respond to patent infringement or for the competent authority to reserve marketing licenses or prevent marketing, and functions as a basis to be qualified for generic exclusivity, where possible.

### **Measures to provide adequate time and opportunity for resolution of patent disputes prior to marketing**

Reservation of licensing or prevention of marketing in patent linkage procedures means the competent authority's measure to reserve licensing or prevent marketing of drugs applied for marketing approval upon the request of the patentee based on the notification of the application for marketing approval.

- This measure of licensing reservation or marketing prevention is a strong tool to protect the patent rights of drugs in the patent linkage procedure, so the authority must withhold approval for a generic drug until the application period for marketing prevention expires, and if the patentee applies for marketing prevention, the authority must consider the application and prevent the marketing of the generic drug for a specified period of time.

### **Generic exclusivity**

Exclusive marketing approval or generic exclusivity linked to patent linkage procedures, but not necessarily inherent in the function of a patent linkage system, means a market monopoly position that allows a person who wins a case against the patent right of a registered drug to exclusively market the generic drug for a certain period of time.

- Generic exclusivity is a tool to promote the release and enhance competitiveness of generic drugs in a patent linkage procedures, so the competent authority must prohibit the marketing of other drugs with the same active ingredients as the generic drug that first won in a patent invalidation trial or a scope confirmation trial, etc. against a registered drug for a specified period of time.

## 4. Patent Linkage Systems in respective APEC economies

### (1) Australia

#### 1) Introduction and Development of a Patent Linkage System

Australia introduced a patent linkage system through the revision of the Therapeutic Goods Act in 2006 as the drug-approval patent linkage system became mandatory as a follow-up action to the 2004 Free Trade Agreement with the United States.<sup>3</sup>

- According to United States-Australia FTA's patent linkage provisions, any patent claimed for a new pharmaceutical product or its approved use is subject to the patent linkage system.<sup>4</sup>
- In order to implement the contents of the Agreement, Australia enacted the FTA Enforcement Act in 2004. The Act stipulated amendments to the Therapeutic Goods Act 1989.

**Table 4-(1)-1. The US-Australia FTA Agreement (2004)<sup>5</sup>**

#### **Article 17.10 Measures related to certain regulated products**

(4) Where a Party permits, as a condition of approving the marketing of a pharmaceutical product, person, other than the person originally submitting the safety or efficacy information, to rely on evidence or information concerning the safety or efficacy of a product that was previously approved, such as evidence or prior marketing approval by the Party or in another territory:

(a) that Party shall provide measures in its marketing approval process to prevent those other person from:

- (i) marketing a product, where that product is claimed in a patent; or
- (ii) marketing a product for an approved use, where that approved use is claimed in a patent, during the term of that patent, unless by consent or acquiescence of the patent owner; and

(b) if the Party permits a third person to request marketing approval to enter the market with:

- (i) a product during the term of a patent identified as claiming the product; or
- (ii) a product for an approved use, during the term of a patent identified as claiming that approved use, the Party shall provide for the patent owner to be notified of such request and the identity of any such other person.

<sup>3</sup> Shin Hye-eun et al., supra note 1, p.65.

<sup>4</sup> Park Sylvia, Kang Eun-jeong, Park Eun-ja, "Korea-the US FTA and Future Directions of Pharmaceutical Policy in Korea", Korea Institute for Health and Social Affairs, 2007, p.229.

<sup>5</sup> For full text on United States-Australia FTA Agreement, please refer to the following website of Office of United States Trade Representative: <https://ustr.gov/trade-agreements/free-trade-agreements/australian-fta/final-text> (last visit on 4 August, 2022).

**Table 4-(1)-2. Australia's the US Free Trade Agreement Implementation Act 2004<sup>6</sup>**

**26B. Certificates required in relation to patents**

(1) The certificate required by this subsection is either:

(a) a certificate to the effect that the applicant, acting in good faith, believes on reasonable grounds that it is not marketing, and does not propose to market, the therapeutic goods in a manner, or in circumstances, that would infringe a valid claim of a patent that has been granted in relation to the therapeutic goods; or

(b) a certificate to the effect that:

(i) a patent has been granted in relation to the therapeutic goods; and

(ii) the applicant proposes to market the therapeutic goods before the end of the term of the patent; and

(iii) the applicant has given the patentee notice of the application for registration or listing of the therapeutic goods under section 23.

The certificate must be signed by, or on behalf of, the applicant and must be in a form approved by the Secretary.

(2) A person is guilty of an offence if:

(a) the person gives a certificate required under subsection (1); and

(b) the certificate is false or misleading in a material particular.

Maximum penalty: 1,000 penalty units.

(3) For the purposes of this section, a patent is taken to have been granted in relation to therapeutic goods if marketing the goods without the authority of the patentee would constitute an infringement of the patent.

(4) In this section: patent has the same meaning as in the Patents Act 1990.

## **2) Operation of a Patent Linkage System**

In Australia, according to the Patent Act, IP Australia is in charge of examining patent applications and granting patents, and according to the Therapeutic Goods Act, the Therapeutic Goods Administration (TGA) under the Department of Health (DH) is in charge of licensing drug sales and verifying the validity and safety of drugs.<sup>7</sup>

- The TGA is responsible for the overall patent linkage procedures, including notification of applicants of drug license to patentees and failure to notify, etc. according to the Therapeutic Goods Act 1989.
- However, Australia's Therapeutic Goods Act 1989 and the Patent Act, etc. have no provisions on registration of drug patents, prevention of marketing, and generic exclusivity.

<sup>6</sup> For full text on Australia's the US Free Trade Agreement Implementation Act 2004, please refer to the following website of Federal Register of Legislation of Australian Government: <https://www.legislation.gov.au/Details/C2005C00021> (last visit on 4 August, 2022).

<sup>7</sup> Park Kuem-nang, "Development of patent-approval linkage system manual", Korea Food & Drug Administration, 2015, p.142.

### 3) Issues in Patent Act related to a Patent Linkage System

#### Extension of the duration of drug patents

Australia has a system to extend the duration of a drug patent to compensate for the period during which the patent right could not be practically exercised due to validity and safety tests, etc. for drug licensing.

- Article 70 of the Australian Patent Act stipulates, as the requirement for extending the duration of the drug patent, that ① a drug substance must be disclosed through a patent and included in the patent claims, and ② products containing or comprising the drug substance must be included in ARTG, a database of the Australia's Therapeutic Goods Administration (TGA), and ③ it must take at least 5 years from the date of patent application for the substance to the first regulatory approval.

**Table 4-(1)-3. Australia's Patent Act 1990 (Includes amendments up to Act No.154, 2020)**

#### **Article 70. Applications for extension of patent**

- (1) The patentee of a standard patent may apply to the Commissioner for an extension of the term of the patent if the requirements set out in subsections (2), (3) and (4) are satisfied.
- (2) Either or both of the following conditions must be satisfied:
- (a) one or more pharmaceutical substances per se must in substance be disclosed in the complete specification of the patent and in substance fall within the scope of the claim or claims of that specification;
  - (b) one or more pharmaceutical substances when produced by a process that involves the use of recombinant DNA technology, must in substance be disclosed in the complete specification of the patent and in substance fall within the scope of the claim or claims of that specification.
- (3) Both of the following conditions must be satisfied in relation to at least one of those pharmaceutical substances:
- (a) goods containing, or consisting of, the substance must be included in the Australian Register of Therapeutic Goods;
  - (b) the period beginning on the date of the patent and ending on the first regulatory approval date for the substance must be at least 5 years.

#### **Practice of a patented invention for the purpose of clinical trials**

The Australian Patent Act has an explicit provision that excludes practicing a patented invention for clinical trials, etc. in the drug licensing procedure from patent infringement.<sup>8</sup>

- Article 119A (1) of the Patent Act stipulates acts that do not infringe the patent right of the patentee of a drug.

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<sup>8</sup> Australian Patent Act 1990 (Includes amendments up to Act No.154, 2020) Article 119A(1).

- The use for therapeutic purposes for inclusion in the products of the Australian Register of Therapeutic Goods or the practice of medical devices not prescribed by the Therapeutic Goods Act 1989 does not infringe on the patent rights of drug patentees. In addition, in the case of the purpose of obtaining similar regulatory approval under foreign laws, it does not infringe on the patent rights of drug patentees.<sup>9</sup>

**Table 4-(1)-4. Australia’s Patent Act 1990 (Includes amendments up to Act No.154, 2020)**

**119A. Infringement exemptions: acts for obtaining regulatory approval of pharmaceuticals**

(1) The rights of a patentee of a pharmaceutical patent are not infringed by a person exploiting an invention claimed in the patent if the exploitation is solely for:

- (a) purposes connected with obtaining the inclusion in the Australian Register of Therapeutic Goods of goods that:
  - (i) are intended for therapeutic use; and
  - (ii) are not medical devices as defined in the Therapeutic Goods Act 1989; or
- (b) purposes connected with obtaining similar regulatory approval under a law of a foreign economy or of a part of an economy.

**4) Structure of a Patent Linkage System**

In Australia, the Therapeutic Goods Act 1989 stipulates:

- ① Notification of application for marketing approval.

In Australia, the Therapeutic Goods Act 1989 does not stipulate:

- ② Registration of applicable drug patents,
- ③ Measures to provide adequate time and opportunity for resolution of patent disputes prior to marketing, and
- ④ Granting generic exclusivity.

**Notification of application for marketing approval**

The Australian Therapeutic Goods Act 1989 requires the applicant for a generic drug license to prove to the drug licensing authority that he/she has informed the patentee of the application for registration of a drug under Article 23 of the Act.<sup>10</sup>

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<sup>9</sup> Australian Patent Act 1990 (Includes amendments up to Act No.154, 2020) Article 119A(1)(a) and (b).

<sup>10</sup> Australian Therapeutic Goods Act 1989 (Includes amendments up to Act No.13, 2021) Article 26B(1).

- According to Article 26B (1) of the Therapeutic Goods Act 1989, the applicant shall prove the facts ① that the product is not marketed or is not planned to be marketed in the event of infringement of the patent's valid claims, and ② that it is a generic drug of a patented product and intends to be marketed before the expiration of the patent period, and the patentee has been notified of the item permit or declaration. A person who has obtained a marketing approval and intends to register a drug patent shall submit an application for registration including a copy of the patent grant to the Ministry of Food and Drug Safety within 30 days from the date of marketing approval or the grant of the patent.<sup>11</sup>

**Table 4-(1)-5. Australia's Therapeutic Goods Act 1989 (Includes amendments up to Act No.13, 2021)**

**26B. Certificates required in relation to patents.**

(1) The certificate required under this subsection is either.

(a) a certificate to the effect that the applicant, acting in good faith, believes on reasonable grounds that it is not marketing, and does not propose to market, the therapeutic goods in a manner, or in circumstances, that would infringe a valid claim of a patent that has been granted in relation to the therapeutic goods; or

(b) a certificate to the effect that:

(i) a patent has been granted in relation to the therapeutic goods; and

(ii) the applicant proposes to market the therapeutic goods before the end of the term of the patent; and

(iii) the applicant has given the patentee notice of the application for registration or listing of the therapeutic goods under section 23.

The certificate must be signed by, or on behalf of, the applicant and must be in a form approved by the Secretary.

**Measures to provide adequate time and opportunity for resolution of patent disputes prior to marketing**

In Australia, the Therapeutic Goods Act 1989 stipulates that the court can issue a preliminary injunction prohibiting generic drug manufacturers from selling drugs. Unlike Korea, it has not introduced legislation on the sales ban, leaving it to the court's decision.<sup>12</sup>

- According to Article 26D (1) of the Therapeutic Goods Act 1989, a patentee or exclusive licensee who has been notified by the applicant under Article 26B(1)(b)(iii) of the Act may request a preliminary injunction prohibiting the sale of the drug to the court where there is a risk that the applicant's sale of the drug infringes the patent.

<sup>11</sup> Shin Hye-eun et al., supra note 1, pp.65-66.

<sup>12</sup> Park Kuem-nang, supra note 8, p.147.

**Table 4-(1)-6. Australia’s Therapeutic Goods Act 1989 (Includes amendments up to Act No.13, 2021)**

**26D. Requirements for interlocutory injunction**

(1) This section applies where:

- (a) an applicant gives notice to a patentee in accordance with subparagraph 26B(1)(b)(iii); and
- (b) the patentee and/or its exclusive licensee (in this section the party or parties is or are referred to as the patentee) applies to a prescribed court for an interlocutory injunction to restrain the applicant from marketing the therapeutic goods the subject of the application on the ground that such conduct will constitute an infringement of its patent.

**Generic exclusivity**

As there is no provision for suspension of licensing procedures for third party’s generic drugs and automatic stop(auto-stay) arising from a patent linkage system, there is no 180-day exclusive market (exclusion right) accordingly.<sup>13</sup>

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<sup>13</sup> The APEC Harmonization center, “Drug Approval System of Australia”, 2016, p.21.

## **(2) Brunei Darussalam**

### **1) Introduction and Development of a Patent Linkage System**

As a result of examining related domestic laws and previous studies, it was found that Brunei Darussalam has not yet introduced a patent linkage system.<sup>14</sup>

- In Brunei Darussalam, the Medicines Order and the Medicines Regulations, etc. which regulate the import, manufacture and sale of drugs, have not introduced a patent linkage system with no provisions on the role of the competent authority in preventing patent infringement in the marketing approval procedure of drugs.<sup>15</sup>
- Brunei Darussalam signed the CPTPP Agreement in March 2018, which already entered into force in December 2018, so Brunei Darussalam needs to make a domestic legislation to introduce a patent linkage system in order to ratify the Agreement and become a party.
- However, Brunei Darussalam has negotiated and signed side letters with other signatories and parties to join the CPTPP, but it is still unclear whether it will join the Agreement. As a result, the prospect for introduction of a patent linkage system is also uncertain.

### **2) Operation of a Patent Linkage System**

Brunei Darussalam's Intellectual Property Office (BRUIPO) is responsible for examining patent applications and granting patents under the Patents Order and the Patents Regulations,<sup>16</sup> and the Department of Pharmaceutical Services (DPS) under the Ministry of Health (MOH) regulates and manages the product license of drugs used in Brunei Darussalam. And Brunei Darussalam's Medicines Control Authority (BDMCA) in the DPS exercises its authority over the product license of drugs, etc. under the Medicines Order.<sup>17</sup>

- In other words, the DPS oversees drug regulation for safe and effective drug supply in Brunei Darussalam, and all drugs must obtain product license from and be registered with the BDMCA before they are sold in Brunei Darussalam.
- Therefore, if Brunei Darussalam introduces a patent linkage system, it is expected that the DPS will oversee its operations and that the BDMCA will be responsible for managing patent lists, notifying patentees, and withholding product licenses, etc.

### **3) Issues in Patent Law related to a Patent Linkage System**

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14 Deborah Gleeson et al., "The Trans Pacific Partnership Agreement, intellectual property and medicines: Differential outcomes for developed and developing countries", *Global Social Policy*, Vol.18 (2018), p.18-19. Kyung-Bok Son et al., "Moderating the impact of patent linkage on access to medicines: lessons from variations in Australia, Canada, Korea and United States", *Globalization and Health*, Vol.14 (2018), pp.5-6.

15 In Brunei Darussalam, laws related to the manufacture and sale of medicines include the Medicines Order 2007, the Medicines Regulations 2010 and the Misuse of Drug Regulations. For more information and full text on laws related to the manufacture and sale of medicines in Brunei Darussalam, please refer to the following website of Ministry of Health of Brunei Darussalam: [https://www.moh.gov.bn/SitePages/Importation%20of%20Medicines\\_Acts%20and%20Regulations.aspx](https://www.moh.gov.bn/SitePages/Importation%20of%20Medicines_Acts%20and%20Regulations.aspx) (last visit on 21 May 2022).

16 For full text on Brunei Darussalam's Patents Order and Patents Regulations, please refer to the following website of Brunei Darussalam's Intellectual Property Office (BRUIPO): <http://bruiipo.gov.bn/SitePages/patent.aspx> (last visit on 21 May 2022).

17 Department of Pharmaceutical Services, *Guide to Application for Registration of Medicinal Products*, 3rd Edition (2012), p.3.

## Extension of the duration of drug patents

Brunei Darussalam's Patent Order has a provision very similar to Article 36A (1) of Singapore's Patent Act which stipulates a system for extending the duration of drug patents as a means of supplementing drug patents that require a long period of time in the process of approval.

- Article 36 of Brunei Darussalam's Patent Order on the extension of the duration of patents stipulates that the duration can be extended once within a maximum of 5 years if the duration of patented inventions is unreasonably shortened due to the marketing approval procedure of drug.<sup>18</sup>

## Practice of a patented invention for the purpose of clinical trials

Brunei Darussalam specifies the practice of a patented invention for marketing approval of drugs as an exception to patent infringement.

- Brunei Darussalam's Patent Order lists exceptions that are not subject to the effect of patent rights in Article 64(2) and specifies the practice of patented inventions for marketing approval of drugs along with private acts for non-profit purposes and experimental acts, etc. as exceptions that do not infringe patents.<sup>19</sup>

**Table 4-(2)-1. Brunei Darussalam's Patent Order (enforced on 23 April, 2019)**

### Extension of term of patent

36. (1) The proprietor of a patent may apply to the Registrar to extend the term of the patent on any of the following grounds –

- (a) that there was an unreasonable delay by the Registrar in granting the patent;
- (b) where the patent was granted on the basis of prescribed information relating to a corresponding application referred to in section 29(2)(c)(ii), that –
  - (i) there was an unreasonable delay in the issue of the corresponding patent; and
  - (ii) the patent office that granted the corresponding patent has extended the term of the corresponding patent on the basis of such delay;
- (c) where the subject of the patent includes any substance which is an active ingredient of any pharmaceutical product, that –
  - (i) there was an unreasonable curtailment of the opportunity to exploit the patent caused by the process of obtaining marketing approval for a pharmaceutical product, being the first pharmaceutical product to obtain marketing approval which uses the substance as an active ingredient; and
  - (ii) the term of the patent has not previously been extended on this ground. ...

(6) Subject to subsections (7), (8) and (9), where the proprietor of a patent has made an application under subsection (1)(c) and has satisfied the Registrar that there was in fact an unreasonable curtailment of the opportunity to exploit the patent under subsection (1)(c), the Registrar shall extend the term of the patent by –

<sup>18</sup> Brunei Darussalam's Patent Order (enforced on 23 April, 2019) Article 36(1)(c) and (6).

<sup>19</sup> Brunei Darussalam's Patent Order (enforced on 23 April, 2019) Article 36(2)(g).

- (a) a period equivalent to the interval between the date of issue of the certificate of grant and the date marketing approval was obtained; /b) the period by which the interval referred to in subsection (5)
- (b) exceeds 2 years; or
- (c) a period of 5 years, whichever is the shortest period. ...

**Meaning of infringement**

**64.** (1) Subject to the provisions of this Order, a person infringes a patent for an invention if, but only if, while the patent is in force, he does any of the following things in Brunei Darussalam in relation to the invention without the consent of the proprietor of the patent –

- (a) where the invention is a product, he makes, disposes of, offers to dispose of, uses or imports the product or keeps it whether for disposal or otherwise;
- (b) where the invention is a process, he uses the process or he offers it for use in Brunei Darussalam when he knows, or it is obvious to a reasonable person in the circumstances, that its use without the consent of the proprietor would be an infringement of the patent; ...

(2) An act which, apart from this subsection, would constitute an infringement of a patent for an invention shall not be so if –

- (a) it is done privately and for purposes which are not commercial;
- (b) it is done for experimental purposes relating to the subject-matter of the invention;
- (c) it consists of the extemporaneous preparation of a medicine for an individual in accordance with a prescription given by a registered medical or dental practitioner or consists of dealing with a medicine so prepared; ...
- (g) it consists of the doing of anything set out in subsection (1) in relation to the subject-matter of the patent to support any application for marketing approval for a pharmaceutical product, provided that anything produced to support the application is not –
  - (i) made, used or sold in Brunei Darussalam; or
  - (ii) exported outside Brunei Dussalam, other than for purposes related to meeting the requirements for marketing approval for that pharmaceutical product; or

### (3) People's Republic of China

#### 1) Introduction and Development of a Patent Linkage System

On 30 October, 2002, the China Food and Drug Administration (CFDA)<sup>20</sup> first mentioned the prevention of patent infringement in the process of applying for registration of drugs under the Measures for the Administration of Drug Registration (For Trial Implementation) (2002).<sup>21,22</sup>

- The Measure states that the applicant must provide a detailed description of the status of the drug or the prescription or technique used, etc., and submit a guaranty that it does not infringe on the patent rights of others and bear the responsibility for the consequences of infringement.
- In addition, it states that if a patent dispute arises after approval of a drug, it must be resolved through consultation between the parties or through a judicial or patent administrative agency, and that, for a drug that has already been patented, an application for registration can be filed within 2 years of the expiration of the patent but manufacturing or import permit can be granted after patent expiration.
- When defining a patent linkage system broadly as a structure that considers the prevention of infringement of patent rights in licensing drug items, some view that China already implemented a patent linkage system under the Measures for the Administration of Drug Registration of 2002.<sup>23</sup>

**Table 4-(3)-1. China's Measures for the Administration of Drug Registration (For Trial Implementation) (No.35, issued on 30 October 2002, effective on 12 January 2002)**

**Article 11** For the drugs applying for registration or the prescriptions or techniques used, the applicant shall provide the patent in China and explanations on its ownership, submit a guaranty of no infringement upon the patents of others, and promise to be responsible for the possible infringement consequences.

**Article 12** Where any dispute arises after the application for drug registration is approved, the parties shall settle the dispute through consultation by themselves, or through judicial bodies or patent administrative bodies pursuant to the relevant laws and regulations.

**Article 13** With respect to any drug to which a Chinese patent has been granted, other applicants may file an application for registration within 2 years before the expiration of the patent of that drug. The SDA shall make examination pursuant to these Measures, and, if the provisions are met, approve the manufacturing or import after the patent expires.

20 China reorganized the China Food and Drug Administration (CFDA) into the Medical Products Administration (NMPA) in 2018.

21 For full text on Measures for the Administration of Drug Registration (For Trial Implementation) (2002 No.35), please refer to the following website of the NMPA: <https://www.nmpa.gov.cn/directory/web/nmpa/xxgk/fgwj/bmgzh/20021031010101123.html> (last visit on 19 July, 2022).

22 Bu Zhenzhen, Shin Hye-eun, "Establishment and Implications of Drug approval-Patent Linkage System in China", Law Research Institute of Chungbuk University, Science, Technology and Law, Vol.10, No.2 (2019), p.156.

23 Shin Hye-eun, Bu Zhenzhen, "Effects of the Revision of the Chinese Patent Law and the Introduction of the Patent-approval Linkage System on the Pharmaceutical Industry", Republic of Korea Intellectual Property Society, Industrial Property Rights, No.69 (2021), p.97.

The Measure was revised on 28 February 2005<sup>24</sup> changing the obligation to submit the ‘a guaranty’ to the ‘a letter (patent declaration)’ and expanding the scope of the patent declaration from ‘drugs or prescriptions or techniques’ to ‘drugs or prescriptions or techniques or uses’.

**Table 4-(3)-2. China’s Measures for the Administration of Drug Registration (No.17, issued on 28 February, 2005, effective on 1 May, 2005)**

**Article 11** For the drug applied for registration or the prescription, techniques or uses of the drug, the applicant shall provide its patent or the patent of any other person in China as well as the explanations on its ownership; if other party holds patent in China, the applicant shall submit a letter stating that the drug will not infringe upon the patent of others.

**Article 12** Where any dispute arises after the application for drug registration is approved, the parties concerned shall settle the dispute through negotiation by themselves, or through the patent administrative department or the people's court pursuant to relevant laws and regulations.

A patentee may, on the basis of the final ruling made by the patent administrative department or valid judgment affirming infringement as made by the people's court, file with the SFDA for cancelling the drug approval document number. Accordingly, the SFDA shall write off the drug approval documents of the infringer.

**Article 13** As for a drug of which the Chinese patent has been obtained by any other person, an applicant may file a registration application within two years prior to the expiration of the drug patent. The SFDA shall conduct an examination pursuant to these Measures, and, if the applicant meets the relevant conditions, issue to it the drug approval document number, Import Drug License or Pharmaceutical Product License after the patent expires.

The revision of 10 July 2007<sup>25</sup> added that the drug regulatory department should publish the information on the status of patent and its ownership or the declaration that it does not infringe others’ patents submitted by the applicant on the administrative agency's website.

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24 For full text on Measures for the Administration of Drug Registration (2005 No.17), please refer to the following website of the NMPA: <https://www.nmpa.gov.cn/directory/web/nmpa/xxgk/fgwj/bmgzh/20050228010101137.html> (last visit on 19 July 2022).

25 For full text on Measures for the Administration of Drug Registration (2007 No.28), please refer to the following website of the NMPA: <https://www.nmpa.gov.cn/directory/web/nmpa/xxgk/fgwj/bmgzh/200707100101011795.html> (last visit on 29 July 2022).

**Table 4-(3)-3. China's Measures for the Administration of Drug Registration (No.28, issued on 10 July 2007, effective on 1 October 2007)**

**Article 18** An applicant shall provide the information on patent and its ownership of the applicant or other parties in China, in respect of the drug applied for registration, its formula, manufacturing processes and/or uses, etc. Where another party owns the patent in China, the applicant shall provide a statement of non-infringement. The drug regulatory department shall publish the information or the statement submitted by the applicant on its official website.

Where a patent dispute occurs in the process of drug registration, it shall be settled in accordance with relevant laws and regulations on patent.

**Article 19** For a drug patented in China, applicants other than the patentee may submit the application for registration two years prior to the expiry date of the patent. The SFDA shall review the drug application in accordance with the Measures, and after the expiry date of the patent, check and issue the drug approval number, Import Drug License or a Pharmaceutical Product License if the application conforms with the provisions.

The revision on 22 January 2020<sup>26</sup> removed the provisions on the patent declaration and the restriction on the deadline for applying for generic drugs, and added that the NMPA shall establish, update, and disclose a catalogue of chemical medicines that have been newly approved drugs and generic drugs which have passed quality and effectiveness consistency evaluation.

**Table 4-(3)-4. China's Measures for the Administration of Drug Registration (No.27, issued on 22 January 2020, effective on 1 July 2020)**

**Article 18** NMPA establish the catalogue of chemical medicines recording newly approved drugs and generic drugs which have passed quality and effectiveness consistency evaluation. The catalogue record the drug name, API, dosage form, specifications, whether reference on or not, MAH and so forth, timely updated and made public. The CDE establishes the procedure and requirement of catalogue of chemical medicines and make public.

Since 2017, various government departments in China have proposed the introduction of a patent linkage system for drugs and promoted policy changes by publishing various policy documents and opinions.

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<sup>26</sup> For full text on Measures for the Administration of Drug Registration (2020 No.27), please refer to the following website of the NMPA: <https://www.nmpa.gov.cn/directory/web/nmpa/xxgk/fgwj/bmgzh/20200330180501220.html> (last visit on 29 July 2022).

- On 12 May 2017, the CFDA stated the plan and direction of establishing a patent linkage system for drugs, including patent declaration, notification to patent holders, and waiting period, by directly mentioning the term ‘Patent Linkage System (专利链接制度)’ in the Relevant Policies on Protecting Innovator Interests to Encourage Innovations in Drugs and Medical Devices (Draft for Public Comment) (2017 No. 55).<sup>27</sup>

**Table 4-(3)-5. China’s Relevant Policies on Protecting Innovator Interests to Encourage Innovations in Drugs and Medical Devices (Draft for Public Comment) (No.55, Published on 12 May 2017)**

1. Establishing a drug patent linkage system. When submitting an application for a drug registration, the applicant shall also submit a statement setting forth what it knows or should know of related rights. If the applicant challenges related drug patents, the applicant must declare that it is not infringing the related drug patents, and provide notice to the patent holder within 20 days after it has submitted the registration application. If the patent holder considers this to be an infringement of its patent rights, the patent holder shall file a patent infringement suit with the judicial authority within 20 days after notification and inform the Center of Drug Evaluation (“CDE”). After receiving the relevant documents evidencing that the patent infringement filing has been accepted by the judicial authority, CDE may establish an approval waiting period of not more than 24 months. During this period, [CDE] will not stop its technical evaluation. During the approval waiting period, if both parties reach a settlement or if the judicial authority issues a verdict of infringement or non-infringement, on the basis of the settlement or the ruling, CDE shall decide whether to not approve or to approve the marketing authorization for the drug. If the judicial authority has not issued an infringement judgment after the approval waiting period is complete, CDE may approve the marketing authorization application for the drug. If an applicant has not declared a relevant patent in a drug application accepted for filing, and the patent holder files an infringement action, CDE shall place the application in the approval waiting period in accordance with the judicial authority’s acceptance of the case. In the case of intellectual property litigation arising from the distribution of drugs that have received marketing authorization, the rulings of the judicial authority shall control. ....

- On 8 October 2017, the Central Office of the Communist Party of China and the General Office of the State Council of the People’s Republic of China emphasized the willingness to establish a Chinese patent linkage system for drugs and clarified policy guidelines in the Opinion on Encouraging the Innovation of Drugs and Medical Devices by Deepening the Reform of Review and Approval System.<sup>28</sup>

<sup>27</sup> For full text on Measures for Relevant Policies on Protecting Innovator Interests to Encourage Innovations in Drugs and Medical Devices (Draft for Public Comment) (2017 No.55), please refer to the following website of the NMPA: <https://www.nmpa.gov.cn/directory/web/nmpa/xxgk/zhqyj/zhqyjyp/20170512174201528.html> (last visit on 20 July 2022).

<sup>28</sup> For full text on Measures for Opinion on Encouraging the Innovation of Drugs and Medical Devices by Deepening the Reform of Review and Approval System, please refer to the following website of the State Council of The People’s Republic of China: [http://www.gov.cn/zhengce/2017-10/08/content\\_5230105.htm](http://www.gov.cn/zhengce/2017-10/08/content_5230105.htm) (last visit on 19 July, 2022).

**Table 4-(3)-6. China’s Opinion on Encouraging the Innovation of Drugs and Medical Devices by Deepening the Reform of Review and Approval System (Published on 8 October, 2017)**

**3. Accelerating Drug Innovation and Generic Drug Development .....**

**(16) Exploring and establishing a drug patent linkage system.** To protect the legitimate rights and interests of patentees and reduce the risks from patent infringement by generic drugs, encourage the development of generic drugs, (the State will) explore and establish a drug review and approval and drug patent linkage system. When submitting an application for drug registration, an applicant shall specify the relevant patents and ownership status thereof, and shall send a notice to relevant drug patentees within the specified period. In case of any dispute over patents, any concerned party may file a lawsuit with a competent court, and the technical review of the drugs will not be suspended during the dispute period. With respect to the drugs passing the technical review, the food and drug authority shall, in accordance with the effective judgement, decree or the mediation letter rendered by the court, determine whether to approve the marketing of such drugs. If no effective judgement, decision or mediation letter is issued within a specified period, the food and drug authority may approve the marketing.

- On 24 November 2019, the Central Office of the Communist Party of China and the General Office of the State Council of the People’s Republic of China reiterated that they would introduce a patent linkage system and patent term compensation system for drugs in order to improve the intellectual property protection system in new areas, announcing the Opinions on Strengthening Intellectual Property Protection.<sup>29</sup>

**Table 4-(3)-7. China’s Opinions on Strengthening Intellectual Property Protection (Published on 24 November 2019)**

**2. Strengthen systemic constraints, establishing a policy orientation for intellectual property rights protections ...**

**(4) Improve systems for the protection of new business types and new fields.** Targeting new situations developing from new business types and new fields, research strengthening increasing protections for patents, trademarks, copyrights, new plant varieties, circuit layout designs, and so forth. Explore the establishment of a pharmaceutical patent link system, and compensation system for pharmaceutical patent periods. Research strengthening protections of intellectual property rights in broadcast of sports competitions. Strengthen the wide use of notarization electronic certificate storage. Research the establishment of rules for protection of intellectual property rights in cross-border e-commerce, drafting protection management standards for e-commerce platforms. Compile and publish handbooks for protection of enterprise intellectual property rights, draft model contracts and operational guides such as for rights protection processes, encourage enterprises to increase establishment of risk protection mechanisms, and continue to optimize the protective environment public entrepreneurship and innovation. Research drafting measures for protections in areas such as traditional

<sup>29</sup> For full text on Measures for Opinions on Strengthening Intellectual Property Protection, please refer to the following website of the State Council of The People’s Republic of China: [http://www.gov.cn/zhengce/2019-11/24/content\\_5455070.htm](http://www.gov.cn/zhengce/2019-11/24/content_5455070.htm) (last visit on 19 July 2022).

culture and traditional knowledge, strengthening intellectual property rights protections for Traditional Chinese Medicine.

As patent linkage was a part of the Economic and Trade Agreement between the Government of United States and the Government of the People's Republic of China<sup>30</sup> signed on 15 January 2020, there was an increasing discussion on the necessity to introduce a patent linkage system in China.<sup>31</sup>

- The Agreement stipulates in Article 1.11 that China will provide a system to provide notice to the patent holder; adequate time and opportunity for the patent holder to seek, prior to the marketing of an allegedly infringing product, available remedies; and procedures for judicial or administrative proceedings and expeditious remedies the timely resolution of disputes concerning the validity or infringement of an applicable patent.
- Compared to Republic of Korea which introduced a patent linkage system through Republic of Korea-United States FTA, the China-United States Economic and Trade Agreement increased the need to introduce the system in China, but China's patent linkage system has been internally discussed for more than 20 years, so it is difficult to say that the Agreement itself directly affected the introduction of that system.<sup>32</sup>

**Table 4-(3)-8. Economic and Trade Agreement between the Government of the United States and the Government of the People's Republic of China (Signed on 15 January 2020)**

**Article 1.11. Effective Mechanism for Early Resolution of Patent Disputes**

1. If China permits, as a condition of approving the marketing of a pharmaceutical product, including a biologic, persons, other than the person originally submitting the safety and efficacy information, to rely on evidence or information concerning the safety and efficacy of a product that was previously approved, such as evidence of prior marketing approval by China or in another territory, China shall provide:
  - (a) a system to provide notice to a patent holder, licensee, or holder of marketing approval, that such other person is seeking to market that product during the term of an applicable patent claiming the approved product or its approved method of use;
  - (b) adequate time and opportunity for such a patent holder to seek, prior to the marketing of an allegedly infringing product, available remedies in subparagraph (c); and
  - (c) procedures for judicial or administrative proceedings and expeditious remedies, such as preliminary injunctions or equivalent effective provisional measures, for the timely resolution of disputes concerning the validity or infringement of an applicable patent claiming an approved pharmaceutical product or its approved method of use.
2. China shall establish a system for pharmaceutical products consistent with paragraph 1, including by providing a cause of action to allow the patent holder, licensee, or holder of marketing approval to seek, prior to the

30 For full text on Measures for Economic and Trade Agreement between the Government of United States and the Government of the People's Republic of China, please refer to the following website of the Office of United States Trade Representative: <https://ustr.gov/countries-regions/china-mongolia-taiwan/peoples-republic-china/phase-one-trade-agreement/text> (last visit on 19 July 2022).

31 孙瑜晨, “专利链接制度的竞争风险及法律因应研究\_基于美、加、欧、印、澳、韩经验的比较”, 中国科技论坛, 第9期 (2021年9月), 164页.

32 Bu Zhenzhen, “A Study on the Introduction of the Chinese Medicines Approval-Patent Linkage System”, Chungbuk University (2021), p.129.

marketing approval of an allegedly infringing product, civil judicial proceedings and expeditious remedies for the resolution of disputes concerning the validity or infringement of an applicable patent. China may also provide for administrative proceedings for the resolution of such disputes.

On 17 October 2020, China made the fourth amendment to the Patent Law and introduced a patent linkage system formally, and it came into effect on 1 June 2021.

- Article 42(3) of the 4th revised Patent Law introduced a provision on the ‘extension of the duration of drug patents’ that had not existed in the China’s Patent Law, laying the legal foundation for the full-fledged implementation of a patent linkage system.
- In addition, Article 76 introduced a provision on the ‘early resolution of drug disputes’ that a party may file a complaint with the People's Court or request an administrative adjudication<sup>33</sup> with the patent administrative department of the State Council in the event of a patent dispute related to the drug between the applicant, the patentee, and the stakeholders during the review and approval process before the marketing of a pharmaceutical product.
- In other words, it can be said that China completed the introduction of a patent linkage system, which had been progressing gradually, through the 4th revised Patent Law.

**Table 4-(3)-9. China’s Patent Law (revised on 17 December 2020, enforced on 1 June 2021)**

**Article 42.** ... In order to compensate for the time taken for the review and approval process before the marketing of a new pharmaceutical product, the patent administration department under the State Council shall, at the request of the patentee, extend the term of the new pharmaceutical-related invention which has been approved for marketing in China. The compensation term may not be more than five years, and the total effective term of the patent right may not be more than fourteen years from the date of marketing approval.

**Article 76.** In the review and approval process before the marketing of a pharmaceutical product, where the applicant for marketing approval of the pharmaceutical product has any disputes over the relevant patent right associated with the pharmaceutical product applied for registration with the relevant patentee or interested party, the party concerned may file a lawsuit before the People's Court and request a judgment on whether the technical solution related to the pharmaceutical product that is applied for registration falls within the protection scope of any pharmaceutical product patent right owned by others. The medical product regulatory department under the State Council may, within a prescribed time limit, make a decision on whether to suspend the marketing approval of the pharmaceutical product according to the effective judgment or written order of the People's Court.

The applicant for marketing approval of the pharmaceutical product, the relevant patentee or the interested party may also petition the patent administration department under the State Council for an administrative adjudication on the disputes over the patent right associated with the drug applied for registration.

33 Administrative adjudication is, as one of dispute settlement means, an act of arbitrating civil disputes closely related to administrative management activities by an administrative agency based on the authority delegated by law at the request of a party. In other words, in general, patent administrative agency performs administrative functions such as patent examination and registration, but in China, patent administrative agency also exercises law enforcement rights over patent infringement disputes by combining judicial protection and administrative protection.

The medical products regulatory department under the State Council shall, in conjunction with the patent administration department under the State Council, formulate specific cohesive measures for patent right dispute resolutions at the stages of pharmaceutical product marketing license approval and pharmaceutical product marketing license application, which shall be implemented after the approval of the State Council.

However, as the 4th revised Patent Law stipulated only principles of the patent linkage system, each government agency and court announced the regulations and measures containing the details of the patent linkage system to prevent confusion in practice.

- On 1 June 2021, the 4th revised Patent Law came into force, but the detailed rules of the Law were still being revised, so the China Intellectual Property Administration (CNIPA) announced and enforced the Interim Measures for the Processing of Related Examination Businesses Regarding the Implementation of the Revised Patent Law<sup>34</sup> to ensure the implementation of the 4th revised Patent Law.
- On 4 July 2021, the NMPA and the CNIPA announced and enforced the Implementation Measures for the Mechanism for Early Settlement of Drug Patent Disputes (for Trial Implementation),<sup>35</sup> specifying the details of the patent linkage system, such as the registration of drug patent information, patent declaration, waiting period, monopoly period, etc. This was evaluated as substantially establishing the patent linkage system in China.
- On 5 July 2021, the CNIPA announced and enforced the Measures for Administrative Adjudication of the Mechanism for Early Settlement of Drug Patent Disputes<sup>36</sup> in accordance with the 4th revised Patent Law and the Implementation Measures for the Mechanism for Early Settlement of Drug Patent Disputes.
- On 5 July, 2021, the Supreme People's Court announced and enforced a supplementary judicial interpretation, the Provisions of the Supreme People's Court on Several Issues concerning the Application of Law in the Trial of Civil Cases involving Patent Disputes Related to Drugs of Which Applications for Registration are Filed<sup>37</sup> and designated the Beijing Intellectual Property Court as the exclusive jurisdiction of drug patent litigation.

On 15 April 2022, the Beijing Intellectual Property Court of China first handed down a ruling on patent linkage of drug licensing.

- The Plaintiff, JW Pharmaceutical Corporation, developed the osteoporosis treatment 'Eldecacitol Soft Capsule' and obtained marketing approval in China and registered related patents.
- The defendant, Haihe Pharmaceutical Industry, applied to the NMPA for marketing approval for a generic drug of 'Eldecacitol Soft Capsule' and declared that the generic drug was not within the scope of the Plaintiff's patent right.

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34 For full text on the Interim Measures for the Processing of Related Examination Businesses Regarding the Implementation of the Revised Patent Law, please refer to the following website of the CNIPA: [https://www.cnipa.gov.cn/art/2021/5/25/art\\_74\\_159631.html](https://www.cnipa.gov.cn/art/2021/5/25/art_74_159631.html) (last visit on 24 July 2022).

35 For full text on the Implementation Measures for the Mechanism for Early Settlement of Drug Patent Disputes (for Trial Implementation), please refer to the following website of the State Council of The People's Republic of China: [http://www.gov.cn/zhengce/zhengceku/2021-07/04/content\\_5622330.htm](http://www.gov.cn/zhengce/zhengceku/2021-07/04/content_5622330.htm) (last visit on 24 July 2022).

36 For full text on the Measures for Administrative Adjudication of the Mechanism for Early Settlement of Drug Patent Disputes, please refer to the following website of the CNIPA: [https://www.cnipa.gov.cn/art/2021/7/5/art\\_74\\_160566.html](https://www.cnipa.gov.cn/art/2021/7/5/art_74_160566.html) (last visit on 24 July 2022).

37 For full text on the Provisions of the Supreme People's Court on Several Issues concerning the Application of Law in the Trial of Civil Cases involving Patent Disputes Related to Drugs of Which Applications for Registration are Filed, please refer to the following website of the Supreme People's Court of The People's Republic of China: <https://www.court.gov.cn/fabu-xiangqing-311791.html> (last visit on 24 July 2022).

- In response, the Plaintiff filed a lawsuit with the court seeking confirmation that the Defendant's generic drug falls within the scope of protection of the Plaintiff's patent right.
- The court dismissed the Plaintiff's claim, judging that the generic drug does not fall within the scope of protection of the patent right in this case.
- This case is significant in that it was the first lawsuit on patent linkage of drug licensing since the 4th revised Patent Law came into effect.

## 2) Operation of a Patent Linkage System

In China, the CNIPA is in charge of examining patent applications and granting patents under the Patent Law, and the NMPA is in charge of marketing approval of drugs under the Drug Administration Law.<sup>38</sup> In accordance with Article 76 of the Patent Law, the NMPA implements measures to prevent patent infringement in the marketing approval process of drugs together with the CNIPA.

- Article 76 of the Patent Law of China stipulates that the medical products regulatory department under the State Council (present NMPA), together with the patent administration department under the State Council (present CNIPA), formulates specific cohesive measures for patent right dispute resolutions at the stages of pharmaceutical product marketing license approval and pharmaceutical product marketing license application and implements it after the approval of the State Council.
- The NMPA is responsible for overall patent linkage procedures, such as the establishment and management of the Patent Information Registration Platform for Marketed Drugs, disclosure of patent information of licensed drugs, applications for marketing approval of drugs, disclosure of applications, administrative review, technical review, setting of waiting period or monopoly period.
- The CNIPA is responsible for administrative adjudication on whether the technical methods of the drug applied for marketing approval fall within the scope of patent protection and provides relevant information to NMPA.

## 3) Issues in Patent Law related to a Patent Linkage System

### Extension of the duration of drug patents

To compensate for the time required for the review and approval process before the marketing of a new pharmaceutical product, China established a clause on the extension of the duration of drug patents, etc. in Article 42 through the 4th revision of the Patent Law in 2020.

- According to Article 42 of the Patent Law, the patent administration department under the State Council shall compensate for the duration of the patent on a new drug licensed in China at the request of the patentee within the extent of not exceeding 5 years, and the entire duration of the of the patent right may not be more than fourteen years from the date of marketing approval.

### Table 4-(3)-10. China's Patent Law (revised on 17 December 2020, enforced on 1 June 2021)

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<sup>38</sup> For full text on China's Drug Administration Law, please refer to the following website of the State Administration for Market Regulation (SAMR): [https://gkml.samr.gov.cn/nsjg/fgs/201909/t20190917\\_306828.html](https://gkml.samr.gov.cn/nsjg/fgs/201909/t20190917_306828.html) (last visit on 24 July, 2022).

**Article 42.** ... In order to compensate for the time taken for the review and approval process before the marketing of a new pharmaceutical product, the patent administration department under the State Council shall, at the request of the patentee, extend the term of the new pharmaceutical-related invention which has been approved for marketing in China. The compensation term may not be more than five years, and the total effective term of the patent right may not be more than fourteen years from the date of marketing approval.

### **Practice of a patented invention for the purpose of clinical trials**

On 27 December 2008, China established a provision that recognized the implementation of a patent invention for drug item licensing as an exception to patent infringement through the 3rd revision of the Patent Law.

- The Chinese Patent Law did not provide an exemption from patent infringement for the implementation of patents for obtaining drug item permission, such as clinical trials, until the 3rd revision was made.
- Although ‘where the relevant patent is used specially for the purposes of scientific research and experimentation’ did not fall under patent infringements, it was not clear whether clinical trials for drug item permission, etc. were included because the ‘practice of a patented invention for the purpose of research or testing for obtaining permission for items of medicines, etc.’ was not directly specified as in Republic of Korea.
- On 16 February 2006, the Second Intermediate People's Court in Beijing determined, in the so-called ‘China's first case on the Bolar exception’, that the act of manufacturing a drug using the patent in this case for the purpose of conducting a clinical trial and applying for marketing approval does not constitute a patent infringement.
- However, it was criticized by the academic community for lack of legal grounds, and on 27 December 2008, the People's Congress Standing Committee established a clause that ‘the act of manufacturing, using, or importing patented medical products or devices for the purposes of providing information needed for the administrative examination and approval’ is considered as an exception to patent infringement through the 3rd revision of the Patent Law.

**Table 4-(3)-11. China's Patent Law (revised on 17 December 2020, enforced on 1 June 2021)**

**Article 75.** None of the following shall be deemed as infringement of the patent right: ...

- (4) where the relevant patent is used specially for the purposes of scientific research and experimentation;  
or
- (5) where for the purposes of providing information needed for the administrative examination and approval, any person manufactures, uses, or imports patented drugs or patented medical apparatus and instruments, or any other person manufactures or imports patented drugs or patented medical apparatus and instruments especially for that person.

### **4) Structure of a Patent Linkage System**

In the People's Republic of China, the Implementation Measures for the Mechanism for Early Settlement of Drug Patent Disputes stipulate:

- ① Registration of applicable drug patents,
- ② Notification of application for marketing approval,
- ③ Measures to provide adequate time and opportunity for resolution of patent disputes prior to marketing, and
- ④ Granting generic exclusivity.

### **Registration of applicable drug patents**

The Implementation Measure has a drug patent information registration system by stipulating that the medical products regulatory department under the State Council establishes a ‘Patent Information Registration Platform for Marketed Drugs in China’<sup>39</sup> to allow drug license holders to register patent information related to licensed drugs.

- The drug review institution is responsible for establishing and maintaining the Patent Information Registration Platform for Marketed Drugs, and publicizing the patent information of the drugs approved for marketing.<sup>40</sup>
- Drug marketing authorization holders shall, within 30 days after obtaining the drug registration certificate, register the drug name, dosage form, specifications, drug marketing authorization holders, relevant patent number, patent name, patentee, patent licensee, patent grant date, expiration date of patent protection, patent status, patent type, corresponding relationship between medicine and related patent claims, correspondence address, contact person, contact information and other contents by itself.<sup>41</sup>
- In case of any change to the relevant information, drug marketing authorization holders shall complete the update within 30 days after such change takes effect.<sup>42</sup>
- The Measures do not apply to relevant patent information that is not registered on the Patent Information Registration Platform for Marketed Drugs.<sup>43</sup>
- Drug marketing authorization holders shall be responsible for the authenticity, accuracy and completeness of the patent information registered by the drug marketing authorization holder, and shall verify, deal with and record the relevant oppositions received in a timely manner.<sup>44</sup>
- While the Ministry of Food and Drug Safety manages and discloses the drug patent registration list in Republic of Korea, the Chinese patent linkage system does not require the NMPA to conduct a preliminary examination of the contents of the patent information registration platform, and there is no mechanism to correct patent information if it is incorrectly entered.

### **Notification of application for marketing approval**

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39 For the Patent Information Registration Platform for Marketed Drugs in China, please refer to the following website: <https://zldj.cde.org.cn/home> (last visit on 27 July 2022).

40 China’s Implementing Measures for Mechanism for Early Resolution of Drug Patent Disputes (published on 4 July 2021) Article 3.

41 China’s Implementing Measures for Mechanism for Early Resolution of Drug Patent Disputes (published on 4 July 2021) Article 4.

42 China’s Implementing Measures for Mechanism for Early Resolution of Drug Patent Disputes (published on 4 July 2021) Article 4.

43 China’s Implementing Measures for Mechanism for Early Resolution of Drug Patent Disputes (published on 4 July 2021) Article 2.

44 China’s Implementing Measures for Mechanism for Early Resolution of Drug Patent Disputes (published on 4 July 2021) Article 4.

The Implementation Measure has a notification system of marketing approval applications, etc. by obligating applicants who apply for marketing approval for chemical generic drugs to make a 'patent declaration' against the patent information on the Patent Information Registration Platform for Marketed Drugs, and to 'notify' the declaration and the basis of the declaration to the marketing authorization holder and the patent holder.

- **(Patent declaration)** When an applicant for a chemical generic drug submits an application for a drug marketing authorization, said applicant shall, based on the patent information that has been publicized on the Patent Information Registration Platform for Marketed Drugs, make a declaration on each drug patent related to the generic drug. The declarations are divided into four categories.<sup>45</sup>
  - ① (Category I Declaration) There is no patent information related to the corresponding original drug on the Patent Information Registration Platform for Marketed Drugs.
  - ② (Category II Declaration) The patent rights related to the corresponding original drug recorded on the Patent Information Registration Platform for Marketed Drugs have been terminated or declared invalid, or the applicant of generic drugs has obtained relevant patent license from the patentee.
  - ③ (Category III Declaration) For the patent of the corresponding original drug on the Patent Information Registration Platform for Marketed Drugs, the generic drug applicant promises not to put the generic drug on the market until the date on which such corresponding patent right will expire.
  - ④ (Category IV Declaration) The patent right recorded on the Patent Information Registration Platform for Marketed Drugs related to the corresponding original drug shall be declared invalid, or the generic drug does not fall within the protection scope of that such patent right.
- **(Notification)** The drug review institution shall release the application information and corresponding declarations to the public via the information platform within 10 working days from an application for generic drugs is accepted, and a generic drug applicant shall notify the marketing authorization holder of the corresponding declarations and the basis thereof, and where the marketing authorization holder is not the patentee, the marketing authorization holder shall notify the patentee of the same.<sup>46</sup>

### **Measures to provide adequate time and opportunity for resolution of patent disputes prior to marketing**

The Implementation Measure allows patentees or interested parties to set a 'waiting period' for an application of the registration of chemical generic drug through a certain procedure if there is an objection to Category IV declaration.

- **(Procedure for the waiting period)** If the patentee or interested party has any objection to Category IV declaration, the 'waiting period' may be set through the following procedure.

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<sup>45</sup> China's Implementing Measures for Mechanism for Early Resolution of Drug Patent Disputes (published on 4 July 2021) Article 6.

<sup>46</sup> China's Implementing Measures for Mechanism for Early Resolution of Drug Patent Disputes (published on 4 July 2021) Article 6.

- ① The patentee or any interested party who has any objection to Category IV declaration may, within 45 days from the date when the drug review institution makes public the application for the drug marketing authorization, file a lawsuit before People's court or petition the patent administration department under the State Council for an administrative adjudication, regarding whether the relevant technical solutions of the drug applied for marketing approval fall within the protection scope of the patent rights.<sup>47</sup>
  - ② If the patentee or any interested party files a lawsuit or petitions for an administrative adjudication within the prescribed time limit, the patentee or the interested party shall, within 15 working days from the date when the case is docketed by the people's court or accepted by the patent administration department under the State Council, submit a copy of the notification of case docket or acceptance to the drug review institution and notify the generic drug applicants.<sup>48</sup>
  - ③ After receiving the copy of the notice of case docket by the people's court or the notice of accepting the case by the administrative department for patent under the State Council, the drug regulatory and administrative department under the State Council shall set up a 9-month waiting period for the application of the registration of chemical generic drugs.<sup>49</sup>
- **(Effect of the waiting period)** During the waiting period, the drug review institution temporarily suspends administrative review of the application for registration of the chemical generic drug and conducts only technical review.<sup>50</sup>
  - **(Restriction of the waiting period)** The waiting period shall only be set once from the date on which the case is docketed by the people's court or the date on which the patent administrative department under the State Council accepts the case, and the drug review institution shall not stop the technical review during the waiting period.<sup>51</sup>

### Generic exclusivity

The Chinese Implementation Method has a generic exclusivity system by stipulating that a market exclusive period is granted to chemical generic drugs that succeed in the first patent challenge and obtain the first marketing approval.<sup>52</sup>

- **(Qualification of generic exclusivity)** A person who succeeded in the first patent challenge of a chemical generic drug and obtained the first marketing approval.
- **(Requirement for generic exclusivity)** The applicant of chemical generic drugs shall file a patent invalidation trial after submitting Category IV declaration, and then the patent shall be invalidated accordingly and the applicant shall obtain marketing approval for the generic drug.

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47 China's Implementing Measures for Mechanism for Early Resolution of Drug Patent Disputes (published on 4 July 2021) Article 7.

48 China's Implementing Measures for Mechanism for Early Resolution of Drug Patent Disputes (published on 4 July 2021) Article 7.

49 China's Implementing Measures for Mechanism for Early Resolution of Drug Patent Disputes (published on 4 July 2021) Article 8.

50 China's Implementing Measures for Mechanism for Early Resolution of Drug Patent Disputes (published on 4 July 2021) Article 8.

51 China's Implementing Measures for Mechanism for Early Resolution of Drug Patent Disputes (published on 4 July 2021) Article 8.

52 China's Implementing Measures for Mechanism for Early Resolution of Drug Patent Disputes (published on 4 July 2021) Article 11.

- **(Effect of generic exclusivity)** During a market exclusivity period, the drug regulatory and administrative department under the State Council shall not approve the marketing of any generic drug of the same variety within 12 months from the date of approval of the drug except for successful joint patent challenges.
- **(Restriction on generic exclusivity)** The market exclusivity period shall not exceed the patent term of the challenged drug, and during the exclusive period of the market, the drug review institution will not stop the technical review, and the chemical generic drug registration application that has passed technical review shall be forwarded to the administrative review and approval process before the expiration of the market exclusivity period.

## (4) Japan

### 1) Introduction and Development of a Patent Linkage System

Japan has not introduced a general type of patent linkage system derived from the Hatch-Waxman Act of the United States, but it has developed its own ‘Japanese-style patent linkage system’.

- In Japan, there are no provisions on a patent linkage system stipulated in law. Drug licenses are linked to patents in a manner such as not approving drugs that are likely to infringe on patent rights during the approval and examination of generic drugs based on the notification of the Ministry of Health, Labour and Welfare of Japan (MHLW), which is an administrative agency.
- When a patent linkage system is broadly defined as a structure in which the regulation authority considers the presence or absence of patent rights related to original drugs in the approval process for generic drugs, it can be said that the Japan operates ‘Japanese-style patent linkage system’.

On 5 June 2009, the MHLW announced the Notification on Handling of Drug Patents in the Process of Approval Review for Generic Drugs and Listing on Drug Price List under the Pharmaceutical Affairs Law (hereinafter referred to as ‘2009 Notification’<sup>53</sup> in line with the trend of promoting the use of generic drugs.

- The 2009 Notification partially revised the Notification on Handling of Pharmaceutical Patent Information for Approval Review (hereinafter referred to as ‘1994 Notification’) issued on 4 October, 1994, and stipulated to check whether generic drugs violate patent rights in the approval review from the perspective of promoting a stable supply of drugs.
- This is only a kind of internal management guideline for administrative agencies, but currently, in Japan, approval for manufacturing and selling drugs is made in accordance with this Notification.<sup>54</sup>
- Mainly, it stipulates that ① if there is a patent in the active ingredient of original drugs, and ② if there is a patent in some efficacy, effect, usage, and dosage of original drugs (hereinafter referred to as ‘efficacy and effect’), pharmaceutical affair<sup>55</sup> is not approved for the efficacy and effect, etc.

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53 For full text on Japan’s Notification on Handling of Drug Patents in the Process of Approval Review for Generic Drugs and Listing on Drug Price List under the Pharmaceutical Affairs Law, please refer to the following website of the MHLW:  
[https://www.mhlw.go.jp/web/t\\_doc?dataId=00tb5511&dataType=1&pageNo=1](https://www.mhlw.go.jp/web/t_doc?dataId=00tb5511&dataType=1&pageNo=1) (last visit on 1 July 2022).

54 Shin Hye-eun, Bu Zhenzhen, “Japan's Drug Approval-patent Linkage System and Its Implications for Us”, Republic of Korea Intellectual Property Society, Industrial Property Rights, No.66 (2021), p.144.

55 Pharmaceutical affair refers to matters related to medicine, that is, matters related to the manufacture, storage, import, and sale of medicines.

## 2) Operation of a Patent Linkage System

In Japan, the Japan Patent Office (JPO) under the Ministry of Economy, Trade and Industry (METI) is in charge of examining patent applications and granting patents according to the Patent Act,<sup>56</sup> and the MHLW is in charge of pharmaceutical regulations under the Pharmaceutical Affairs Law<sup>57</sup> (excluding animal medicines under the jurisdiction of the Ministry of Agriculture, Forestry and Fisheries). In the case of patent linkage, the MHLW takes measures to prevent patent infringement in the marketing approval procedure for drugs according to internal notice.

- The MHLW is responsible for medical treatment, long-term treatment, pension, labour, childcare, and public assistance in Japan, and takes charge of the licensing of manufacturing and sales business of pharmaceuticals, etc., approval of manufacturing and sales, review and re-evaluation, etc.
- In particular, the Pharmaceutical and Food Safety Bureau (PFSB) and the Pharmaceutical Affairs and Food Sanitation Council (PAFSC) under the Ministry of Health and Labour perform matters related to pharmaceuticals. The PFSB is in charge of manufacturing and sales business licensing, manufacturing and sales approval, review and re-evaluation, etc. to ensure the quality and safety of medicines, non-medication products, cosmetics, and medical devices, and the PAFSC serves as an advisory body to the MHLW.<sup>58</sup>
- The MHLW, which is an administrative agency, operates a Japanese-style patent linkage to prevent problems in the stable supply of generic drugs due to patent infringement lawsuits, based on internal notifications (1994 and 2009 Notifications).<sup>59</sup>

## 3) Issues in Patent Law related to a Patent Linkage System

### Extension of the duration of drug patents

Japan revised the Patent Act in 1987 and introduced a system extending the duration of drug patents, etc. to compensate for the period for which the patent right could not be exercised due to validity and stability tests for obtaining licensing for drug items.

- According to Article 67 of Japan's Patent Act, the duration of a patent right (20 years from the date of filing a patent application) can be extended up to 5 years where there is a period in which a patented invention cannot be implemented as prescribed by the Enforcement Decree because it takes a considerable period of time to implement the disposition of permission, etc. for the purpose of securing safety, etc. for the implementation of the patented invention.

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56 For full text on Japan's Patent Act, please refer to the following website of the E-Gov Japan: [https://elaws.e-gov.go.jp/document?lawid=334AC0000000121\\_20220525\\_504AC0000000048&keyword=%E7%89%B9%E8%A8%B1%E6%B3%95](https://elaws.e-gov.go.jp/document?lawid=334AC0000000121_20220525_504AC0000000048&keyword=%E7%89%B9%E8%A8%B1%E6%B3%95) (last visit on 12 July 2022).

57 For full text on Japan's Pharmaceutical Affairs Law (PAL), please refer to the following website of the E-Gov Japan: <https://elaws.e-gov.go.jp/document?lawid=335AC0000000145> (last visit on 10 July 2022).

58 The APEC Harmonization Center, "Japan Pharmaceutical Licensing System (License and Permit Report Series 5)", 2016, pp.6-7.

59 On the other hand, it is pointed out that the Ministry of Health, Labour and Welfare tends to take a passive attitude of not granting item permits in cases of infringement concerns, in terms of ① it being a pharmaceutical expert not a patent expert, and ② the method of operation of the patent linkage system being not specified in the law, etc. Shin Hye-eun et al., *supra* note 56, p.163.

**Table 4-(4)-1. Japan’s Patent Act (Act No. 121 of 13 April 1959, revised on 25 May 2021)**

**Patent Term**

**Article 67** (1) The term of a patent right expires after a period of 20 years from the filing date of the patent application....

(4) Where there is a period during which the patented invention is unable to be worked because approval prescribed by relevant Acts that are intended to ensure safety, etc. or any other disposition designated by Cabinet Order as requiring considerable time for its proper execution in light of its purpose, procedures, etc., is necessary to be obtained for the working of the patented invention, the duration prescribed in paragraph (1) (if it is extended pursuant to paragraph (2), including the period of extension; the same shall apply in the proviso to Article 67-5 (3), Article 68-2, and Article 107 (1)) may be extended, upon the filing an application to register an extension of the duration, by a period not exceeding 5 years.

**Practice of a patented invention for the purpose of clinical trials**

There is no explicit provision in the Japan’s Patent Act that excludes the implementation of a patented invention for clinical trials, etc. in the procedure for permission of drug items from patent infringements.

- The Japan’s Patent Act stipulates in Article 69 (1) that the effect of a patent right does not reach the implementation of a patented invention for testing or research.
- However, it does not directly specify the case of the ‘practice of a patented invention for the purpose of research or testing for obtaining permission for items of medicines, etc.’ like in Republic of Korea, so it is not clear whether ‘the practice of a patented invention for experimental or research purposes’ includes clinical trials for permission of drug items, etc.
- Therefore, the Supreme Court of Japan determined that producing chemicals or medicines within the technical scope of the patented invention and conducting tests necessary to obtain the data to be attached to the application for manufacturing approval by using them during the duration of the patent in order to apply for manufacturing approval prescribed in Article 14 of the Pharmaceutical Affairs Act for the purpose of manufacturing and selling generic drugs after the end of the term of the patent right falls under the implementation of a patent invention for the test or research under Article 69 (1) of the Patent Act.<sup>60</sup>

**Table 4-(4)-2. Japan’s Patent Act (Act No. 121 of 13 April 1959, revised on 25 May 2021)**

**Limitations of Patent Right**

**Article 69** (1) A patent right is not effective against the working of the patented invention for experimental or research purposes.

(2) A patent right is not effective against the following products:

- (i) vessels or aircraft merely passing through Japan, or machines, apparatus, equipment or other products used in them; and
- (ii) products present in Japan prior to the filing of the patent application.

<sup>60</sup> 最高裁小二法廷平成 11 年 4 月 16 日判決(平成 10(受)153)(民集 53 卷 4 号 627 頁). For full text on Japan’s the Supreme Court ruling, please refer to the following website of the Court of Japan: [https://www.courts.go.jp/app/hanrei\\_jp/detail2?id=52235](https://www.courts.go.jp/app/hanrei_jp/detail2?id=52235) (last visit on 12 July 2022).

(3) A patent right for a medical invention (medicine meaning a product used in the diagnosis, therapy, treatment or prevention of human diseases; hereinafter the same applies in this paragraph) that is to be manufactured by two or more medicines being mixed together or for the invention of a process by which a medicine is manufactured by two or more medicines being mixed together has not effect against the act of preparation of a medicine as per a physician's or dentist's prescription nor against medicine prepared as per a physician's or a dentist's prescription.

#### 4) Structure of a Patent Linkage System

Japan has developed and operated its own patent linkage system. In Japan, MHLW Notifications and the Pharmaceutical Affairs Law, etc. stipulate:

- ① Drug patent information report,
- ② Re-examination, and
- ③ Prior adjustment.

However, Japan's MHLW Notifications and the Pharmaceutical Affairs Law, etc. do not stipulate:

- ① Registration of applicable drug patents,
- ② Notification of application for marketing approval,
- ③ Measures to provide adequate time and opportunity for resolution of patent disputes prior to marketing, and
- ④ Generic exclusivity.

#### Drug Patent Information Report

In Japan, according to the 1994 and 2009 Notifications, a manufacturer of original drugs submits a 'Drug Patent Information Report' to the MHLW. And then, the Ministry decides whether to approve generic drugs by using the 'Drug Patent Information Report'.<sup>61</sup>

- The drug patent information report contains information on substance patents or use patents for active ingredients of drugs (excluding in vitro diagnostic drugs) already approved and submitted to the MHLW by the pharmaceutical manufacturer of the drugs.
- The submission of the drug patent information report is voluntary, and the report is generally not disclosed.
- The submission period is before the end of the investigation period of the re-examination, and if the re-examination period has already ended but the duration of the patent has not expired, it is until the expiration of the patent period.

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61 石埜ほか4人, “日本のパテントリンケージの運用実態について”, パテント, 2018, 55 頁.

- The MHLW uses or references the drug patent information report for approval of generic drugs, but it does not play an active role to collect and manage the patent list, etc. In this respect, there is no drug patent registration system in Japan such as the US Orange Book or Republic of Korea's Green List.

### Re-examination

Japan operates the re-examination system for new drugs under Article 14-4 of the Pharmaceutical Affairs Act, and implements patent linkage by prohibiting approval of generic drugs during the re-examination period, and practically withholding approval where a relevant patent exists while allowing an application for approval of generic drugs after the re-examination period.

- A re-examination refers to a system that collects data on the actual use performance of the drug after a certain period of time has elapsed after approval of a new drug and reconfirms the quality, effectiveness, and stability of the drug.
- The MHLW can extend the re-examination period to a maximum of 10 years after approval of new drugs.
- It is not allowed to apply for approval for manufacturing and sales of generic drugs during the re-examination.
- The approval of generic drugs cannot be directly denied even during the duration of patents. Therefore, in some cases, generic drug companies take the risk of patent infringement lawsuits and obtain permission to market generic drugs to impede the stable supply of drugs after the re-examination period has elapsed even though patent rights still exist.<sup>62</sup>
- To prevent this problem, the MHLW implements patent linkage by allowing applications for the approval of manufacturing and sales of generic drugs after the re-examination period has elapsed, but practically by suspending approval of generic drugs if a substance patent or use patent exists on the drug.<sup>63</sup>

**Table 4-(4)-3. Japan's Pharmaceutical Affairs Law (Act No. 145 of 10 August 1960, revised on 25 May 2021)**

**Article 14-4** (1) A person who has received approval prescribed in Article 14 for the pharmaceuticals set forth in the following items must apply within the period specified in each for the pharmaceuticals concerned for re-examination by the Minister of Health, Labour and Welfare ...

(2) The Minister of Health, Labour and Welfare may, when finding it especially necessary to provide proper re-examinations of new pharmaceuticals, extend the investigation period to a period not exceeding 10 years from the date of approval after hearing the opinion of the Pharmaceutical Affairs and Food Sanitation Council. ...

<sup>62</sup> Shin Hye-eun et al., supra note 56, pp.139-140.

<sup>63</sup> Ibid.

## Prior Adjustment

The MHLW requires the parties to conduct ‘prior adjustment’ over items that may infringe upon patent rights between the approval of the pharmaceutical affair of the generic drug and the acceptance of the drug price.<sup>64</sup>

- In Japan, the procedure to release generic drugs consists of two steps: ‘pharmaceutical affair approval’ and ‘listing of the drug price’. And the MHLW requires the parties to go through a prior adjustment process on whether the generic drug violates patent rights in the process of the listing of the drug price.
- The deadline for prior adjustment is up to 2 months from the date of approval of the manufacturing and sales of generic drugs.<sup>65</sup>
- In other words, the MHLW double-checks the patent relationship between original and generic drugs by checking whether the substance or use patent is violated through the drug patent information report in the pharmaceutical affair approval stage and by requiring the parties to check whether patents other than the substance or use patent are violated through prior adjustment at the stage before the listing of the drug price.<sup>66</sup>
- However, if conflicting claims between original and generic drug companies are not adjusted despite prior adjustment, the MHLW recognizes the drug price of generic drugs on the condition that the generic drug company submits a pledge not to stop supplying the drug even if it receives a prohibition claim from the original drug company in lawsuit, etc.<sup>67</sup>
- Since the MHLW cannot make a judgment on the difference between original and generic drug companies (which can be determined by the Japan Patent Office or ultimately the court), it seems to recognize the manufacturing and selling of generic drugs under the responsibility of the manufacturer if the generic drug company strongly claims non-infringement of patent rights.<sup>68</sup>
- In summary, the MHLW directly decides whether to approve the manufacture and sale of drugs for substance or use patents that are easy to determine patent infringements and if it is difficult to decide, requires the parties to make adjustment, and if no agreement is reached despite prior adjustment, recognizes the drug price under the responsibility of the generic drug company.

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64 石埜ほか4人, “日本のパテントリンケージの運用実態について”, パテント, 2018, 55 頁.

65 It is 1 month before the deadline for withdrawing the application for acceptance of the drug price (1 month before the acceptance).

66 石埜ほか4人, “日本のパテントリンケージの運用実態について”, パテント, 2018, 57 頁.

67 石埜ほか4人, “日本のパテントリンケージの運用実態について”, パテント, 2018, 57 頁.

68 石埜ほか4人, “日本のパテントリンケージの運用実態について”, パテント, 2018, 57 頁.

## **(5) Republic of Korea**

### **1) Introduction and Development of a Patent Linkage System**

Republic of Korea introduced a patent linkage system for the first time in accordance with the FTA, which was signed by Republic of Korea and the United States in June 2007 and took effect in March 2012.

- The Agreement obliges a patent linkage system by requiring that the patent owner be notified of the identity of any other person that requests marketing approval to enter the market during the term of the patent and the implementation of measures to prevent other persons from marketing a pharmaceutical product without the patent owner's consent during the term of the patent. See paragraph 5 of Article 18.9 of the Agreement.

**Table 4-(5)-1. Provisions related to a patent linkage under the FTA between Republic of Korea and the United States**

#### **ARTICLE 18.9: MEASURES RELATED TO CERTAIN REGULATED PRODUCTS**

5. Where a Party permits, as a condition of approving the marketing of a pharmaceutical product, persons, other than the person originally submitting safety or efficacy information, to rely on that information or on evidence of safety or efficacy information of a product that was previously approved, such as evidence of prior marketing approval in the territory of the Party or in another territory, that Party shall:

- (a) provide that the patent owner shall be notified of the identity of any such other person that requests marketing approval to enter the market during the term of a patent notified to the approving authority as covering that product or its approved method of use; and
- (b) implement measures in its marketing approval process to prevent such other persons from marketing a product without the consent or acquiescence of the patent owner during the term of a patent notified to the approving authority as covering that product or its approved method of use.

Following the conclusion of this Agreement, Republic of Korea revised the Pharmaceutical Affairs Act on 2 December 2011 as the implementation legislation related to a patent linkage system, and introduced provisions related to the registration and notification of drug patent list (Article 31-3) and notification of application for marketing approval of drugs (Article 31-4).

**Table 4-(5)-2. Republic of Korea's Pharmaceutical Affairs Act (Act No. 11118, revised in 2 December 2011)**

**Article 31-3 (Patent Lists of Drugs)** (1) If a person who has obtained a product license pursuant to Article 31 (2) or (3) desires to have the matters prescribed by Ordinance of the Ministry of Health and Welfare, such as an owner of a patent right, duration, and the extent of the patent of the product-licensed drug, (hereinafter referred to as "patent information") registered in the patent list for drugs (hereinafter referred to as "patent list"), he/she shall file an application for registration with the Minister of Food and Drug Safety.

(2) If the patent of a drug, the registration of which was applied for pursuant to paragraph (1) satisfies the subject matter and standards determined by Ordinance of the Prime Minister, the Minister of Food and Drug Safety shall register the patent information of the relevant drug in the patent list. ...

**Article 31-4 (Notification of Application for Product License)** (1) A person who has filed an application for a product license under Article 31 (2) or (3) based on the data on the safety and effectiveness of the registered drugs shall notify the persons who have obtained product licenses of the registered drugs and the holders of the patent rights (hereinafter referred to as "patent right holder, etc.") of matters prescribed by Ordinance of the Ministry of Health and Welfare, such as the fact that he/she has filed such application: Provided, That the same shall not apply to any of the following cases:

1. Where the duration of the patent of a registered drug expires;
2. Where an application for a product license is filed to sell the relevant drug after the duration of the patent of a registered drug expires;
3. Where the holder of the patent right, etc. of a registered drug has agreed to the omission of notification;
- ...

Since then, Republic of Korea revised the Pharmaceutical Affairs Act again on 13 March 2015 to further reflect the contents of the FTA between Republic of Korea and the United States, effectively protect drug patents and improve some other deficiencies, etc., newly establishing a separate chapter to stipulate the provisions related to a patent linkage system.

- The Pharmaceutical Affairs Act revised on 13 March 2015 introduced new provisions related to the prohibition of marketing of generic drugs subject to patent trials and lawsuits (Articles 50-5 and 50-6), and the exclusive marketing approval of generic drugs which won in patent trials, etc. (Articles 50-7 to 50-10), and changed the order of related provisions such as the entry into the drug patent list (deletion of Article 31-3, introduction of Article 50-2), and improved some procedures.

**Table 4-(5)-3. Republic of Korea's Pharmaceutical Affairs Act (Act No. 13219, revised in 13 March 2015)**

**CHAPTER V-II REGISTRATION OF DRUG PATENT AND PREVENTION OF MARKETING, ETC.**

**SECTION 1 Registration of Drug Patent**

**Article 50-2 (Registration of Drug Patent)** (1) Each person, who has obtained marketing approval of a drug referred to in Article 31 (2) and (3) or revised approval of a drug referred to in paragraph (9) of the same Article (hereinafter referred to as “marketing approval or revised approval”), shall file an application for registration of the patent information of the drug in the drug patent list (hereinafter referred to as “patent list”) in which the Minister of Food and Drug Safety registers and manages patents of drugs approved (hereinafter referred to as “drug patent”). ...

**Article 50-3 (Change, Etc. of Registered Information)** (1) A person, who has registered the patent information of a drug in the patent list after filing an application for registration of a drug patent pursuant to Article 50-2 (1) (hereinafter referred to as “registered patentee”), may file an application for the change or deletion of the patent information registered in the patent list pursuant to Article 50-2 (4) (hereinafter referred to as “registered information”) with the Minister of Food and Drug Safety. ...

**SECTION 2 Notice of Application for Marketing Approval and Prevention of Marketing, Etc.**

**Article 50-4 (Notice of Application for Marketing Approval, etc.)** (1) Each person, who has filed an application for marketing approval of a drug pursuant to Article 31 (2) or (3) based on the information on safety and efficacy of a listed drug, or who has filed an application for approval of the change of the efficacy and effectiveness pursuant to paragraph (9) of the same Article, shall notify the registered patentee and patentee, etc. of a listed drug of the matters prescribed by Ordinance of the Prime Minister, such as the fact that the application for marketing approval has been filed and the filing date of the application: Provided, That this shall not apply in any of the following cases:

1. Where the period of a registered patent expires; ...

**Article 50-5 (Application for Prevention of Marketing)** (1) A patentee, etc. of a listed drug may file an application for the prevention of marketing of the notified drug with the Minister of Food and Drug Safety by attaching the statement including the following, within 45 days from the date of receipt of notice pursuant to Article 50-4:

1. An application for marketing prevention shall have been filed based on the patent registered lawfully;
2. A petition for trial or litigation referred to in paragraph (2) shall have been filed in good faith, there is a prospect of winning a case, and the trial or litigation shall not be delayed unreasonably.

(2) A patentee, etc. of a listed drug shall institute any of the following patent-related litigations or file or take a petition for any of the following patent-related trials before he/she files an application for marketing prevention:

1. A litigation to seek injunction for, or prevention of infringement of patent rights pursuant to Article 126

of the Patent Act;

2. A trial to confirm the scope of patent rights pursuant to Article 135 of the Patent Act. ...

**Article 50-6 (Marketing Prevention, Etc.)** (1) Where the Minister of Food and Drug Safety in receipt of an application for marketing prevention under Article 50-5 (1) grants marketing approval or revised approval for the drug for which the application for marketing prevention was filed, he/she shall prevent the marketing of such drug for nine months from the date when the patentee, etc. of a listed drug is notified pursuant to Article 50-4 (hereinafter referred to as “date of receipt of notice”), except in any of the following cases: ...

### **SECTION 3 Exclusive Marketing Approval**

**Article 50-7 (Application for Exclusive Marketing Approval)** (1) Where a person, who shall notify pursuant to Article 50-4, files an application for marketing approval or revised approval of a drug, he/she may also file an application for exclusive marketing approval of the drug with the Minister of Food and Drug Safety, prior to the marketing of drugs meeting all of the following requirements (hereinafter referred to as “exclusive marketing approval”): ...

**Article 50-8 (Exclusive Marketing Approval)** (1) Upon receipt of an application for exclusive marketing approval pursuant to Article 50-7, the Minister of Food and Drug Safety shall grant exclusive marketing approval together with marketing approval or revised approval of a drug, when the applicant meets all of the following requirements: ...

## **2) Operation of a Patent Linkage System**

In Republic of Korea, the Korean Intellectual Property Office is in charge of examining patent applications and granting patents under the Patent Act (Act No. 18505) while the Ministry of Food and Drug Safety is in charge of granting marketing approval of drugs under the Pharmaceutical Affairs Act (Act No. 18307), and in accordance with Chapter V-II of the Pharmaceutical Affairs Act which provides for a patent linkage system, the Ministry of Food and Drug Safety implements measures to prevent patent infringement in the marketing approval process of drugs.

- In other words, in Republic of Korea, the Ministry of Food and Drug Safety is in charge of the overall patent linkage system such as registering and managing drug patents in the “drug patent list”, notifying the patentee of applications for marketing approval of drugs, marketing prevention of notified drugs subject to patent trials, and exclusive marketing approval.
- On the other hand, Republic of Korea's Pharmaceutical Affairs Act mandated the impact assessment of the patent linkage system, and accordingly, the Minister of Food and Drug Safety should analyze and evaluate the impact of marketing prevention and exclusive marketing approval, etc. on the domestic pharmaceutical industry, health policy, and employment, etc.<sup>69</sup>

## **3) Issues in Patent Act related to a Patent Linkage System**

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<sup>69</sup> Republic of Korea's Pharmaceutical Affairs Act (Act No. 18307, revised in 20 July 2021) Article 31(2).

## Extension of the duration of drug patents

As a means of supplementing drug patents that require a long period of time in developing new drugs and in the process of approval, Republic of Korea revised the Patent Act on 31 December 1986 and introduced a system for extending the duration of drug patents for the first time.<sup>70</sup>

- Republic of Korea's Patent Act (Act No. 18505) stipulates that the duration of a patent right can be extended once within a period of 5 years in the case of an invention that takes a long time due to a test of efficacy, safety, etc. necessary for permission or registration, etc.

**Table 4-(5)-4. Republic of Korea's Patent Act (Act No. 18505, revised in 19 October 2021)**

**Article 89 (Extension of Patent Terms by Permission)** (1) Notwithstanding Article 88 (1), the term of a patent on an invention may be extended only once by up to five years to compensate for the period during which the invention cannot be practiced, if the invention is specified by Presidential Decree and requires permission, registration, etc. under any other statute (hereinafter referred to as "permission, etc.") to practice patented invention but it takes a long time to undergo necessary tests for validity, safety, etc. for such permission, registration, etc.

(2) For the purposes of paragraph (1), the period required due to a cause attributable to the person who has obtained permission, etc. shall not be included in "period during which the invention cannot be practiced" in paragraph (1).

- The Enforcement Decree of the Patent Act (Presidential Decree No. 32590) lists inventions subject to extension of the patent duration in Article 7, and specifies "the first marketing-approved drug as a drug manufactured with a new substance as an active ingredient under the Pharmaceutical Affairs Act."<sup>71</sup>

## Practice of a patented invention for the purpose of clinical trials

Republic of Korea recognized testing for marketing approval of drugs as an exception to patent infringement as a judicial precedent, but revised the Patent Act on 27 January 2010 to exclude practice of a patented invention for clinical trials from patent infringement.

- Republic of Korea's Patent Act (Act No. 18505) lists exceptions for infringement not subject to the effect of patent rights in Article 96, and specifies "practice of a patented invention for the purpose of research or testing for obtaining permission for items of medicines, etc. under the Pharmaceutical Affairs Act."<sup>72</sup>

## 4) Structure of a Patent Linkage System

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70 For full text on Republic of Korea's Patent Act, please refer to the following website of Republic of Korea's Ministry of Government Legislation: <https://www.law.go.kr/LSW/eng/engLsSc.do?menuId=2&section=lawNm&query=patent&x=0&y=0> (last visit on 29 May 2022).

71 Republic of Korea's Enforcement Decree of the Patent Act (Presidential Decree No. 32590, revised in 18 April, 2022) Article 7(1).

72 Republic of Korea's Patent Act (Act No. 18505, revised in 19 October 2021), Article 96 (1).

In Republic of Korea, the Pharmaceutical Affairs Act (Act No. 18307)<sup>73</sup> stipulates:

- ① Registration of applicable drug patents,
- ② Notification of application for marketing approval,
- ③ Measures to provide adequate time and opportunity for resolution of patent disputes prior to marketing, and
- ④ Granting generic exclusivity.

### **Registration of applicable drug patents**

Republic of Korea's Pharmaceutical Affairs Act has a drug patent registration system, stipulating that a person who has obtained a marketing approval or a revised marketing approval can apply for a patent right for the drug to be registered in the drug patent list.<sup>74</sup>

- Drug patents subject to registration of drug patents are limited to patents related to substances, formulations, compositions, and pharmaceutical uses.<sup>75</sup>
- A person who has obtained a marketing approval and intends to register a drug patent shall submit an application for registration including a copy of the patent grant to the Ministry of Food and Drug Safety within 30 days from the date of marketing approval or the grant of the patent.<sup>76</sup>

### **Notification to the patentee**

Republic of Korea's Pharmaceutical Affairs Act requires a person who has filed an application for marketing approval of a drug based on the information on safety and efficacy of a listed drug, or who has filed an application for approval of the change of the efficacy and effectiveness to notify the registered patentee and patentee, etc. of a listed drug of the fact that the application for marketing approval has been filed, etc.

- A person who intends to apply for manufacture, sale and import approval of a drug based on data on the safety and efficacy of the registered drug shall submit a confirmation letter of patent relationship. This document classifies the patent relationship between the registered drug and the drug applied for marketing approval into the following 5 categories:
  - ① Where the period of a registered patent expires;
  - ② Where an application for approval or revised approval of a drug is filed to market the drug after the period of a registered patent expires;
  - ③ Where a registered patentee and a patentee, etc. of a listed drug express their consent for the exemption from providing notice;

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73 For full text on Republic of Korea's Pharmaceutical Affairs Act, please refer to the following website of Republic of Korea's Ministry of Government Legislation:  
<https://www.law.go.kr/LSW/eng/engLsSc.do?menuId=2&section=lawNm&query=pharmaceutical+affairs+act&x=33&y=35> (last visit on 29 May 2022).

74 Republic of Korea's Pharmaceutical Affairs Act did not provide specific provisions on the list of drug patents, which is interpreted to include all drugs that have "marketing approval or revised marketing approval" such as new drugs and generic drugs. Shin Hye-eun et al., supra note 1, p.101.

75 Republic of Korea's Pharmaceutical Affairs Act (Act No. 18307, revised in 20 July 2021) Article 50-2(4).

76 Republic of Korea's Pharmaceutical Affairs Act (Act No. 18307, revised in 20 July 2021) Article 50-2(2) and (4).

- ④ Where the registered patent on pharmaceutical use is not related to the efficacy or effectiveness of the drug applied for approval or revised approval; or
- ⑤ Where the registered patent is invalid or deemed not to infringe the patent.

And the obligation to notify pursuant to Article 50-4 of the Pharmaceutical Affairs Act is incurred only in the case of ⑤.<sup>77</sup>

- A person who chooses ⑤ on the confirmation letter of patent relationship shall notify the registered patentee, etc. of the fact that an application for marketing approval has been filed within 20 days from the date of the application for approval or revised approval, and if not notified, the Ministry of Food and Drug Safety shall not grant a marketing approval.<sup>78</sup>

### **Measures to provide adequate time and opportunity for resolution of patent disputes prior to marketing**

Articles 50-5 and 50-6 of Republic of Korea's Pharmaceutical Affairs Act stipulate the qualifications and procedures, etc. of application for prevention of marketing, and the Ministry of Food and Drug Safety shall not grant approval or revised approval to the notified drug except in certain cases during the application period for prevention of marketing, i.e. until 45 days have elapsed from the date the patentee was notified of the application for marketing approval.<sup>79</sup>

- **(Application for prevention of marketing)** A registered patentee, etc. may apply to the Ministry of Food and Drug Safety for prevention of marketing of the notified drug with a statement within 45 days from the date of receiving the notification of the application for marketing approval. The registered patentee, etc. must file the following lawsuit, request a trial, or receive a trial against the notified drug before applying for such prevention of marketing.<sup>80</sup>
  - ① Claim for the prohibition or prevention of patent infringement under Article 126 of the Patent Act;
  - ② Trial for confirming the scope of rights under Article 135 of the Patent Act
- **(Effect of prevention of marketing)** The Ministry of Food and Drug Safety shall prevent marketing of the drug for 9 months from the date when the registered patentee, etc. received the notification unless the drug for which prevention of marketing has been applied for falls under the reason for refusal of the application for prevention of marketing.<sup>81</sup>
- **(Restriction on prevention of marketing)** No additional prevention of marketing can be applied for a drug that has been prevented from marketing once, but additional prevention of marketing can be applied for a drug that has been notified due to an application for approval of a change in its efficacy and effectiveness.<sup>82</sup>

### **Generic exclusivity**

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77 Republic of Korea's Pharmaceutical Affairs Act (Act No. 18307, revised in 20 July 2021) Article 50-4(1).

78 Republic of Korea's Pharmaceutical Affairs Act (Act No. 18307, revised in 20 July 2021) Article 50-4(4) and (6).

79 Republic of Korea's Pharmaceutical Affairs Act (Act No. 18307, revised in 20 July 2021) Article 50-5(4).

80 Republic of Korea's Pharmaceutical Affairs Act (Act No. 18307, revised in 20 July 2021) Article 50-5(1) and (2).

81 Republic of Korea's Pharmaceutical Affairs Act (Act No. 18307, revised in 20 July 2021) Article 50-6(1).

82 Republic of Korea's Pharmaceutical Affairs Act (Act No. 18307, revised in 20 July 2021) Article 50-5(3).

Republic of Korea's Pharmaceutical Affairs Act provides for a generic exclusivity system that allows a generic drug that succeeded in challenging the patent of the registered drugs to be sold exclusively through exclusive marketing approval procedures, etc. as prescribed in Articles 50-7 to 50-10.

- **(Application for exclusive marketing approval)** A person who is obligated to notify pursuant to Article 50-4 of the Pharmaceutical Affairs Act may apply for exclusive marketing approval to sell the drug in preference to the same drug for a prescribed period of time when applying for marketing approval, etc.<sup>83</sup>
- **(Requirements for exclusive marketing approval)** A person who intends to obtain exclusive marketing approval must first request one of the following trials before applying for marketing approval or revised approval, and receive a judgment or ruling that the patent of the registered drug is invalid, the registration of extension of duration is invalid, or the drug does not fall within the scope of patent rights.<sup>84</sup>
  - ① Trial of invalidation of a patent under Article 133 of the Patent Act
  - ② Trial of invalidation of registration of extension of duration of a patent under Article 134 of the Patent Act
  - ③ Trial of confirming the scope of rights under Article 135 of the Patent Act
- **(Effect of exclusive marketing approval)** When the Ministry of Food and Drug Safety approves marketing, etc. for a drug which is the same as the one that has been approved for exclusive marketing and has the same active ingredient as the registered drug, it may prevent the marketing of the drug for 9 months from the date a person who has obtained exclusive marketing approval of his/her drug may distribute his/her drug.<sup>85</sup>

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83 Republic of Korea's Pharmaceutical Affairs Act (Act No. 18307, revised in 20 July 2021) Article 50-7(1).

84 Republic of Korea's Pharmaceutical Affairs Act (Act No. 18307, revised in 20 July 2021) Article 50-8(1).

85 Republic of Korea's Pharmaceutical Affairs Act (Act No. 18307, revised in 20 July 2021) Article 50-9(1) and (2).

## **(6) Malaysia**

### **1) Introduction and Development of a Patent Linkage System**

As a result of examining related domestic laws and previous studies, it was found that Malaysia has not yet introduced a patent linkage system.<sup>86</sup>

- In Malaysia, the Pharmaceutical Sales Act and the Control of Drugs and Cosmetics Regulation that regulate marketing approval of drugs have not introduced a patent linkage system because they do not provide any provisions regarding the role of the competent authority in preventing patent infringement in the marketing approval procedure of drugs.<sup>87</sup>
- Malaysia signed the CPTPP Agreement in March 2018, which already entered into force in December 2018, so Malaysia needs to make a domestic legislation to introduce a patent linkage system in order to ratify the Agreement and become a party.
- However, Malaysia has negotiated and signed side letters with other signatories and parties to join CPTPP, but it is still unclear whether it will join the Agreement.<sup>88</sup> As a result, the prospect for the introduction of a patent linkage system is also uncertain.

### **2) Operation of a Patent Linkage System**

In Malaysia, the Intellectual Property Corporation (MyIPO) is responsible for examining patent applications and granting patents under the Patent Act, and the Drug Control Authority (DCA)<sup>89</sup> is responsible for administering and supervising marketing approval of drugs under the Control of Drugs and Cosmetics Regulation, and the Pharmaceutical Regulatory Agency (NPRA) under the Ministry of Health is in charge of practical affairs concerning marketing approval of drugs and quality inspection, etc.

- In other words, the DCA oversees the registration, quality control/inspection, and side effect monitoring of medicines in Malaysia, and all medicines must be registered with the DCA in accordance with the DCA regulations before being sold in Malaysia.
- Therefore, if Malaysia introduces a patent linkage system, the DCA is expected to oversee its operation, and the NPRA is expected to be in charge of practical affairs such as managing patent lists, notifying patentees, and reserving marketing approval.

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86 Raju, K.D., "Patent Linkage and Its Impact on Access to Medicines: Challenges, Opportunities for Developing Countries", Correa, C.M. & Hilty, R.M.(eds), Access to Medicines and Vaccines, Springer, Cham (2021), p.349. Chew Kherk Ying & Raymond Tan, "Patent Linkage: Malaysia", Baker McKenzie, Global Guide to Patent Linkage (2019), p.98. Kyung-Bok Son et al., supra note 16, pp.5-6. Deborah Gleeson et al., supra note 16, pp.18-19.

87 For full text on Malaysia's Control of Drugs and Cosmetics Regulation, please refer to the following website of Attorney General's Chambers of Malaysia: <https://lom.agc.gov.my/subsid.php?type=pua> (last visit on 16 May 2022).

88 For more information on the prospect for ratification of CPTPP by Malaysia, please refer to the following website of Ministry of International Trade and Industry of Malaysia: [https://fta.miti.gov.my/index.php/pages/view/tpp\\_cptpp?mid=40](https://fta.miti.gov.my/index.php/pages/view/tpp_cptpp?mid=40) (last visit on 16 May 2022).

89 Malaysia's Drug Control Authority (DCA) is a committee established under the Control of Drugs and Cosmetics Regulation 1984 to ensure the safety and effectiveness of medicines, chaired by the Minister of Health and served as a secretariat by the Pharmaceutical Regulatory Agency (NPRA). For information on the composition and responsibilities of the DCA, please refer to the following website of the NPRA: [npa.gov.my](http://npa.gov.my) (last visit on 16 May 2022).

### 3) Issues in Patent Act related to a Patent Linkage System

#### Extension of the duration of drug patents

Article 35 of the Patent Act of Malaysia stipulates the duration of the patent right to 20 years,<sup>90</sup> but there is no provision for the extension of the right of a drug patent that requires a long period of time during marketing approval procedure.

- In this regard, Article 18.48 of the CPTPP Agreement stipulates the adjustment of the duration of the drug patent and obliges the parties to adjust the duration of the drug patent to compensate for the reduction of the patent period due to marketing approval.
- Therefore, Malaysia needs to consider a domestic legislation to ratify the CPTPP Agreement to extend the duration of the drug patent, but there is no immediate need to accept an extension of the duration of the drug patent as Article 18.48 has been suspended in Annex to the Agreement.<sup>91</sup>

**Table 4-(6)-1. Provisions related to extending the duration of the drug patent under the Comprehensive and Progressive Trans-Pacific Partnership (CPTPP)**

#### **Article 18.48: Patent Term Adjustment for Unreasonable Curtailment**

1. Each Party shall make best efforts to process applications for marketing approval of pharmaceutical products in an efficient and timely manner, with a view to avoiding unreasonable or unnecessary delays.
2. With respect to a pharmaceutical product that is subject to a patent, each Party shall make available an adjustment of the patent term to compensate the patent owner for unreasonable curtailment of the effective patent term as a result of the marketing approval process.
3. For greater certainty, in implementing the obligations of this Article, each Party may provide for conditions and limitations, provided that the Party continues to give effect to this Article.
4. With the objective of avoiding unreasonable curtailment of the effective patent term, a Party may adopt or maintain procedures that expedite the processing of marketing approval applications.

#### **Practice of a patented invention for the purpose of drug information submission**

Malaysia's Patent Law stipulates restrictions on patent rights (Article 37) and non-infringement acts (Article 58) and specifies the practice of a patented invention in connection with the submission of information to drug authority as an exception not subject to the effect of the patent.<sup>92</sup>

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90 For full text on Malaysia Patents Act, please refer to the following website of Intellectual Property Corporation of Malaysia (MyIPO): <https://www.myipo.gov.my/en/patent-act-1983/> (last visit on 16 May 2022).

91 The Comprehensive and Progressive Trans-Pacific Partnership (CPTPP) suspended some of the provisions of the TPP Agreement on strengthening intellectual property protection, including patent period adjustment due to unreasonable delay in examination (Article 18.46), patent period adjustment due to unreasonable shortening (Article 18.48), and protection of undisclosed clinical or other data (Article 18.50). These suspended provisions are listed in Annex II pursuant to Article 2 of this Agreement, and such suspension may be terminated by agreement between the parties.

92 Malaysia Patent Act (revised on 4 March, 2022, promulgated on 16 March, 2022) Article 37(1A).

- In particular, Malaysia’s Patent Law does not restrict the practice of patented inventions not subject to the effect of the patent in relation to the submission of drug information to “research and test for marketing approval”, but comprehensively stipulates “manufacture, use, provision and sale of patented inventions.”

**Table 4-(6)-2. Malaysia’s Patent Act (revised on 4 March 2022, promulgated on 16 March 2022)**

**Section 37. Limitation of rights**

- (1) The rights under the patent shall extend only to acts done for industrial or commercial purposes and shall not extend to acts done for experimental or scientific research purpose.
- (1A) The rights under the patent shall not extend to acts done to make, use, offer to sell or sell a patented invention solely for uses reasonably related to the development and submission of information to the relevant authority either in Malaysia or outside Malaysia which regulates the manufacture, use or sale of pharmaceutical products.
- (2) Without prejudice to section 58A, the rights under the patent shall not extend to acts in respect of products which have been put on the market –
- (i) by the owner of the patent;
  - (ii) by a person having the right referred to in section 38;
  - (iii) by a person having the right referred to in section 43;
  - (iv) by the beneficiary of a compulsory licence within the meaning of section 48. ...

**Section 58A. Acts deemed to be non-infringement**

- (1) It shall not be an act of infringement to import, offer for sale, sell or use -
- (a) any patented product; or
  - (b) any product obtained directly by means of the patented process or to which the patented process has been applied,
- which is produced by, or with the consent, conditional or otherwise, of the owner of the patent or his licensee.
- (2) For the purposes of this section, “patent” includes a patent granted in any economy outside Malaysia in respect of the same or essentially the same invention as that for which a patent is granted under this Act.

## **(7) New Zealand**

### **1) Introduction and Development of a Patent Linkage System**

The Comprehensive and Progressive Agreement for Trans-Pacific Partnership took effect on 30 December 2018. As a member of CPTPP, it is necessary that New Zealand implement the CPTPP provisions which stipulate a patent linkage system.

- The Ministry of Foreign Affairs and Trade of New Zealand had noted that CPTPP contains two requirements in relation to a patent linkage system as follows:<sup>93</sup>
  - ① Enabling pharmaceutical patent holders to be notified that a generic version of their product has been submitted to the New Zealand Medicines and Medical Devices Safety Authority (MEDSAFE) for approval to enter the New Zealand market; and
  - ② Ensuring that there is sufficient time and opportunity for a patent owner to seek preliminary injunctions to resolve patent disputes before a generic version of its patented medicine enters the market.
- According to the Ministry of Foreign Affairs and Trade of New Zealand, New Zealand's current law and practice already satisfies these requirements through the information the MEDSAFE publishes on its website, such as the availability of injunctive relief and the time it takes the MEDSAFE to process applications.<sup>94</sup>
- In relation to the paragraph ① in CPTPP, it does not strictly require that express notification be provided to the patent holder, but rather that the patent holder is made known of the submission for marketing authorization of a generic version of its product. Hence, the publication by the MEDSAFE of information on its website might be considered to satisfy in part the patent linkage obligations under CPTPP.<sup>95</sup>

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93 For information on the New Zealand's CPTPP, please refer to the following website of the Ministry of Foreign Affairs and Trade of New Zealand: <https://www.mfat.govt.nz/en/trade/free-trade-agreements/free-trade-agreements-in-force/cptpp/understanding-cptpp/intellectual-property/> (last visit on 18 August, 2022).

94 For information on the New Zealand's CPTPP, please refer to the following website of the Ministry of Foreign Affairs and Trade of New Zealand: <https://www.mfat.govt.nz/en/trade/free-trade-agreements/free-trade-agreements-in-force/cptpp/understanding-cptpp/intellectual-property/> (last visit on 18 August, 2022).

95 Bridgette Kathleen McLellan, "An Analysis of TRIPS-Plus Protections relating to Pharmaceuticals and Geographical Indications in CETA and the CPTPP Implications for a European Union – New Zealand Free Trade Agreement", University of Canterbury, Degree of Master of Laws, 2019, pp.52-53.

**Table 4-(7)-1. Provisions related to a patent linkage system under the Comprehensive and Progressive Trans-Pacific Partnership (CPTPP)**

**Article 18.53: Measures Relating to the Marketing of Certain Pharmaceutical Products**

1. If a Party permits, as a condition of approving the marketing of a pharmaceutical product, persons, other than the person originally submitting the safety and efficacy information, to rely on evidence or information concerning the safety and efficacy of a product that was previously approved, such as evidence of prior marketing approval by the Party or in another territory, that Party shall provide:
  - (a) a system to provide notice to a patent holder or to allow for a patent holder to be notified prior to the marketing of such a pharmaceutical product, that such other person is seeking to market that product during the term of an applicable patent claiming the approved product or its approved method of use;
  - (b) adequate time and opportunity for such a patent holder to seek, prior to the marketing of an allegedly infringing product, available remedies in subparagraph (c); and
  - (c) procedures, such as judicial or administrative proceedings, and expeditious remedies, such as preliminary injunctions or equivalent effective provisional measures, for the timely resolution of disputes concerning the validity or infringement of an applicable patent claiming an approved pharmaceutical product or its approved method of use.
2. As an alternative to paragraph 1, a Party shall instead adopt or maintain a system other than judicial proceedings that precludes, based upon patent-related information submitted to the marketing approval authority by a patent holder or the applicant for marketing approval, or based on direct coordination between the marketing approval authority and the patent office, the issuance of marketing approval to any third person seeking to market a pharmaceutical product subject to a patent claiming that product, unless by consent or acquiescence of the patent holder.

## **2) Operation of a Patent Linkage System**

The Intellectual Property Office of New Zealand is in charge of overall affairs concerning intellectual property rights such as examining applications for patents, trademarks, designs, plant variety rights and geographical indications in New Zealand, and implementing international agreements.<sup>96</sup> New Zealand Medicines and Medical Devices Safety Authority (MEDSAFE) is responsible for drug regulation, and seems to be responsible for patent linkage system even if there is no explicit provision.

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<sup>96</sup> For more information on the New Zealand Intellectual Property Office, please refer to the following website of the New Zealand Intellectual Property Office: <https://www.iponz.govt.nz/about-iponz/> (last visit on 1 August 2022).

- The MEDSAFE is an agency under the Ministry of Health (MoH) and is responsible for administering the Medicines Act 1981 and the Medicines Regulations 1984 which regulate medicines, related products, medical devices, and controlled drugs used as medicines for therapeutic purposes.<sup>97</sup>
- The primary areas that the Investigation and Enforcement Team (IET) under the MEDSAFE investigate include: the import, export, manufacture, advertising, and supply of therapeutic products.<sup>98</sup>

### 3) Issues in Patent Act related to a Patent Linkage System

#### Extension of the duration of drug patents

The New Zealand Patent Act does not have a system to extend the duration of a drug patent to compensate for the period during which the patent right could not be practically exercised due to validity and safety tests, etc. for drug licensing.

Although the Trans-Pacific Partnership Agreement Amendment Act 2016 contains content on the revision of the Patent Act,<sup>99</sup> in particular, specifying a provision related to the extension of the duration of drug patents, the relevant parts of the Trans-Pacific Partnership Agreement Amendment Act 2016 have not been brought into force.

- For your reference, Article 111D(1)(a) in the Trans-Pacific Partnership Agreement Amendment Act 2016 stipulates that if one or more drugs or biologics are disclosed in a complete specification related to a patent and one or more drugs or biologics are included in the full scope of the claims or in the claims of the specification, a request for extension of the duration of a patent may be made.<sup>100</sup>
- In addition, if an application for approval to market a product containing or composed of substances or biologics mentioned in Article 111D(1)(a) is made or permission is granted, a request for extension of the duration of a patent may be made.<sup>101</sup>
- It is unclear whether it has been implemented or not, but there were legislative activities for the introduction of the drug patent extension system.

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<sup>97</sup> For more information on the New Zealand's Medicines and Medical Devices Safety Authority, please refer to the following website of the New Zealand's MEDSAFE website: <https://www.medsafe.govt.nz/other/about.asp> (last visit on 1 August 2022).

<sup>98</sup> For more information on the New Zealand's Medicines and Medical Devices Safety Authority, please refer to the following website of the New Zealand's MEDSAFE website: <https://www.medsafe.govt.nz/other/aboutmiet.asp> (last visit on 3 August 2022).

<sup>99</sup> New Zealand's Trans-Pacific Partnership Agreement Amendment Act 2016 (assented on 21 November 2016) Article 111D.

<sup>100</sup> New Zealand's Trans-Pacific Partnership Agreement Amendment Act 2016 (assented on 21 November 2016) Article 111D (1) (a).

<sup>101</sup> New Zealand's Trans-Pacific Partnership Agreement Amendment Act 2016 (assented on 21 November 2016) Article 111D (1) (b).

**Table 4-(7)-2. New Zealand's Trans-Pacific Partnership Agreement Amendment Act 2016 (assented on 21 November 2016)**

**111D. Requests for extension of patent if unreasonable curtailment of effective patent term as result of marketing approval process**

- (1) A patentee may, in the prescribed manner, request an extension of the term of the patent if—
- (a) 1 or more pharmaceutical substances per se or biologics were disclosed in the complete specification relating to the patent and were wholly within the scope of the claim or claims of that specification; and
  - (b) the patentee made a marketing approval application to distribute a product containing or consisting of a substance or biologic that is one of those referred to in paragraph (a) and marketing approval of that product has been granted; and
  - (c) that marketing approval is the first marketing approval for a product that contains or consists of any of the substances or biologics referred to in paragraph (a); and
  - (d) the term of the patent has not been previously extended under section 111E.
- (2) The request may be made only—
- (a) during the term of the patent; and
  - (b) within the prescribed time limit; and
  - (c) if a certificate from the Regulator for the purpose of section 111F (2) is filed within the prescribed time limit.

**Practice of a patented invention for the purpose of clinical trials**

The New Zealand Patent Act lists matters that do not constitute patent infringement and states that experimental use is included in matters that do not constitute infringement.<sup>102</sup> However, it does not clearly mention the practice of a patented invention for research or testing for drug item permission and declaration, etc. with respect to the scope within which the effect of a patent right is excluded.

- Article 143(1) of the New Zealand Patent Act states that the practice of related inventions for experimental purposes does not constitute patent infringement.<sup>103</sup> In addition, paragraph 2 of the same article lists acts conducted for experimental purposes.<sup>104</sup>
- However, it is not clear whether the "practice of patented inventions for research and testing" includes clinical trials for drug licensing, etc. as it does not directly specify the "practice of patented inventions to conduct research and testing for drug licensing, etc." like in Korea.

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<sup>102</sup> For the full text on the New Zealand's Patent Act, please refer to the following website of Parliamentary Counsel Office of New Zealand: <https://www.legislation.govt.nz/act/public/2013/0068/latest/DLM1419043.html> (last visit on 1 August 2022).

<sup>103</sup> New Zealand's Patents Act 2013 (version as at 28 October 2021) Article 143(1).

<sup>104</sup> New Zealand's Patents Act 2013 (version as at 28 October 2021) Article 143(2).

**Table 4-(7)-3. New Zealand’s Patent Act 2013 (version as of 28 October 2021)**

**143. No infringement for experimental use**

- (1) It is not an infringement of a patent for a person to do an act for experimental purposes relating to the subject matter of an invention.
- (2) In this section, act for experimental purposes relating to the subject matter of an invention includes an act for the purpose of—
- (a) determining how the invention works:
  - (b) determining the scope of the invention:
  - (c) determining the validity of the claims:
  - (d) seeking an improvement of the invention (for example, determining new properties, or new uses, of the invention).

**4) Structure of a Patent Linkage System**

In the New Zealand, the Medicines Act 1981 stipulates:

- ① Notification of application for marketing approval, and
- ② Measures to provide adequate time and opportunity for resolution of patent disputes prior to marketing.

In the New Zealand, the Therapeutic Goods Act 1989 does not stipulate:

- ③ Registration of applicable drug patents, and
- ④ Granting generic exclusivity.

**Registration of applicable drug patents**

Although the list of drugs<sup>105</sup> is disclosed in Gazette in New Zealand, there is no procedure under a patent linkage system for submitting patent information related to the licensed drug to the competent authority for review to be included and managed in the list of drug patents.

**Notification to the patentee**

As to the obligation of notification by a person who has filed an application for marketing approval of a drug to the patentee of a patented drug, New Zealand has no express provisions in the Medicines Act 1981.

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<sup>105</sup> Under Article 20 of the Medicines Act 1981 of New Zealand, the Minister of Health lists a list of drugs referred to the Minister of Health under Article 24(5) of the Act and approved for distribution in New Zealand as specified in the Schedule to the Act in Gazette, please refer to the following website of New Zealand's Gazette: <https://gazette.govt.nz/> (last visit on 4 August 2022).

- However, the Ministry of Foreign Affairs and Trade of New Zealand, as mentioned above, had noted:

“CPTPP requires New Zealand to maintain a system that:

- enables pharmaceutical patent holders to be notified that a generic version of their product has been submitted to Medsafe for approval to enter the New Zealand market, and
- ensures there is sufficient time and opportunity for a patent owner to seek preliminary injunctions to resolve patent disputes before a generic version of its patented medicine enters the market.

New Zealand’s current law and practice already satisfies these requirements through the information Medsafe publishes on its website, the availability of injunctive relief and the time it takes Medsafe to process applications.”

### **Measures to provide adequate time and opportunity for resolution of patent disputes prior to marketing**

In general, under a patent linkage system, measures to provide adequate time and opportunity for resolution of patent disputes prior to marketing of generic drugs is based on the result of notification of the application for permission of the drug item. However, the New Zealand Medicines Act does not specify that those measures are based on the result of notification of the application for permission of the drug item, but only specifies that the Minister may prohibit the import, sale, and manufacture, etc.<sup>106</sup>

- According to Article 37(1) of the Medicines Act 1981, the Minister may prohibit import, manufacture, packing, sale, possession, supply, administration, or any other use of drugs or medical devices of a particular type for a period as long as the Minister deems appropriate to the extent not exceeding 1 year.

**Table 4-(7)-4. New Zealand’s Medicines Act 1981 (version as of 1 July 2022)**

#### **37. Powers of Minister to prohibit import, etc. of medicines**

(1) The Minister may from time to time, by notice, prohibit the import, manufacture, packing, sale, possession, supply, administration, or other use of medicines of any specified description or medical devices of any specified kind, either absolutely or subject to such conditions as he thinks fit, for any specified period not exceeding 1 year; but he shall not exercise this power more than once in respect of medicines or medical devices so specified.

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106 New Zealand’s Medicines Act 1981 (version as at 1 July, 2022) Article 37(1).

## **(8) Papua New Guinea**

### **1) Introduction and Development of a Patent Linkage System**

As a result of examining related domestic laws<sup>107</sup> and the accession status of related agreements, Papua New Guinea has not yet introduced a patent linkage system.

- Medicines and Cosmetics Act(1999) and Medicines and Cosmetics Regulation(2002) which regulate the import, manufacture, and sale of drugs in Papua New Guinea have no provisions on the role of the competent authority in preventing patent infringement in the drug licensing procedure, so Papua New Guinea has not introduced a patent linkage system.<sup>108</sup>
- Papua New Guinea is not a member of the TPP or CPTPP agreements, which might serve as a motivation to introduce a patent linkage system. In addition, there is no related bilateral or multilateral FTAs negotiated or concluded.
- And also, there have been no legislative activities for the introduction of a patent linkage system either.

### **2) Operation of a Patent Linkage System**

The Intellectual Property Office of Papua New Guinea (IPOPNG) is responsible for the registration and maintenance of patents, trademarks, and industrial designs.<sup>109</sup> The Department of Health (NDOH) requires registration procedures under the Medicines and Cosmetics Act (1999) and Medicines and Cosmetics Regulation (2002) for all medicines in Papua New Guinea to ensure the quality, safety and effectiveness of medicines.<sup>110</sup> It seems that there is currently no authority in charge of the patent linkage system,

- The Pharmaceutical Services Standards Branch under the NDOH is responsible for the administration and implement of the Medicines and Cosmetics Act (1999). It consists of Product Registration Unit, Compliance Licensing & Inspecting Unit, and Pharmaceutical Care Unit.<sup>111</sup>
- If Papua New Guinea introduces a patent linkage system, it is expected that the NDOH will oversee its operation and will be responsible for practical affairs such as managing the patent list.

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107 Papua New Guinea's Patents and Industrial Designs Act (2000), Patents and Industrial Designs Regulation (2002), Medicines and Cosmetics Regulation (2002), Medicines and Cosmetics Act (1999).

108 The Medicines and Cosmetics Act of Papua New Guinea was enacted in 1999 and recently revised in 2016. For more information on the revised The Medicines and Cosmetics Act, please refer to the following website of Papua New Guinea's Parliament: <https://parliament.gov.pg/index.php/bills-and-legislation/view/medicine-and-cosmetics-amendment-act-20161> (last visit on 1 August, 2022).

109 For more information on the Papua New Guinea's Intellectual Property Office, please refer to the following website of the IPONG: <http://ipopng.gov.pg/about-ipopng/> (last visit on 29 July, 2022).

110 The APEC Harmonization center, "Drug Approval System of Papua New Guinea", 2018, p.6.

111 For more information on the Papua New Guinea's Ministry of Health, please refer to the following website of the Papua New Guinea's Ministry of Health: <https://www.health.gov.pg/subindex.php?pharm=1> (last visit on 1 August 2022).

### 3) Issues in Patent Act related to a Patent Linkage System

#### Extension of the duration of drug patents

Papua New Guinea does not have a system to extend the duration of a drug patent to compensate for the period during which the patent right could not be practically exercised due to validity and safety tests, etc. for drug licensing. In addition, there is a provision on the duration of patents under the Patent and Industrial Design Act,<sup>112</sup> but there is no provision on the extension of the duration.

- Article 31(1) of the Patent and Industrial Design Act stipulates the duration of patents. According to the article, patent rights expire 20 years after the filing date.<sup>113</sup>

**Table 4-(8)-1. Papua New Guinea’s Patents and Industrial Designs Act (2000) (Certified on 19 January 2001)**

#### Article 31 Duration of patent and annual fees

(1) Subject to this section, a patent shall expire 20 years after the filing date of the application for the patent.

#### Practice of a patented invention for the purpose of clinical trials

The Papua New Guinea Patent and Industrial Design Act provides for the practice of patents for experimental purposes as an example in the provision on exceptions to the scope of patent rights, but there is no explicit provision for the practice of a patented invention for clinical trials, etc. as an exception to patent infringement in the drug licensing procedure.

- The Papua New Guinea Patent and Industrial Design Act stipulates that the patent right does not reach the practice of a patented invention for experimental purposes only, along with exhaustion of rights, ships and aircrafts temporarily passing the territory, in Article 29(4) that lists exceptions to the scope of patent rights.<sup>114</sup>
- However, it is not clear whether the ‘practice of patented inventions for research and testing’ includes clinical trials for drug licensing, etc. as it does not directly specify the ‘practice of patented inventions to conduct research and testing for drug licensing, etc.’ like in Korea.

**Table 4-(8)-2. Papua New Guinea’s Patents and Industrial Designs Act (2000) (Certified on 19 January 2001)**

#### Article 29 Rights conferred by a patent

(4) The rights of an owner of a patent shall not extend to –

- (a) acts in respect of articles which have been put on the market in Papua New Guinea by the owner of the patent or with his consent; or
- (b) the use of articles on, or in the construction or operation of, aircraft, land, vehicles or vessels of other

<sup>112</sup> For full text on the Papua New Guinea’s Patents and Industrial Designs Act (2000), please refer to the following website of the Pacific Islands Legal Information Institute: [http://www.pacii.org/pg/legis/consol\\_act/paida2000312/](http://www.pacii.org/pg/legis/consol_act/paida2000312/) (last visit on 1 August 2022).

<sup>113</sup> Papua New Guinea’s Patents and Industrial Designs Act (2000) (Certified on 19 January 2001) Article 31(1).

<sup>114</sup> Papua New Guinea’s Patents and Industrial Designs Act (2000) (Certified on 19 January 2001) Article 29(4).

countries which temporarily or accidentally enter the air space, territory or waters of Papua New Guinea;  
or  
(c) acts done only for experimental purposes relating to a patented invention; or ...

#### 4) Structure of a Patent Linkage System

In Papua New Guinea, the Medicines and Cosmetics (1999) does not stipulate:

- ① Notification of application for marketing approval.
- ② Registration of applicable drug patents,
- ③ Measures to provide adequate time and opportunity for resolution of patent disputes prior to marketing, and
- ④ Granting generic exclusivity, among the components that generally constitute the patent linkage system.

#### Registration of applicable drug patents

Papua New Guinea's Medicines and Cosmetics Act (1999) does not stipulate the registration of drug patents, but the provisions on the role of the Pharmacy Board confirm that a list of drugs exists.

- The Pharmacy Board may request the Minister of the relevant department to add and delete the list of drugs.<sup>115</sup>

**Table 4-(8)-3. Papua New Guinea's Medicines and Cosmetics Act (1999) (Certified on 2000)**

#### Article 22 Functions of the pharmacy board

The functions of the Pharmacy Board are—

- (a) to determine the standards of knowledge and skill to be attained by a person seeking to become a pharmacist or pharmacy technician and to review those standards from time to time; and
- (b) to provide for formal registration of pharmacists and pharmacy technicians; and
- (c) to establish and maintain a register to be known as the Register of Pharmacies and to enter in that register the names of pharmacies registered under this Act; and
- (d) to establish and maintain a register to be known as the Register of Pharmacists and Pharmacy Technicians and enter in that register the names of pharmacists and pharmacy technicians registered under this Act; and
- (e) to publish from time to time a list of all those persons whose names are entered in the Register of pharmacists and Pharmacy Technicians; and
- (f) to recommend to the Minister addition and deletion of items in the medicinal products list; and ...

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115 Papua New Guinea's Medicines and Cosmetics Act (1999) (Certified on 2000) Article 22.

## (9) Singapore

### 1) Introduction and Development of a Patent Linkage System

Singapore introduced a patent linkage system for the first time under the FTA between Singapore and the United States, which took effect on 1 January 2004.<sup>116</sup>

- In Article 16.8(4)(c), the Agreement stipulates a patent linkage system by specifying that the parties shall not grant marketing approval to any third party without the consent of the patent owner during the duration of the patent term.
- In addition, the Agreement has a notification system in Article 16.8(4)(b), which stipulates that the patent owner shall be notified of the identity of any third party requesting marketing approval during the term of the patent.

**Table 4-(9)-1. Provisions related to a patent linkage system under the FTA between Singapore and the United States (USSFTA)**

#### **ARTICLE 16.8 : CERTAIN REGULATED PRODUCTS**

1. If a Party requires the submission of information concerning the safety and efficacy of a pharmaceutical or agricultural chemical product prior to permitting the marketing of such product, the Party shall not permit third parties not having the consent of the party providing the information to market the same or a similar product on the basis of the approval granted to the party submitting such information for a period of at least five years from the date of approval for a pharmaceutical product and ten years from the date of approval for an agricultural chemical product.
2. If a Party provides a means of granting approval to market a product specified in paragraph 1 on the basis of the grant of an approval for marketing of the same or similar product in another economy, the Party shall defer the date of any such approval to third parties not having the consent of the party providing the information in the other economy for at least five years from the date of approval for a pharmaceutical product and ten years from the date of approval for an agricultural chemical product in the territory of the Party or in the other economy, whichever is later.
3. Where a product is subject to a system of marketing approval pursuant to paragraph 1 or 2 and is also subject to a patent in the territory of that Party, the Party shall not alter the term of protection that it provides pursuant to paragraph 1 or 2 in the event that the patent protection terminates on a date earlier than the end of the term of such protection.
4. With respect to any pharmaceutical product that is subject to a patent:
  - (a) each Party shall make available an extension of the patent term to compensate the patent owner for unreasonable curtailment of the patent term as a result of the marketing approval process;
  - (b) the Party shall provide that the patent owner shall be notified of the identity of any third party

<sup>116</sup> Raju, K.D., supra note 88, p.347.

requesting marketing approval effective during the term of the patent; and

(c) the Party shall not grant marketing approval to any third party prior to the expiration of the patent term, unless by consent or with the acquiescence of the patent owner.

Accordingly, Singapore revised the Medicines Act 1975 in June 2004 as an implementation legislation of the patent linkage system, and newly established provisions regarding clarification of patent relationship upon application for drug license (Article 12A (1) and (2)), notification of application for drug license (Article 12A (3)), and prohibition of granting license to similar medicines relying on previously licensed medicines (Article 19D).<sup>117</sup>

- The revised Medicines Act of December 2021 retains Article 12A of the Medicines Act of 2004, which requires the competent authority to decide whether to grant a drug license application in consideration of patent infringement.<sup>118</sup> To this end, the license applicant shall report the existence of a patent related to the medicine applied for and its relationship with the patent.<sup>119</sup>
- In addition, if the applicant claims invalidation or non-infringement of the patent when reporting the relationship with the patent, the patentee shall be notified of the application for a drug license in accordance with the order of the competent authority.<sup>120</sup>

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117 For full text on Singapore's Medicines Act, please refer to the following website of the Legislation Division of the Attorney-General's Chambers of Singapore: <https://sso.agc.gov.sg/Acts-Supp/26-2004/Published/20040630?DocDate=20040630> (last visit on 13 May 2022).

118 Singapore's Medicines Act (revised on 1 December 2021, enforced on 31 December 2021) Article 12A(1).

119 Singapore's Medicines Act (revised on 1 December 2021, enforced on 31 December 2021) Article 12A(2).

120 Singapore's Medicines Act (revised on 1 December 2021, enforced on 31 December 2021) Article 12A(3).

**Table 4-(9)-2. Singapore’s Medicines Act (revised on 1 December 2021, enforced on 31 December 2021)**

**Whether medicinal product subject to patent**

**12A.**—(1) Subject to the provisions of this Part, in dealing with an application for a product licence, the licensing authority must consider whether a patent under the Patents Act 1994 is in force in respect of any medicinal product to which the application relates and, if so —

- (a) whether the applicant is the proprietor of the patent; or
- (b) if the applicant is not the proprietor of the patent, whether —
  - (i) the proprietor has given consent to or has acquiesced in the grant of the licence to the applicant; or
  - (ii) the patent is invalid or will not be infringed by the doing of the act for which the licence is sought.

(2) Unless the licensing authority otherwise determines, an applicant for a product licence must, at the time of the applicant’s application and at such other time as the licensing authority may require, make and furnish to the licensing authority a declaration in the prescribed form —

- (a) stating whether a patent under the Patents Act 1994 is in force in respect of any medicinal product to which the application relates;
- (b) if the applicant states that there is such a patent, stating whether the applicant is the proprietor of the patent; and
- (c) if the applicant states that the applicant is not the proprietor of the patent, stating —
  - (i) the name and other particulars of the proprietor of the patent;
  - (ii) whether —
    - (A) the proprietor has consented to or has acquiesced in the grant of the licence to the applicant; or
    - (B) in the applicant’s opinion and to the best of the applicant’s belief, the patent is invalid or will not be infringed by the doing of the act for which the licence is sought; and
  - (iii) any other information that may be prescribed.

(3) The licensing authority may, if the applicant has declared that in the applicant’s opinion and to the best of the applicant’s belief the patent is invalid or will not be infringed by the doing of the act for which the licence is sought, or if the licensing authority considers it appropriate in any particular case, require the applicant to do the following within such time as the licensing authority may determine:

- (a) serve on the proprietor of the patent a notice in the prescribed form of the applicant’s application;
- (b) furnish to the licensing authority such evidence of the service as the licensing authority may require.

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Later, Singapore enacted the Health Products Act 2007 to regulate medical devices, treatment products, and Western medicines that are not subject to regulation under the Medicines Act, which did not have a patent linkage clause. But in November 2016, it stipulated the patent linkage system by enacting the Health Products (Treatment Products) Regulation,<sup>121</sup> which is a subordinate statute.

- Articles 23 through 25 of the Health Products (Treatment Products) Regulation enforced in the January 2022 stipulate the patent linkage system. Article 23 of the Regulation consists of almost the same structure as Article 12A of the Medicines Act regarding clarification of the patent relationship and notification to the patentee, etc.
- In other words, according to this Regulation, the competent authority must consider whether an application for registration of treatment products infringes patents.<sup>122</sup> To this end, the applicant for registration of treatment products must report the existence of a patent related to the treatment product and the relationship with the patent,<sup>123</sup> and notify the patentee if the applicant claims invalidation or non-infringement of the patent upon reporting the patent relationship.<sup>124</sup>

**Table 4-(9)-3. Singapore’s Health Products (Treatment Products) Regulation (enforced on 3 January 2022)**

**Whether therapeutic product subject to patent**

**23.**—(1) In dealing with an application for the registration of a therapeutic product, the Authority must consider whether a patent under the Patents Act (Cap. 221) is in force in respect of the therapeutic product and, if so —

- (a) whether the applicant for the registration of the therapeutic product is the proprietor of the patent; or
- (b) if the applicant is not the proprietor of the patent, whether —
  - (i) the proprietor has consented to or has acquiesced in the grant of the registration of the therapeutic product to the applicant; or
  - (ii) the patent is invalid or will not be infringed by the doing of the act for which the registration of the therapeutic product is sought.

(2) Unless the Authority otherwise determines, the applicant must, at the time of the application and at such other time before the determination of the application as the Authority may require, make and furnish to the Authority a declaration in the form specified on the Authority’s website, stating —

- (a) whether a patent under the Patents Act is in force in respect of the therapeutic product; and
- (b) whether the applicant is the proprietor of the patent.

(3) If the applicant is not the proprietor of the patent in respect of the therapeutic product and there is such a patent in force, the applicant must further state in the declaration mentioned in paragraph (2) —

- (a) the name and address of the proprietor of the patent;
- (b) whether —
  - (i) the proprietor has consented to or has acquiesced in the grant of the registration of the

121 For full text on Singapore’s Health Products (Therapeutic Products) Regulations, please refer to the following website of the Legislation Division of the Attorney-General’s Chambers of Singapore: <https://sso.agc.gov.sg/SL/HPA2007-S329-2016?DocDate=20211231&ValidDate=20220103> (last visit on 13 May 2022).

122 Singapore’s Health Products (Treatment Products) Regulation (enforced on 3 January 2022) Article 23(1).

123 Singapore’s Health Products (Treatment Products) Regulation (enforced on 3 January 2022) Article 23(2) and (3).

124 Singapore’s Health Products (Treatment Products) Regulation (enforced on 3 January 2022) Article 23(5).

- therapeutic product by the applicant; or
- (ii) in the opinion of the applicant and to the best of the applicant's belief, the patent is invalid or will not be infringed by the doing of the act for which the registration of the therapeutic product is sought; and

(c) such other information as the Authority may require in any particular case. ...

(5) Where the applicant is not the proprietor of a patent under the Patents Act that is in force in respect of the therapeutic product, the Authority may require the applicant to serve, in accordance with section 67 of the Act, on the proprietor of the patent, a notice in the form specified on the Authority's website, and within such time as the Authority may determine, if —

- (a) the applicant has declared that, in the applicant's opinion and to the best of the applicant's belief, the patent is invalid or will not be infringed by the doing of the act for which the registration is sought; or
- (b) the Authority considers it appropriate in any particular case for the applicant to do so. ...

## 2) Operation of a Patent Linkage System

Singapore regulates medicines through the Medicines Act and the Health Products Act, and the Medicines Act covers oriental and traditional medicines while the Health Product Act covers treatment products and so-called Western medicines.

- Accordingly, in Singapore, in the case of applications for license of oriental and traditional medicines, the patent linkage system under the Medicines Act is applied, and in the case of applications for license of treatment products, etc., the patent linkage system in the Health Products (Treatment Products) Regulation under the Health Products Act is applied.

In Singapore, the Intellectual Property Office of Singapore (IPOS) under the Ministry of Justice is in charge of examining patent applications and granting patents, and the Health Sciences Authority (HSA) under the Ministry of Health is in charge of registering and licensing medicines under the Medicines Act and the Health Products Act.<sup>125</sup> In accordance with the Medicines Act and the Health Products (Treatment Products) Regulation, the HSA implements measures to prevent patent infringement in the drug registration and approval procedures.

- In other words, the HSA is responsible for the overall approval procedures, such as notification to the patentee of applications for approval, reservation or cancellation of drug approval due to neglect of notification obligations, or patent litigation, for medicines under the Medicines Act and the Health Products Act.
- However, Singapore's Medicines Act and the Health Products (Treatment Products) Regulation, etc. do not stipulate provisions regarding the registration of drug patents and generic exclusivity, but the HSA operates a drug registration and search information system including information on medicines.<sup>126</sup>

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<sup>125</sup> Singapore's Medicines Act (revised on 1 December 2021, enforced on 31 December 2021) Article 2(1) and Health Products Act (revised on 1 December 2021, enforced on 31 December 2021) Article 2(1).

<sup>126</sup> For Singapore's drug registration and search information system, please refer to the following website of Singapore's Health Sciences Authority: [www.hsa.gov.sg/e-services/infosearch](http://www.hsa.gov.sg/e-services/infosearch) (last visit on 9 May 2022).

### 3) Issues in Patent Act related to a Patent Linkage System

#### Extension of the duration of drug patents

Singapore revised the Patents Act of 1994 in June 2004 to establish an extension system of the duration of drug patents, etc. as a means of supplementing drug patents that require a long period of time in developing new drugs and in the process of approval.

- In addition, Singapore's Patent Act revised in December 2021 stipulates in Article 36A that the duration of the patent right can be extended once within a maximum of 5 years if the duration to practice patented inventions is unreasonably shortened during the marketing approval procedure of drugs.<sup>127</sup><sup>128</sup><sup>129</sup>

#### Practice of a patented invention for the purpose of clinical trials

Singapore specifies the practice of a patented invention for marketing approval of drugs as an exception to patent infringement.

- Article 66.2 of Singapore's Patent Act revised in December 2021 lists exceptions that do not constitute patent infringement, including the practice of a patented inventions intended to meet the requirements related to marketing approval of drugs as well as non-profit private acts, research or experimental acts.<sup>130</sup>

### 4) Structure of a Patent Linkage System

Singapore's Medicines Act (revised on 1 December 2021, enforced on 31 December 2021) and Health Products Act (revised on 1 December 2021, enforced on 31 December 2021), etc. stipulate:

- ② Notification of application for marketing approval,
- ③ Reservation and cancellation of marketing approval.

However, Singapore's Medicines Act (revised on 1 December 2021, enforced on 31 December 2021) and Health Products Act (revised on 1 December 2021, enforced on 31 December 2021), etc. do not stipulate:

- ① Registration of drug patents, and
- ④ Granting generic exclusivity, among the components that generally constitute the patent linkage system.

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127 Singapore's Patents Act (revised on 1 December, 2021, enforced on 31 December, 2021) Article 36A(1) and Patents Rules (enforced on 1 April, 2022) Article 51A(8).

128 For full text on Singapore's Patents Act, please refer to the following website of the Legislation Division of the Attorney-General's Chambers of Singapore: <https://sso.agc.gov.sg/Act/PA1994?ValidDate=20220401> (last visit on 9 May 2022).

129 For full text on Singapore's Patents Rules, please refer to the following website of the Legislation Division of the Attorney-General's Chambers of Singapore: <https://sso.agc.gov.sg/SL/PA1994-R1?DocDate=20220325&ValidDate=20220401> (last visit on 9 May 2022).

130 Singapore's Patents Act (revised on 1 December, 2021, enforced on 31 December, 2021) Article 66(2)(h).

## Notification to the patentee

Singapore's Medicines Act and Health Products (Treatment Products) Regulation have a notification system to the patentee of applications for approval and reports by mandating that if a person who has applied for marketing approval of generic drugs claims invalidation or non-infringement of the patent related to the drug, he or she should notify the patentee of the application for approval and registration of the drug and verify the fact of notification to the HSA.

- A person who applies for a drug license or registration shall report the patent relationship with the patent valid under the patent law to the HSA.<sup>131</sup> This report procedure classifies the patent relationship between the drug and the patent valid under the patent law into the following 4 categories:<sup>132</sup>
  - ① Where there is no valid patent for the drug.
  - ② Where the applicant is the patentee of the valid patent for the drug or the patentee agrees to the license of the drug.
  - ③ Where the applicant requests the license and registration of the drug after the expiration of valid patent for the drug.
  - ④ Where the patent for the drug is invalid, or the drug applied for license does not infringe the patent right.

And the obligation to notify to the patentee under the Medicines Act and Health Products (Treatment Products) Regulation is incurred only in the case of ④.<sup>133</sup>

- A person who chooses ④ in the patent relationship report shall notify the patentee, etc. of the application for license or registration of the drug, and if such notification is not made, the HSA may not determine on the application for license or registration of the drug.<sup>134</sup>

## Reservation of marketing approval

Singapore's Medicines Act and Health Products (Treatment Products) Regulation stipulate the reservation or cancellation of drug licenses.

- **(Procedure for reservation of approval)** The patentee shall, within 45 days from the date of receipt of the notification, take the following action to the court or the Intellectual Property Office:<sup>135</sup>
  - ① Request for an injunction against the act of practicing through the license of the drug;

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131 Singapore's Medicines Act (revised on 1 December 2021, enforced on 31 December 2021) Article 12A(2) and Health Products (Treatment Products) Regulation (enforced on 3 January 2022) Article 23(2).

132 Health Sciences Authority, Guidance on Therapeutic Products Registration in Singapore, HSA (2022), p.16.

133 Singapore's Medicines Act (revised on 1 December 2021, enforced on 31 December 2021) Article 12A(3) and Health Products (Treatment Products) Regulation (enforced on 3 January 2022) Article 23(5).

134 Singapore's Medicines Act (revised on 1 December 2021, enforced on 31 December 2021) Article 12A(4) and Health Products (Treatment Products) Regulation (enforced on 3 January 2022) Article 23(7).

135 Singapore's Medicines Act (revised on 1 December 2021, enforced on 31 December 2021) Article 12A(5) and Health Products (Treatment Products) Regulation (enforced on 3 January 2022) Article 23(8).

- ② Request for confirmation of the fact that the patent is valid or that the act of practicing through the license of the drug violates the patent.
- **(Effect of reservation of approval)** If the patentee files the above claim, the HSA shall reserve the approval of the drug for 30 months from the date the claim is filed and may refuse the drug license if the patentee's claim is accepted during that period.<sup>136</sup>
  - **(Cancellation of approval)** If the court or the Intellectual Property Office makes a decision to confirm that the practice through the drug license violates the patent, or if the applicant has falsely reported the patent relationship, the HSA may cancel the drug license.<sup>137</sup>

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136 Singapore's Health Products (Treatment Products) Regulation (enforced on 3 January 2022) Article 23(9) and (10).

137 Singapore's Health Products (Treatment Products) Regulation (enforced on 3 January 2022) Article 24(1).

## (10) Chinese Taipei

### 1) Introduction and Development of a Patent Linkage System

In August 2016, Chinese Taipei's administrative branch introduced an amendment to the Pharmaceutical Affairs Act, aiming to align the legislation with global trends in intellectual property for pharmaceutical products and promote biotechnology and medical research. This amendment, which introduced the patent linkage system, was subsequently passed by Chinese Taipei's legislative branch on 29 December 2017, and officially took effect on 20 August 2019.

- This amendment newly established Chapter 4-1 under the title of the Drug Approval-Patent Linkage and stipulated the patent linkage-related provisions in Articles 48-3 through 48-22, and overall, it consisted of a system similar to the Hatch-Waxman Act of the United States.
- This amendment had provisions on the registration of drug patents on the list (Articles 48-3 to 48-8), clarification of relationship with patent upon application for marketing approval (Articles 48-9), notification of application for marketing approval (Articles 48-12), reservation of marketing approval due to patent lawsuit (Articles 48-13 to 48-15) and generic exclusivity (Articles 48-16 to 48-18), and there has been no additional amendment until May 2022.

**Table 4-(10)-2. Chinese Taipei's Pharmaceutical Affairs Act (announced on 31 January 2018, enforced on 20 August 2019)**

#### Chapter 4-1 Patent Linkage of Drugs

##### Article 48-3

1. If the holder of a new drug permit deems it necessary to submit the patent information regarding such drug, such holder shall submit relevant documents and information to the Central Competent Health Authority within 45 days after the next day to the receipt of the drug permit. If the holder fails to file such submission within the stipulated period, the regulations under this Chapter do not apply.
2. The drug patent stipulated under Paragraph 1 hereof shall be limited to the following:
  - (1) Substance.
  - (2) Composition or Formulation.
  - (3) Medical use. ...

##### Article 48-8

1. The Central Competent Health Authority shall establish a Registration System for Patent Linkage of Drugs to list and publish the patent information submitted by the holder of a new drug permit. The aforementioned shall also apply to the amendment and deletion of the patent information. ...

##### Article 48-9

The applicant for a generic drug permit shall, with respect to the patent(s) of the approved new drug listed by the holder of said new drug permit, declare one of the following item(s) when applying for a generic drug permit:

- (1) No patent information of said new drug has been listed.
- (2) The patent(s) corresponding to said new drug has extinguished.
- (3) The Central Competent Health Authority will issue the generic drug permit after the patent(s) corresponding to said new drug extinguishes.
- (4) The patent(s) corresponding to said new drugs shall be revoked, or the patent(s) corresponding to said new drugs will not be infringed by the generic drug subject to the application for drug permit.

#### **Article 48-10**

For the application for a generic drug permit that only involves a declaration based on Item 1 or 2 of Article 48-9, if in compliance with the regulations under this Act after examination, the Central Competent Health Authority shall issue the drug permit thereof. ...

#### **Article 48-12**

1. For the application for a generic drug permit that involves a declaration based on Item 4 of Article 48-9, the applicant shall, within 20 days after the next day to its receipt of the notification from the Central Competent Health Authority which indicates that all the documents required for an application of drug permit have been duly prepared, notify the holder of the new drug permit and the Central Competent Health Authority [of the declaration] in writing; if the holder of said new drug permit is different from the patentee or the exclusive licensee, the patentee and the exclusive licensee shall also be notified. ...
3. The Central Competent Health Authority shall dismiss the application for generic drug permit if the applicant fails to issue the notification in accordance with Paragraphs 1 and 2 hereof.

#### **Article 48-13**

1. If the patentee or the exclusive licensee intends to file a patent infringement complaint on the basis of the listed patent(s) after its receipt of the notification stipulated by Paragraph 1 of Article 48-12, it shall file the complaint within 45 days after the next day to its receipt of said notification and notify the Central Competent Health Authority. ...

## **2) Operation of a Patent Linkage System**

In Chinese Taipei, the TIPO under the Ministry of Economic Affairs is in charge of examining patent applications and granting patents while the TFDA under the Ministry of Health and Welfare is in charge of marketing approval of drugs according to the Pharmaceutical Affairs Act, and the TFDA implements measures to prevent patent infringement in the drug marketing approval process in accordance with Chapter IV-1 of the Pharmaceutical Affairs Act.

- In other words, the TFDA is responsible for the overall patent linkage system, including the registration and management of pharmaceutical patents, notification to the patentee of application for marketing approval, etc., reservation of marketing approval due to patent lawsuit, and grant of generic exclusivity.

- Accordingly, the TFDA supports to design generic drugs circumventing patents through the disclosure of drug patent information by establishing and operating the patent linkage information system to register and manage drug patents.<sup>138</sup>

### 3) Issues in Patent Act related to a Patent Linkage System

#### Extension of the duration of drug patents

As a means of supplementing drug patents that require a long period of time in developing new drugs and in the process of approval, Chinese Taipei stipulates the extension of the patent period in Article 53 of the Patent Act, specifying the extension of the duration of drug patents.<sup>139</sup>

- Chinese Taipei's revised patent law, which took effect in November 2019, stipulates that the duration of the patent right can be extended once within a maximum of 5 years if approval or permission is required under other laws to practice patent inventions related to pharmaceuticals and agricultural chemicals, etc.

**Table 4-(10)-3. Chinese Taipei's Patent Act (announced on 1 May 2019, enforced on 1 November 2019)**

#### Article 53 Extension of patent term

1. Where a regulatory approval shall be obtained in accordance with other laws and regulations for the exploitation of an invention patent involving a pharmaceutical or agricultural, or the manufacturing process thereof, if such regulatory approval is obtained after the publication of the concerned invention patent, the patentee may apply for one and only one extension of the patent term of said invention patent based on the first regulatory approval. The said regulatory approval is allowed to be used only once for seeking patent term extension.
2. The extension of the patent term approved under the preceding paragraph shall not exceed the length of time when the patent cannot be exploited because of the filing of a request for the regulatory approval with the Central competent authorities in charge of the business. If the time needed to obtain the said regulatory approval exceeds five (5) years, the granted patent term extension shall still be five (5) years.
3. The term "pharmaceutical" as set forth in Paragraph 1 does not include any veterinary drug.
4. When requesting for patent term extension as provided in the Paragraph 1, a request form and document(s) of proof must be submitted to the Specific Patent Agency within three (3) months after obtaining the first regulatory approval; no request for patent term extension shall be filed within six (6) months prior to the expiry of the original patent term. ...

#### Practice of a patented invention for the purpose of clinical trials

138 For Chinese Taipei's patent linkage information system to register and manage drug patents, please refer to the following website of Chinese Taipei's Food and Drug Administration: <https://pils.fda.gov.tw/?r=2112876311> (last visit on 9 May 2022).

139 For full text on Chinese Taipei's Patent Act, please refer to the following website of Chinese Taipei's Ministry of Justice: <https://law.moj.gov.tw/ENG/LawClass/LawAll.aspx?pcode=J0070007> (last visit on 9 May 2022).

Chinese Taipei's Patent Act stipulates the practice of a patent invention for clinical trial as an exception to patent infringement.

- Chinese Taipei's revised Patent Act, which took effect in November 2019, lists general exceptions not subject to the effect of patent rights in Article 59, specifying "private acts for non-profit purposes", "actions necessary to carry out a patented invention for research or experiment", etc. and separately stipulates "research and test for obtaining marketing approval under the Pharmaceutical Affairs Act" as an exception not subject to the effect of patent rights in Article 60.

#### **4) Structure of a Patent Linkage System**

In the Pharmaceutical Affairs Act (announced on 31 January 2018 and enforced on 20 August 2019), Chinese Taipei stipulates

- ① Registration of applicable drug patents,
- ② Notification of application for marketing approval,
- ③ Measures to provide adequate time and opportunity for resolution of patent disputes prior to marketing, and
- ④ Granting generic exclusivity.

#### **Registration of applicable drug patents**

Chinese Taipei's Pharmaceutical Affairs Act has a drug patent registration system, stipulating that a person who has obtained a marketing approval of a new drug can report the patent information of the approved drug to the health authority,<sup>140</sup> and that the health authority should establish a system for listing and disclosing drug patent information.

- Drug patents subject to registration of drug patents are limited to patents related to substances, compositions or formulations, and pharmaceutical uses.<sup>141</sup>
- A person who has obtained a marketing approval of a new drug and intends to register the patent information of the drug shall submit the relevant document to the TFDA within 45 days from the date of marketing approval or the grant of the patent,<sup>142</sup> and the authority registers and manages such drug patent information in the information system.<sup>143</sup>

#### **Notification to the patentee**

Chinese Taipei's Pharmaceutical Affairs Act has a notification system for the patentee of applications for approval and reports by mandating that if a person who has applied for marketing approval of generic drugs claims invalidation or non-infringement of the patent right of the new drug in relation to a registered new drug, he or she should notify the new drug licensee, the patentee, and the TFDA, etc. of such an application.

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140 Chinese Taipei's Pharmaceutical Affairs Act (announced on 31 January 2018, enforced on 20 August 2019) Article 48-3(1).

141 Chinese Taipei's Pharmaceutical Affairs Act (announced on 31 January 2018, enforced on 20 August 2019) Article 48-3(2).

142 Chinese Taipei's Pharmaceutical Affairs Act (announced on 31 January 2018, enforced on 20 August 2019) Article 48-3(1) and Article 48-5.

143 Chinese Taipei's Pharmaceutical Affairs Act (announced on 31 January 2018, enforced on 20 August 2019) Article 48-8(1).

- A person who intends to apply for marketing approval of a generic drug shall report the patent relationship with the registered new drug to the TFDA.<sup>144</sup> This report procedure classifies the patent relationship between the generic drug and the registered drug into the following 4 categories:
  - ① Where the patent information for the new drug is not listed;
  - ② Where the patent right for the new drug has expired;
  - ③ The central health authority will issue generic drug licenses after the patent right for the new drug has expired; or
  - ④ Where the patent right for the new drug is invalid, or the generic drug applied for approval does not infringe the patent right of the new drug.

And the obligation to notify to the patentee pursuant to paragraph 1 of Article 48-12 of the Pharmaceutical Affairs Act is incurred only in the case of ④.<sup>145</sup>

- If ① and ② are selected in the patent relationship report, the TFDA shall examine compliance with the Pharmaceutical Affairs Act and then issue an approval, and if ③ is selected, the TFDA shall examine compliance with the Pharmaceutical Affairs Act and issue an approval after the patent right of the new drug has expired.<sup>146</sup>
- A person who chooses ④ in the patent relationship report shall notify the patentee, etc. of the approval application and notification within 20 days from the date of receiving a notification from the TFDA that the documents related to the drug approval have been submitted in due course, and if such notification is not made, the TFDA shall reject the application for approval of the generic drug.<sup>147</sup>

### **Measures to provide adequate time and opportunity for resolution of patent disputes prior to marketing**

Articles 48-13 to 48-15 of Chinese Taipei's Pharmaceutical Affairs Act stipulate the procedure for reservation of marketing approval. The TFDA shall continue to examine the application for marketing approval of generic drugs during the reservation period of marketing approval and notify the applicant if the requirements are met, and the notified applicant may apply for the public health insurance drug price, etc.<sup>148</sup>

- **(Procedure for reservation of approval)** The patentee, etc. may file a patent infringement lawsuit based on the registered patent right against the applicant for generic drug approval within 45 days from the date of receiving a notification of the application for marketing approval, and shall notify this to the TFDA.<sup>149</sup>

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144 Chinese Taipei's Pharmaceutical Affairs Act (announced on 31 January 2018, enforced on 20 August 2019) Article 48-9.

145 Chinese Taipei's Pharmaceutical Affairs Act (announced on 31 January 2018, enforced on 20 August 2019) Article 48-12(1).

146 Chinese Taipei's Pharmaceutical Affairs Act (announced on 31 January 2018, enforced on 20 August 2019) Article 48-10 and Article 48-11.

147 Chinese Taipei's Pharmaceutical Affairs Act (announced on 31 January 2018, enforced on 20 August 2019) Article 48-12(1) and (3).

148 Chinese Taipei's Pharmaceutical Affairs Act (announced on 31 January 2018, enforced on 20 August 2019) Article 48-15.

149 Chinese Taipei's Pharmaceutical Affairs Act (announced on 31 January 2018, enforced on 20 August 2019) Article 48-13(1).

- **(Effect of reservation of approval)** If the patentee files such a patent infringement lawsuit, the TFDA shall reserve the marketing approval of the generic drug for 12 months from the date of receiving a notification of the application for approval, unless otherwise specified.<sup>150</sup>
- **(Restriction on reservation of approval)** To prevent unreasonable delays in marketing approval of generic drugs, the TFDA may reserve approval only once for applications for generic drug approval filed by the same applicant for the same drug.<sup>151</sup>

### Generic exclusivity

Chinese Taipei's Pharmaceutical Affairs Act grants generic exclusivity that allows a generic drug that succeeded in challenging the patent of the registered drugs to be sold exclusively through exclusive marketing approval procedures, etc. as prescribed in Articles 48-16 to 48-18.

- **(Qualification for generic exclusivity)** The first person to claim invalidation or non-infringement of the patent right of a new drug among patent relationships under Article 48-9 of the Pharmaceutical Affairs Act, i.e. the first person who is obligated to notify among those who applied for approval of generic drugs, will receive a market monopoly for a certain period of time, and the TFDA cannot approve other generic drugs until the expiration of the period.<sup>152</sup>
- **(Requirements for generic exclusivity)** A person approved for a generic drug must release the drug within 6 months from the date of obtaining the approval for the drug and must submit evidence to the TFDA for the date of initial release within 20 days of the marketing date.<sup>153</sup>
- **(Effect of generic exclusivity)** A person who has generic exclusivity has a market monopoly for 12 months from the date of its initial release based on evidence submitted to the TFDA regarding the release date of the generic drug.<sup>154</sup>

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150 Chinese Taipei's Pharmaceutical Affairs Act (announced on 31 January 2018, enforced on 20 August 2019) Article 48-13(2).

151 Chinese Taipei's Pharmaceutical Affairs Act (announced on 31 January 2018, enforced on 20 August 2019) Article 48-14.

152 Chinese Taipei's Pharmaceutical Affairs Act (announced on 31 January 2018, enforced on 20 August 2019) Article 48-16(1).

153 Chinese Taipei's Pharmaceutical Affairs Act (announced on 31 January 2018, enforced on 20 August 2019) Article 48-17(1).

154 Chinese Taipei's Pharmaceutical Affairs Act (announced on 31 January 2018, enforced on 20 August 2019) Article 48-16(1).

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**Annex 1.**

**Survey on Status of Patent Linkage System in APEC Member Economies**

**(IPEG 04 2021T) Survey Questionnaire (For circulation)**

Dear Representatives,

It gives me great pleasure to introduce myself to you.

I am a general manager of Korea Institute of Intellectual Property (KIIP) established in 2005 as a statutory agency under Invention Promotion Act of Republic of Korea.

With my research team in KIIP, I have undertaken the APEC-funded project as follows:

Project Number: IPEG 04 2021T

Project Title: A Study on the Patent Linkage System for Intellectual Property Rights and Public Health Harmonisation

(For your reference: <https://aimp2.apec.org/sites/PDB/Lists/Proposals/DispForm.aspx?ID=2909>)

This project aims to promote domestic policies and programs in APEC economies, and broader regional efforts for harmonization of patent linkage regimes in the APEC region, from the perspective of health and access to medical services.

As an important part of this project, we plan to survey details on legislations, policies and other programs for patent linkage in respective APEC economies. For this purpose, we are to circulate a questionnaire as attached. The questionnaire contains 12 questions under four sections.

Thank you for taking time out of your busy schedule to respond to the questionnaire.

And, please send your completed response to focal points below **by no later than 25 July, 2022.**

Yours sincerely,

Project Manager  
Korea Institute of Intellectual Property (KIIP)

# Survey Questionnaire

## Survey on Status of Patent Linkage System in APEC member economies

### Note:

1. Republic of Korea, joined by co-sponsors Japan; Mexico; and Chinese Taipei, is circulating this survey to gather information on introduction and development of Patent Linkage System in APEC member economies.
2. The intent of this survey is to collect information as to distinctions in patent linkage system among APEC member economies and to identify difficulties or obstacles experienced/faced by APEC member economies in introducing/implementing patent linkage system. For detailed information, those questions in this Survey Questionnaire are classified into four sections.

### Information

Name of Economy:

Contact Information:

Office/Agency:

Position/Title:

E-mail:

### Background

**Patent linkage system refers to the system that operates the patent system in conjunction with the approval system for drug/pharmaceutical.** Under the patent linkage system, if there is an application for marketing approval of a generic drug relying on the data of a drug patent, the drug authority must take measures to prevent patent infringement in the marketing approval process in consideration of the patent infringement of the generic drug.

**Patent linkage system was designed in the United States to strengthen patent protection for original drugs.** Where patent-related clarification, prohibition of marketing, and notification procedures to the patentee, etc. are required of generic drugs applied for approval, it has the advantage of strengthening the patent protection of the original drug.

**On the other hand, patent linkage system might have the advantage of shortening the clinical trial period and providing incentives for generic drug development,** thereby facilitating generic drugs to enter the market.

**Therefore, patent linkage system needs to be designed in consideration of an appropriate balance between original and generic drugs,** and it is desirable to upgrade it step by step according to the economy's current state of the pharmaceutical industry, public health level, and patent system development, etc.

## **Section One**

### **Competent Authorities and Patent Law Issues related to Patent Linkage System**

**Q1.** What agency/authority is primarily responsible for examination on patent applications in your economy? And what is the legal basis for examination on patent applications?

Agency/Authority:

Legal Basis (law, act, legislation):

Provide citation(s) or links to such materials:

**Q2.** What agency/authority is primarily responsible for marketing approval of drug/pharmaceutical in your economy? And what is the legal basis for marketing approval of drugs/pharmaceuticals?

Agency/Authority:

Legal Basis (law, act, legislation):

Provide citation(s) or links to such materials:

**Q3.** Is it allowed for a patentee to extend the duration of his/her drug patent in your economy?

“Extension for the duration of drug patents means a framework that extends the duration of a drug patent for the period in which the patent could not be practiced due to the licensing process in consideration of the characteristics of drugs that require a long period of time in the licensing process.”

YES

NO

If the answer to Q3 above is “Yes”, please inform us of followings-

Legal Basis (law, act, legislation):

Provide citation(s) or links to such materials:

**Q4.** Is it allowed for a third party to practice/implement a patented invention for clinical trials, research, or experiments necessary for drug licensing in your economy?

“Exception for the practice of a patented invention for clinical trials, etc. means that the act of practicing a patented invention for research or experiments necessary for drug licensing procedures is allowed as an exception that does not constitute patent infringement.”

YES

NO

If the answer to Q4 above is “YES”, please inform us of followings-

Legal Basis (law, act, legislation):

Provide citation(s) or links to such materials:

## **Section Two**

### **Introduction and Development of Patent Linkage System**

**Q5.** Has your economy introduced patent linkage system for preventing patent infringement in the process of marketing approval for drug/pharmaceutical?

- YES
- NO

If the answer to Q5 above is “YES”, please inform us of followings-

The agency/authority primarily responsible for patent linkage system:

The date on which patent linkage system was introduced in your economy:

**Q6.** What are backgrounds to the introduction of patent linkage system in your economy? (Multiple replies are allowed where appropriate)

**Note:** If the answer to Q5 above is “NO”, you don’t have to respond to Q6.

- Recognition of necessity for sui generis regimes in regard to patents for drugs/pharmaceuticals
- Preemptive response to global standard to address patents for drugs/pharmaceuticals
- Conclusion/negotiation of bilateral free trade agreement (FTA)
- Ratification/accession/negotiation of multilateral free trade agreement such as CPTPP
- Other

If the answer to Q6 above is “Other”, please describe those backgrounds in detail:

**Q7.** Does your economy have any plan to introduce/implement patent linkage system?

**Note:** If the answer to Q5 above is “YES”, you don’t have to respond to Q7.

- YES
- NO

If the answer to Q7 above is “YES”, please describe those plans or works in progress in detail:

### **Section Three**

#### **Structure and Key Components of Patent Linkage System**

**Note:** If the answer to Q5 above is “NO”, you don’t have to respond to those Questions under Section Three.

**Q8.** Does your economy have a system for registration and management of drug patents?

“Registration and management of drug patents in patent linkage system refers to a procedure in which patent information related to a licensed drug is submitted to the competent authority for record and management in the list of drug patents.”

- YES
- NO

If the answer to Q8 above is “YES”, please inform us of followings-

Legal Basis (law, act, legislation):

Provide citation(s) or links to such materials:

The number of drug patents registered in the list of drug patents under patent linkage system:

**Q9.** Does your economy have a system for notification to the patentee involved of the fact that any application for marketing approval of generic drugs has been filed?

“Notification in patent linkage system refers to a procedure in which a person applying for marketing approval of a generic drug notifies the owner of a (registered) patent related to the generic drug of the fact that the application for marketing approval has been filed.”

- YES
- NO

If the answer to Q9 above is “YES”, please inform us of followings-

Legal Basis (law, act, legislation):

Provide citation(s) or links to such materials:

The number of applications for marketing approval of (generic) drugs notified to the patentee under patent linkage system:

**Q10.** Does your economy have a system for prevention of marketing or reservation of licensing against generic drugs suspected of patent infringement in the marketing approval process of drugs?

“Prevention of marketing or reservation of licensing in patent linkage procedures means the competent authority’s measure to reserve licensing or prevent marketing of (generic) drugs applied for marketing approval upon the request of the patentee based on the notification mentioned in Q9.”

- YES
- NO

If the answer to Q10 above is “YES”, please inform us of followings-

Maximum term for such prevention of marketing or reservation of licensing: (months)

Legal Basis (law, act, legislation):

Provide citation(s) or links to such materials:

The number of requests by patentees to prevent marketing or reserve licensing of generic drugs under patent linkage system:

The number of measures taken by the competent authority to prevent marketing or reserve licensing of generic drugs under patent linkage system:

**Q11.** Does your economy have a system for exclusive marketing approval or generic exclusivity for a generic drug that succeeds in challenging the (registered) patent related to the generic drug?

“Exclusive marketing approval or generic exclusivity in patent linkage procedures means a market monopoly position that allows a person who wins a case against a (registered) patent to exclusively market his/her generic drug for a certain period of time.”

- YES
- NO

If the answer to Q11 above is “YES”, please inform us of followings-

Maximum term for such exclusive marketing approval or generic exclusivity: (months)

Legal Basis (law, act, legislation):

Provide citation(s) or links to such materials:

The number of applications for exclusive marketing approval or generic exclusivity under patent linkage system:

Average term allowed in practice for such exclusive marketing approval or generic exclusivity under patent linkage system: (months)

#### **Section Four**

#### **Obstacles in Introducing Patent Linkage System**

**Note:** If the answer to Q5 above is “YES”, you don’t have to respond to those Questions under Section Four.

**Q12.** Choose which one is the most advantageous point not to attempt on introduction of patent linkage system in your economy. (Multiple replies are allowed where appropriate)

- In aspect of pharmaceutical industry, consideration of pharmaceutical industry competitiveness
- In aspect of public health, improvement of public's access to medicines
- In aspect of social infrastructure, no additional cost required to complicate the current drug approval process
- In aspect of socio-political view, the resolution of political conflicts
- Other (please, describe details, if possible)

## **Submission**

Please send your completed response to focal points below **by no later than 25 July, 2022.**

Project Overseer

Korean Intellectual Property Office (KIPO)

Project Manager

Korea Institute of Intellectual Property (KIIP)

Thank you for your responses. The results of this survey will be included in the final report of project “IPEG 04 2021T”.

**Annex 2.**

**Questionnaire Responses from respective APEC Member Economies**

## (1) Australia

### Survey Questionnaire

#### Survey on Status of Patent Linkage System in APEC member economies

##### Note:

1. Republic of Korea, joined by co-sponsors Japan; Mexico; and Chinese Taipei, is circulating this survey to gather information on introduction and development of Patent Linkage System in APEC member economies.
2. The intent of this survey is to collect information as to distinctions in patent linkage system among APEC member economies and to identify difficulties or obstacles experienced/faced by APEC member economies in introducing/implementing patent linkage system. For detailed information, those questions in this Survey Questionnaire are classified into four sections.

##### Information

Name of Economy: [Australia](#)

Contact Information:

Office/Agency: IP Australia

Position/Title: [Policy Officer](#)

##### Background

**Patent linkage system refers to the system that operates the patent system in conjunction with the approval system for drug/pharmaceutical.** Under the patent linkage system, if there is an application for marketing approval of a generic drug relying on the data of a drug patent, the drug authority must take measures to prevent patent infringement in the marketing approval process in consideration of the patent infringement of the generic drug.

**Patent linkage system was designed in the United States to strengthen patent protection for original drugs.** Where patent-related clarification, prohibition of marketing, and notification procedures to the patentee, etc. are required of generic drugs applied for approval, it has the advantage of strengthening the patent protection of the original drug.

**On the other hand, patent linkage system might have the advantage of shortening the clinical trial period and providing incentives for generic drug development,** thereby facilitating generic drugs to enter the market.

**Therefore, patent linkage system needs to be designed in consideration of an appropriate balance between original and generic drugs,** and it is desirable to upgrade it step by step according to the economy's current state of the pharmaceutical industry, public health level, and patent system development, etc.

## **Section One**

### **Competent Authorities and Patent Law Issues related to Patent Linkage System**

**Q1.** What agency/authority is primarily responsible for examination on patent applications in your economy? And what is the legal basis for examination on patent applications?

Agency/Authority: [IP Australia](#)

Legal Basis (law, act, legislation): [Patents Act 1990 \(Cth\)](#); [Patents Regulations 1991](#).

Provide citation(s) or links to such materials:

[Patents Act 1990 https://www.legislation.gov.au/Details/C2021C00369](https://www.legislation.gov.au/Details/C2021C00369);

[Patents Regulations 1991 https://www.legislation.gov.au/Details/F2021C00881](https://www.legislation.gov.au/Details/F2021C00881)

**Q2.** What agency/authority is primarily responsible for marketing approval of drug/pharmaceutical in your economy? And what is the legal basis for marketing approval of drugs/pharmaceuticals?

Agency/Authority: [Therapeutic Goods Administration \(TGA\)](#)

Legal Basis (law, act, legislation): [Therapeutic Goods Act 1989 \(Cth\)](#); [Therapeutic Goods Regulations 1990](#).

Provide citation(s) or links to such materials:

[Therapeutic Goods Act 1989 https://www.legislation.gov.au/Details/C2021C00376](https://www.legislation.gov.au/Details/C2021C00376)

[Therapeutic Goods Regulations 1990 https://www.legislation.gov.au/Details/F2022C00384](https://www.legislation.gov.au/Details/F2022C00384)

**Q3.** Is it allowed for a patentee to extend the duration of his/her drug patent in your economy?

“Extension for the duration of drug patents means a framework that extends the duration of a drug patent for the period in which the patent could not be practiced due to the licensing process in consideration of the characteristics of drugs that require a long period of time in the licensing process.”

YES

NO

If the answer to Q3 above is “Yes”, please inform us of followings-

Legal Basis (law, act, legislation): [Patents Act 1990 \(Cth\)](#) (see sections 70-77; Schedule 1);

[Patents Regulations 1991](#) (see regulation 6.8).

The Patents Act allows patentees to apply for an extension of term of up to 5 years for a standard patent that claims a pharmaceutical substance. In order to obtain an extension of term for a patent, the following requirements must be met:

- the patent must, in substance, disclose and claim a pharmaceutical substance per se, or a pharmaceutical substance when produced by recombinant DNA technology;
- goods containing or consisting of that pharmaceutical substance must be included in the Australian Register of Therapeutic Goods (ARTG); and
- the first regulatory approval for that pharmaceutical substance must have occurred more than 5 years after the date of the patent.

Provided the requirements of the Act are satisfied, the term of the patent may be extended. The exclusive rights of the patent owner are limited during the extension to the pharmaceutical substance and to therapeutic uses.

Provide citation(s) or links to such materials:

Patents Act 1990 <https://www.legislation.gov.au/Details/C2021C00369>;

Patents Regulations 1991 <https://www.legislation.gov.au/Details/F2021C00881>

Patent Manual of Practice and Procedure <https://manuals.ipaustralia.gov.au/patent/3.12-extension-of-term-of-standard-patents-relating-to-pharmaceutical-substances>

**Q4.** Is it allowed for a third party to practice/implement a patented invention for clinical trials, research, or experiments necessary for drug licensing in your economy?

“Exception for the practice of a patented invention for clinical trials, etc. means that the act of practicing a patented invention for research or experiments necessary for drug licensing procedures is allowed as an exception that does not constitute patent infringement.”

YES

NO

If the answer to Q3 above is “YES”, please inform us of followings-

Legal Basis (law, act, legislation):

Provide citation(s) or links to such materials:

The rights of a patentee of a pharmaceutical patent are not infringed by a person exploiting an invention claimed in the patent solely for purposes connected with obtaining the inclusion in the Australian Register of Therapeutic Goods of goods that are intended for therapeutic use and are not medical devices, or purposes connected with obtaining similar regulatory approval under a law of a foreign country or of a part of a foreign country.

Patents Act 1990 <https://www.legislation.gov.au/Details/C2021C00369>; (see section 119A).

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## **Section Two**

### **Introduction and Development of Patent Linkage System**

**Q5.** Has your economy introduced patent linkage system for preventing patent infringement in the process of marketing approval for drug/pharmaceutical?

- YES  
 NO

Australia is unable to answer a simple yes or no to this question, as it does not fit well with our system.

Australia has a patent certificate system as part of its implementation of Article 17.10.4 of the Australia-United States Free Trade Agreement (AUSFTA).

In 2005, section 26B was introduced to the Therapeutic Goods Act 1989 to provide that an applicant seeking to include therapeutic goods in the Australian Register of Therapeutic Goods (ARTG) must provide one of two certificates to the TGA. The TGA must receive a certificate from the applicant prior to listing the therapeutic good on the ARTG.

The applicant must certify, in good faith, either:

- (i) That they do not propose to market the therapeutic good in a way or circumstances that would involve an infringement of a patent covering the product; or
- (ii) That they intend to market a generic version of a patented product before the patent expires, because they believe the patent is invalid, and they have notified the patent owner of their application to include the therapeutic good in the ARTG.

A person is guilty of an offence if the person gives the TGA a certificate that is false or misleading.

The Therapeutic Goods Act 1989 (section 26C) imposes penalties and damages on pharmaceutical patent owners if they take unreasonable legal action against generic manufacturers. A patent owner must also notify the Attorney-General of the Commonwealth, State or Territory before it can apply for an interlocutory injunction against a generic manufacturer who has notified the patent owner of its intention to enter the market before the end of the patent.

[Department of Health and Aged Care | Australia-United States Free Trade Agreement \(AUSFTA\)](#)

Therapeutic Goods Act 1989 <https://www.legislation.gov.au/Details/C2021C00376>; (see sections 26B and 26C).

If the answer to Q5 above is “YES”, please inform us of followings-

The agency/authority primarily responsible for patent linkage system:

The date on which patent linkage system was introduced in your economy:

**Q6.** What are backgrounds to the introduction of patent linkage system in your economy? (Multiple replies are allowed where appropriate)

**Note:** If the answer to Q5 above is “NO”, you don’t have to respond to Q6.

- Recognition of necessity for sui generis regimes in regard to patents for drugs/pharmaceuticals
- Preemptive response to global standard to address patents for drugs/pharmaceuticals
- Conclusion/negotiation of bilateral free trade agreement (FTA)
- Ratification/accession/negotiation of multilateral free trade agreement such as CPTPP
- Other

If the answer to Q6 above is “Other”, please describe those backgrounds in detail:

**Q7.** Does your economy have any plan to introduce/implement patent linkage system?

**Note:** If the answer to Q5 above is “YES”, you don’t have to respond to Q7.

- YES
- NO

If the answer to Q7 above is “YES”, please describe those plans or works in progress in detail:

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### **Section Three**

#### **Structure and Key Components of Patent Linkage System**

**Note:** If the answer to Q5 above is “NO”, you don’t have to respond to those Questions under Section Three.

**Q8.** Does your economy have a system for registration and management of drug patents?

“Registration and management of drug patents in patent linkage system refers to a procedure in which patent information related to a licensed drug is submitted to the competent authority for record and management in the list of drug patents.”

- YES
- NO

If the answer to Q8 above is “YES”, please inform us of followings-

Legal Basis (law, act, legislation):

Provide citation(s) or links to such materials:

The number of drug patents registered in the list of drug patents under patent linkage system:

**Q9.** Does your economy have a system for notification to the patentee involved of the fact that any application for marketing approval of generic drugs has been filed?

“Notification in patent linkage system refers to a procedure in which a person applying for marketing approval of a generic drug notifies the owner of a (registered) patent related to the generic drug of the fact that the application for marketing approval has been filed.”

- YES
- NO

If the answer to Q9 above is “YES”, please inform us of followings-

Legal Basis (law, act, legislation):

Provide citation(s) or links to such materials:

The number of applications for marketing approval of (generic) drugs notified to the patentee under patent linkage system:

**Q10.** Does your economy have a system for prevention of marketing or reservation of licensing against generic drugs suspected of patent infringement in the marketing approval process of drugs?

“Prevention of marketing or reservation of licensing in patent linkage procedures means the competent authority’s measure to reserve licensing or prevent marketing of (generic) drugs applied for marketing approval upon the request of the patentee based on the notification mentioned in Q9.”

- YES
- NO

If the answer to Q10 above is “YES”, please inform us of followings-

Maximum term for such prevention of marketing or reservation of licensing: (months)

Legal Basis (law, act, legislation):

Provide citation(s) or links to such materials:

The number of requests by patentees to prevent marketing or reserve licensing of generic drugs under patent linkage system:

The number of measures taken by the competent authority to prevent marketing or reserve licensing of generic drugs under patent linkage system:

**Q11.** Does your economy have a system for exclusive marketing approval or generic exclusivity for a generic drug that succeeds in challenging the (registered) patent related to the generic drug?

“Exclusive marketing approval or generic exclusivity in patent linkage procedures means a market monopoly position that allows a person who wins a case against a (registered) patent to exclusively market his/her generic drug for a certain period of time.”

- YES
- NO

If the answer to Q11 above is “YES”, please inform us of followings-

Maximum term for such exclusive marketing approval or generic exclusivity: (months)

Legal Basis (law, act, legislation):

Provide citation(s) or links to such materials:

The number of applications for exclusive marketing approval or generic exclusivity under patent linkage system:

Average term allowed in practice for such exclusive marketing approval or generic exclusivity under patent linkage system: (months)

#### **Section Four**

#### **Obstacles in Introducing Patent Linkage System**

**Note:** If the answer to Q5 above is “YES”, you don’t have to respond to those Questions under Section Four.

**Q12.** Choose which one is the most advantageous point not to attempt on introduction of patent linkage system in your economy. (Multiple replies are allowed where appropriate)

- In aspect of pharmaceutical industry, consideration of pharmaceutical industry competitiveness
- In aspect of public health, improvement of public's access to medicines
- In aspect of social infrastructure, no additional cost required to complicate the current drug approval process
- In aspect of socio-political view, the resolution of political conflicts
- Other (please, describe details, if possible)

## (2) Brunei Darussalam

### Survey Questionnaire

#### Survey on Status of Patent Linkage System in APEC member economies

##### Note:

1. Republic of Korea, joined by co-sponsors Japan; Mexico; and Chinese Taipei, is circulating this survey to gather information on introduction and development of Patent Linkage System in APEC member economies.
2. The intent of this survey is to collect information as to distinctions in patent linkage system among APEC member economies and to identify difficulties or obstacles experienced/faced by APEC member economies in introducing/implementing patent linkage system. For detailed information, those questions in this Survey Questionnaire are classified into four sections.

##### Information

Name of Economy: **Brunei Intellectual Property Office (BruIPO)**

Contact Information:

Office/Agency: **BruIPO**

Position/Title: **Deputy Registrar**

##### Background

**Patent linkage system refers to the system that operates the patent system in conjunction with the approval system for drug/pharmaceutical.** Under the patent linkage system, if there is an application for marketing approval of a generic drug relying on the data of a drug patent, the drug authority must take measures to prevent patent infringement in the marketing approval process in consideration of the patent infringement of the generic drug.

**Patent linkage system was designed in the United States to strengthen patent protection for original drugs.** Where patent-related clarification, prohibition of marketing, and notification procedures to the patentee, etc. are required of generic drugs applied for approval, it has the advantage of strengthening the patent protection of the original drug.

**On the other hand, patent linkage system might have the advantage of shortening the clinical trial period and providing incentives for generic drug development,** thereby facilitating generic drugs to enter the market.

**Therefore, patent linkage system needs to be designed in consideration of an appropriate balance between original and generic drugs,** and it is desirable to upgrade it step by step according to the economy's current state of the pharmaceutical industry, public health level, and patent system development, etc.

## Section One

### Competent Authorities and Patent Law Issues related to Patent Linkage System

**Q1.** What agency/authority is primarily responsible for examination on patent applications in your economy? And what is the legal basis for examination on patent applications?

Agency/Authority: **Brunei Intellectual Property Office (BruIPO)**

Legal Basis (law, act, legislation): **Patent Order, 2011 and Patent Rules, 2012.**

Provide citation(s) or links to such materials:

[http://www.bruipo.gov.bn/Shared%20Documents/PDF/Legislation/PA/Patents\\_Order\\_2011.pdf](http://www.bruipo.gov.bn/Shared%20Documents/PDF/Legislation/PA/Patents_Order_2011.pdf)

[http://www.bruipo.gov.bn/Shared%20Documents/PDF/Legislation/PA/Patents\\_Rules\\_2012.pdf](http://www.bruipo.gov.bn/Shared%20Documents/PDF/Legislation/PA/Patents_Rules_2012.pdf)

**Q2.** What agency/authority is primarily responsible for marketing approval of drug/pharmaceutical in your economy? And what is the legal basis for marketing approval of drugs/pharmaceuticals?

Agency/Authority: **Brunei Darussalam Medicines Control Authority**

Legal Basis (law, act, legislation): **Medicines Order, 2007**

Provide citation(s) or links to such materials:

<https://www.agc.gov.bn/AGC%20Images/LOB/Order/MNOP/Medicines%20Order.%202007.pdf>

**Q3.** Is it allowed for a patentee to extend the duration of his/her drug patent in your economy?

“Extension for the duration of drug patents means a framework that extends the duration of a drug patent for the period in which the patent could not be practiced due to the licensing process in consideration of the characteristics of drugs that require a long period of time in the licensing process.”

YES

NO

If the answer to Q3 above is “Yes”, please inform us of followings-

Legal Basis (law, act, legislation): **Patent Order, 2011 s.36**

Provide citation(s) or links to such materials:

**Q4.** Is it allowed for a third party to practice/implement a patented invention for clinical trials, research, or experiments necessary for drug licensing in your economy?

“Exception for the practice of a patented invention for clinical trials, etc. means that the act of practicing a patented invention for research or experiments necessary for drug licensing procedures is allowed as an exception that does not constitute patent infringement.”

YES

NO

If the answer to Q3 above is “YES”, please inform us of followings-

Legal Basis (law, act, legislation): **Patent Order, 2011 s. 64 (2)**

Provide citation(s) or links to such materials:

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## **Section Two**

### **Introduction and Development of Patent Linkage System**

**Q5.** Has your economy introduced patent linkage system for preventing patent infringement in the process of marketing approval for drug/pharmaceutical?

~~YES~~

NO

If the answer to Q5 above is “YES”, please inform us of followings-

The agency/authority primarily responsible for patent linkage system:

The date on which patent linkage system was introduced in your economy:

**Q6.** What are backgrounds to the introduction of patent linkage system in your economy? (Multiple replies are allowed where appropriate)

**Note:** If the answer to Q5 above is “NO”, you don’t have to respond to Q6.

- Recognition of necessity for sui generis regimes in regard to patents for drugs/pharmaceuticals
- Preemptive response to global standard to address patents for drugs/pharmaceuticals
- Conclusion/negotiation of bilateral free trade agreement (FTA)
- Ratification/accession/negotiation of multilateral free trade agreement such as CPTPP
- Other

If the answer to Q6 above is “Other”, please describe those backgrounds in detail:

**Q7.** Does your economy have any plan to introduce/implement patent linkage system?

**Note:** If the answer to Q5 above is “YES”, you don’t have to respond to Q7.

~~YES~~

NO

If the answer to Q7 above is “YES”, please describe those plans or works in progress in detail:

### **Section Three**

#### **Structure and Key Components of Patent Linkage System**

**Note:** If the answer to Q5 above is “NO”, you don’t have to respond to those Questions under Section Three.

**Q8.** Does your economy have a system for registration and management of drug patents?

“Registration and management of drug patents in patent linkage system refers to a procedure in which patent information related to a licensed drug is submitted to the competent authority for record and management in the list of drug patents.”

- YES
- NO

If the answer to Q8 above is “YES”, please inform us of followings-

Legal Basis (law, act, legislation):

Provide citation(s) or links to such materials:

The number of drug patents registered in the list of drug patents under patent linkage system:

**Q9.** Does your economy have a system for notification to the patentee involved of the fact that any application for marketing approval of generic drugs has been filed?

“Notification in patent linkage system refers to a procedure in which a person applying for marketing approval of a generic drug notifies the owner of a (registered) patent related to the generic drug of the fact that the application for marketing approval has been filed.”

- YES
- NO

If the answer to Q9 above is “YES”, please inform us of followings-

Legal Basis (law, act, legislation):

Provide citation(s) or links to such materials:

The number of applications for marketing approval of (generic) drugs notified to the patentee under patent linkage system:

**Q10.** Does your economy have a system for prevention of marketing or reservation of licensing against generic drugs suspected of patent infringement in the marketing approval process of drugs?

“Prevention of marketing or reservation of licensing in patent linkage procedures means the competent authority’s measure to reserve licensing or prevent marketing of (generic) drugs applied for marketing approval upon the request of the patentee based on the notification mentioned in Q9.”

- YES
- NO

If the answer to Q10 above is “YES”, please inform us of followings-

Maximum term for such prevention of marketing or reservation of licensing: (months)

Legal Basis (law, act, legislation):

Provide citation(s) or links to such materials:

The number of requests by patentees to prevent marketing or reserve licensing of generic drugs under patent linkage system:

The number of measures taken by the competent authority to prevent marketing or reserve licensing of generic drugs under patent linkage system:

**Q11.** Does your economy have a system for exclusive marketing approval or generic exclusivity for a generic drug that succeeds in challenging the (registered) patent related to the generic drug?

“Exclusive marketing approval or generic exclusivity in patent linkage procedures means a market monopoly position that allows a person who wins a case against a (registered) patent to exclusively market his/her generic drug for a certain period of time.”

- YES
- NO

If the answer to Q11 above is “YES”, please inform us of followings-

Maximum term for such exclusive marketing approval or generic exclusivity: (months)

Legal Basis (law, act, legislation):

Provide citation(s) or links to such materials:

The number of applications for exclusive marketing approval or generic exclusivity under patent linkage system:

Average term allowed in practice for such exclusive marketing approval or generic exclusivity under patent linkage system: (months)

## **Section Four**

### **Obstacles in Introducing Patent Linkage System**

**Note:** If the answer to Q5 above is “YES”, you don’t have to respond to those Questions under Section Four.

**Q12.** Choose which one is the most advantageous point not to attempt on introduction of patent linkage system in your economy. (Multiple replies are allowed where appropriate)

- ~~In aspect of pharmaceutical industry, consideration of pharmaceutical industry competitiveness~~
- In aspect of public health, improvement of public's access to medicines
- ~~In aspect of social infrastructure, no additional cost required to complicate the current drug approval process~~
- ~~In aspect of socio-political view, the resolution of political conflicts~~
- ~~Other (please, describe details, if possible)~~

### (3) Chile

## Survey Questionnaire

### Survey on Status of Patent Linkage System in APEC member economies

#### Note:

1. Republic of Korea, joined by co-sponsors Japan; Mexico; and Chinese Taipei, is circulating this survey to gather information on introduction and development of Patent Linkage System in APEC member economies.
2. The intent of this survey is to collect information as to distinctions in patent linkage system among APEC member economies and to identify difficulties or obstacles experienced/faced by APEC member economies in introducing/implementing patent linkage system. For detailed information, those questions in this Survey Questionnaire are classified into four sections.

#### Information

Name of Economy.

**CHILE**

Contact Information.

Office/Agency: **Undersecretariat of International Economic Affairs, Ministry of Foreign Affairs**

Position/Title: **Head of IP Division**

#### Background

**Patent linkage system refers to the system that operates the patent system in conjunction with the approval system for drug/pharmaceutical.** Under the patent linkage system, if there is an application for marketing approval of a generic drug relying on the data of a drug patent, the drug authority must take measures to prevent patent infringement in the marketing approval process in consideration of the patent infringement of the generic drug.

**Patent linkage system was designed in the United States to strengthen patent protection for original drugs.** Where patent-related clarification, prohibition of marketing, and notification procedures to the patentee, etc. are required of generic drugs applied for approval, it has the advantage of strengthening the patent protection of the original drug.

**On the other hand, patent linkage system might have the advantage of shortening the clinical trial period and providing incentives for generic drug development,** thereby facilitating generic drugs to enter the market.

**Therefore, patent linkage system needs to be designed in consideration of an appropriate balance between original and generic drugs,** and it is desirable to upgrade it step by step according to the economy's current state of the pharmaceutical industry, public health level, and patent system development, etc.

## **Section One**

### **Competent Authorities and Patent Law Issues related to Patent Linkage System**

**Q1.** What agency/authority is primarily responsible for examination on patent applications in your economy? And what is the legal basis for examination on patent applications?

Agency/Authority: **Industrial Property Institute (INAPI by its acronym in Spanish).**

Legal Basis (act, law, legislation): **Industrial Property Law N° 19.039 last amended by Law N° 21.335.**

**Q2.** What agency/authority is primarily responsible for marketing approval of drug/pharmaceutical in your economy? And what is the legal basis for marketing approval of drugs/pharmaceuticals?

Agency/Authority: **Public Health Institute (ISP by its acronym in Spanish).**

Legal Basis (act, law, legislation): **Sanitary Code last amended by Lay N° 21.388.**

**Q3.** Is it allowed for a patentee to extend the duration of his/her drug patent in your economy?

“Extension for the duration of drug patents means a framework that extends the duration of a drug patent for the period in which the patent could not be practiced due to the licensing process in consideration of the characteristics of drugs that require a long period of time in the licensing process.”

**YES X**

NO

If the answer to Q3 above is “Yes”, please inform us of followings-

Legal Basis (act, law, legislation): **Articles 53 bis 1 and following of Law N° 19.039 last amended by Law N° 21.335.**

Provide citation(s) or links to such materials: <https://www.bcn.cl/levchile/navegar?idNorma=250708>

**Q4.** Is it allowed for a third party to practice/implement a patented invention for clinical trials, research, or experiments necessary for drug licensing in your economy?

“Exception for the practice of a patented invention for clinical trials, etc. means that the act of practicing a patented invention for research or experiments necessary for drug licensing procedures is allowed as an exception that does not constitute patent infringement.”

**YES X**

NO

If the answer to Q4 above is “YES”, please inform us of followings-

Legal Basis (act, law, legislation): **Article 49 of Law N° 19.039 last amended by Law N° 21.335.**

Provide citation(s) or links to such materials: <https://www.bcn.cl/levchile/navegar?idNorma=250708>

## **Section Two**

### **Introduction and Development of Patent Linkage System**

**Q5.** Has your economy introduced patent linkage system for preventing patent infringement in the process of marketing approval for drug/pharmaceutical?

- YES X  
 NO

If the answer to Q5 above is “YES”, please inform us of followings-

The agency/authority primarily responsible for patent linkage system: **Under the Chilean system infringements concerning the patent linkage system are submitted to general courts.**

The date on which patent linkage system was introduced in your economy: **Unable to inform.**

**Q6.** What are backgrounds to the introduction of patent linkage system in your economy? (Multiple replies are allowed where appropriate)

**Note:** If the answer to Q5 above is “NO”, you don’t have to respond to Q6.

- Recognition of necessity for sui generis regimes in regard to patents for drugs/pharmaceuticals  
 Preemptive response to global standard to address patents for drugs/pharmaceuticals  
 Conclusion/negotiation of bilateral free trade agreement (FTA)  
 Ratification/accession/negotiation of multilateral free trade agreement such as CPTPP  
 **Other X**

If the answer to Q6 above is “Other”, please describe those backgrounds in detail:

**Recognition of the necessity to count with a solution for all kinds of controversies among parties about patentability or patent infringement, including linkage.**

**Q7.** Does your economy have any plan to introduce/implement patent linkage system?

**Note:** If the answer to Q5 above is “YES”, you don’t have to respond to Q7.

- YES  
 NO

If the answer to Q7 above is “YES”, please describe those plans or works in progress in detail:

---

### **Section Three**

#### **Structure and Key Components of Patent Linkage System**

**Note:** If the answer to Q5 above is “NO”, you don’t have to respond to those Questions under Section Three.

**Q8.** Does your economy have a system for registration and management of drug patents?

“Registration and management of drug patents in patent linkage system refers to a procedure in which patent information related to a licensed drug is submitted to the competent authority for record and management in the list of drug patents.”

- YES  
 NO X

If the answer to Q8 above is “YES”, please inform us of followings-

Legal Basis (act, law, legislation):

Provide citation(s) or links to such materials:

The number of drug patents registered in the list of drug patents under patent linkage system:

**Q9.** Does your economy have a system for notification to the patentee involved of the fact that any application for marketing approval of generic drugs has been filed?

“Notification in patent linkage system refers to a procedure in which a person applying for marketing approval of a generic drug notifies the owner of a (registered) patent related to the generic drug of the fact that the application for marketing approval has been filed.”

- YES  
 NO X

If the answer to Q9 above is “YES”, please inform us of followings-

Legal Basis (act, law, legislation):

Provide citation(s) or links to such materials:

The number of applications for marketing approval of (generic) drugs notified to the patentee under patent linkage system:

**Q10.** Does your economy have a system for prevention of marketing or reservation of licensing against generic drugs suspected of patent infringement in the marketing approval process of drugs?

“Prevention of marketing or reservation of licensing in patent linkage procedures means the competent authority’s measure to reserve licensing or prevent marketing of (generic) drugs applied for marketing approval upon the request of the patentee based on the notification mentioned in Q9.”

- YES  
 NO X

If the answer to Q10 above is “YES”, please inform us of followings-

Maximum term for such prevention of marketing or reservation of licensing: (months)

Legal Basis (act, law, legislation):

Provide citation(s) or links to such materials:

The number of requests by patentees to prevent marketing or reserve licensing of generic drugs under patent linkage system:

The number of measures taken by the competent authority to prevent marketing or reserve licensing of generic drugs under patent linkage system:

**Q11.** Does your economy have a system for exclusive marketing approval or generic exclusivity for a generic drug that succeeds in challenging the (registered) patent related to the generic drug?

“Exclusive marketing approval or generic exclusivity in patent linkage procedures means a market monopoly position that allows a person who wins a case against a (registered) patent to exclusively market his/her generic drug for a certain period of time.”

- YES  
 NO X

If the answer to Q11 above is “YES”, please inform us of followings-

Maximum term for such exclusive marketing approval or generic exclusivity:

Legal Basis (act, law, legislation):

Provide citation(s) or links to such materials:

The number of applications for exclusive marketing approval or generic exclusivity under patent linkage system:

Average term allowed in practice for such exclusive marketing approval or generic exclusivity under patent linkage system:

#### **Section Four**

#### **Obstacles in Introducing Patent Linkage System**

**Note:** If the answer to Q5 above is “YES”, you don’t have to respond to those Questions under Section Four.

**Q12.** Choose which one is the most advantageous point not to attempt on introduction of patent linkage system in your economy. (Multiple replies are allowed where appropriate)

- In aspect of pharmaceutical industry, consideration of pharmaceutical industry competitiveness
- In aspect of public health, improvement of public's access to medicines
- In aspect of social infrastructure, no additional cost required to complicate the current drug approval process
- In aspect of socio-political view, the resolution of political conflicts
- Other (please, describe details, if possible)

#### (4) Hong Kong, China

### Survey Questionnaire

#### Survey on Status of Patent Linkage System in APEC member economies

##### Note:

1. Republic of Korea, joined by co-sponsors Japan; Mexico; and Chinese Taipei, is circulating this survey to gather information on introduction and development of Patent Linkage System in APEC member economies.
2. The intent of this survey is to collect information as to distinctions in patent linkage system among APEC member economies and to identify difficulties or obstacles experienced/faced by APEC member economies in introducing/implementing patent linkage system. For detailed information, those questions in this Survey Questionnaire are classified into four sections.

##### Information

Name of Economy: Hong Kong, China

Contact Information:

Office/Agency: Intellectual Property Department

Position/Title: Assistant Director (Advisory)

##### Background

**Patent linkage system refers to the system that operates the patent system in conjunction with the approval system for drug/pharmaceutical.** Under the patent linkage system, if there is an application for marketing approval of a generic drug relying on the data of a drug patent, the drug authority must take measures to prevent patent infringement in the marketing approval process in consideration of the patent infringement of the generic drug.

**Patent linkage system was designed in the United States to strengthen patent protection for original drugs.** Where patent-related clarification, prohibition of marketing, and notification procedures to the patentee, etc. are required of generic drugs applied for approval, it has the advantage of strengthening the patent protection of the original drug.

**On the other hand, patent linkage system might have the advantage of shortening the clinical trial period and providing incentives for generic drug development,** thereby facilitating generic drugs to enter the market.

**Therefore, patent linkage system needs to be designed in consideration of an appropriate balance between original and generic drugs,** and it is desirable to upgrade it step by step according to the economy's current state of the pharmaceutical industry, public health level, and patent system development, etc.

## **Section One**

### **Competent Authorities and Patent Law Issues related to Patent Linkage System**

**Q1.** What agency/authority is primarily responsible for examination on patent applications in your economy? And what is the legal basis for examination on patent applications?

Agency/Authority: Intellectual Property Department

Legal Basis (law, act, legislation): Patents Ordinance (Cap. 514), Patents (General) Rules (Cap. 514C)

Provide citation(s) or links to such materials: <https://www.elegislation.gov.hk/hk/cap514>,  
<https://www.elegislation.gov.hk/hk/cap514C>

**Q2.** What agency/authority is primarily responsible for marketing approval of drug/pharmaceutical in your economy? And what is the legal basis for marketing approval of drugs/pharmaceuticals?

Agency/Authority: Pharmacy and Poisons Board (for non-Chinese medicine); Chinese Medicine Council (for Chinese medicine)

Legal Basis (law, act, legislation): Pharmacy and Poisons Ordinance (Cap.138), Pharmacy and Poisons Regulations (Cap. 138A), Chinese Medicine Ordinance (Cap. 549), Chinese Medicines Regulation (Cap. 549F)

Provide citation(s) or links to such materials: <https://www.elegislation.gov.hk/hk/cap138>,  
<https://www.elegislation.gov.hk/hk/cap138A>, <https://www.elegislation.gov.hk/hk/cap549>,  
<https://www.elegislation.gov.hk/hk/cap549F>

**Q3.** Is it allowed for a patentee to extend the duration of his/her drug patent in your economy?

“Extension for the duration of drug patents means a framework that extends the duration of a drug patent for the period in which the patent could not be practiced due to the licensing process in consideration of the characteristics of drugs that require a long period of time in the licensing process.”

YES

NO

If the answer to Q3 above is “Yes”, please inform us of followings-

Legal Basis (law, act, legislation):

Provide citation(s) or links to such materials:

**Q4.** Is it allowed for a third party to practice/implement a patented invention for clinical trials, research, or experiments necessary for drug licensing in your economy?

“Exception for the practice of a patented invention for clinical trials, etc. means that the act of practicing a patented invention for research or experiments necessary for drug licensing procedures is allowed as an exception that does not constitute patent infringement.”

YES

NO

If the answer to Q3 above is “YES”, please inform us of followings-

Legal Basis (law, act, legislation):

Provide citation(s) or links to such materials:

## **Section Two**

### **Introduction and Development of Patent Linkage System**

**Q5.** Has your economy introduced patent linkage system for preventing patent infringement in the process of marketing approval for drug/pharmaceutical?

- YES  
 NO

If the answer to Q5 above is “YES”, please inform us of followings-

The agency/authority primarily responsible for patent linkage system:

The date on which patent linkage system was introduced in your economy:

**Q6.** What are backgrounds to the introduction of patent linkage system in your economy? (Multiple replies are allowed where appropriate)

**Note:** If the answer to Q5 above is “NO”, you don’t have to respond to Q6.

- Recognition of necessity for sui generis regimes in regard to patents for drugs/pharmaceuticals  
 Preemptive response to global standard to address patents for drugs/pharmaceuticals  
 Conclusion/negotiation of bilateral free trade agreement (FTA)  
 Ratification/accession/negotiation of multilateral free trade agreement such as CPTPP  
 Other

If the answer to Q6 above is “Other”, please describe those backgrounds in detail:

**Q7.** Does your economy have any plan to introduce/implement patent linkage system?

**Note:** If the answer to Q5 above is “YES”, you don’t have to respond to Q7.

- YES  
 NO

If the answer to Q7 above is “YES”, please describe those plans or works in progress in detail:

### **Section Three**

#### **Structure and Key Components of Patent Linkage System**

**Note:** If the answer to Q5 above is “NO”, you don’t have to respond to those Questions under Section Three.

**Q8.** Does your economy have a system for registration and management of drug patents?

“Registration and management of drug patents in patent linkage system refers to a procedure in which patent information related to a licensed drug is submitted to the competent authority for record and management in the list of drug patents.”

- YES  
 NO

If the answer to Q8 above is “YES”, please inform us of followings-

Legal Basis (law, act, legislation):

Provide citation(s) or links to such materials:

The number of drug patents registered in the list of drug patents under patent linkage system:

**Q9.** Does your economy have a system for notification to the patentee involved of the fact that any application for marketing approval of generic drugs has been filed?

“Notification in patent linkage system refers to a procedure in which a person applying for marketing approval of a generic drug notifies the owner of a (registered) patent related to the generic drug of the fact that the application for marketing approval has been filed.”

- YES  
 NO

If the answer to Q9 above is “YES”, please inform us of followings-

Legal Basis (law, act, legislation):

Provide citation(s) or links to such materials:

The number of applications for marketing approval of (generic) drugs notified to the patentee under patent linkage system:

**Q10.** Does your economy have a system for prevention of marketing or reservation of licensing against generic drugs suspected of patent infringement in the marketing approval process of drugs?

“Prevention of marketing or reservation of licensing in patent linkage procedures means the competent authority’s measure to reserve licensing or prevent marketing of (generic) drugs applied for marketing approval upon the request of the patentee based on the notification mentioned in Q9.”

- YES
- NO

If the answer to Q10 above is “YES”, please inform us of followings-

Maximum term for such prevention of marketing or reservation of licensing: (months)

Legal Basis (law, act, legislation):

Provide citation(s) or links to such materials:

The number of requests by patentees to prevent marketing or reserve licensing of generic drugs under patent linkage system:

The number of measures taken by the competent authority to prevent marketing or reserve licensing of generic drugs under patent linkage system:

**Q11.** Does your economy have a system for exclusive marketing approval or generic exclusivity for a generic drug that succeeds in challenging the (registered) patent related to the generic drug?

“Exclusive marketing approval or generic exclusivity in patent linkage procedures means a market monopoly position that allows a person who wins a case against a (registered) patent to exclusively market his/her generic drug for a certain period of time.”

- YES
- NO

If the answer to Q11 above is “YES”, please inform us of followings-

Maximum term for such exclusive marketing approval or generic exclusivity: (months)

Legal Basis (law, act, legislation):

Provide citation(s) or links to such materials:

The number of applications for exclusive marketing approval or generic exclusivity under patent linkage system:

Average term allowed in practice for such exclusive marketing approval or generic exclusivity under patent linkage system: (months)

## **Section Four**

### **Obstacles in Introducing Patent Linkage System**

**Note:** If the answer to Q5 above is “YES”, you don’t have to respond to those Questions under Section Four.

**Q12.** Choose which one is the most advantageous point not to attempt on introduction of patent linkage system in your economy. (Multiple replies are allowed where appropriate)

- In aspect of pharmaceutical industry, consideration of pharmaceutical industry competitiveness
- In aspect of public health, improvement of public's access to medicines
- In aspect of social infrastructure, no additional cost required to complicate the current drug approval process
- In aspect of socio-political view, the resolution of political conflicts
- Other (please, describe details, if possible)

In Hong Kong, China, the drug registration system and the patent system are operating independently of each other. There is no plan for the time being on introduction of a patent linkage system out of the following major considerations:

- (a) From the international perspective, the TRIPS Agreement of the World Trade Organization does not require the linkage of patent considerations with registration of drugs.
- (b) In respect of the local landscape, the drug registration system is established for the protection of public health focusing on the scientific criteria of drug safety, efficacy and quality. Such system does not prejudice the rights of patent owners who may institute civil proceedings against infringement of their patents and seek remedies under the domestic patent regime. It is considered that a patent linkage system could cause unnecessary delay in the process of drug registration because of patent reasons, and that such delay would affect the availability of (and also the public access to) drugs.
- (c) As from March 2016, the Pharmacy and Poisons Board has included a condition on the pharmaceutical product registration certificate, stipulating that the registered pharmaceutical product shall not infringe the patent rights of other registered pharmaceutical products in HKC. Otherwise, the Board may consider de-registering the product in question. Such measure provides an additional safeguard in HKC’s pharmaceutical product registration against patent infringement.

## (5) Japan

### Survey Questionnaire

#### Survey on Status of Patent Linkage System in APEC member economies

##### Note:

1. Republic of Korea, joined by co-sponsors Japan; Mexico; and Chinese Taipei, is circulating this survey to gather information on introduction and development of Patent Linkage System in APEC member economies.
2. The intent of this survey is to collect information as to distinctions in patent linkage system among APEC member economies and to identify difficulties or obstacles experienced/faced by APEC member economies in introducing/implementing patent linkage system. For detailed information, those questions in this Survey Questionnaire are classified into four sections.

##### Information

Name of Economy: **JAPAN**

Contact Information:

Office/Agency: **Intellectual Property Division, Economic Bureau,  
Ministry for Foreign Affairs**

Position/Title: **Assistant Director**

##### Background

**Patent linkage system refers to the system that operates the patent system in conjunction with the approval system for drug/pharmaceutical.** Under the patent linkage system, if there is an application for marketing approval of a generic drug relying on the data of a drug patent, the drug authority must take measures to prevent patent infringement in the marketing approval process in consideration of the patent infringement of the generic drug.

**Patent linkage system was designed in the United States to strengthen patent protection for original drugs.** Where patent-related clarification, prohibition of marketing, and notification procedures to the patentee, etc. are required of generic drugs applied for approval, it has the advantage of strengthening the patent protection of the original drug.

**On the other hand, patent linkage system might have the advantage of shortening the clinical trial period and providing incentives for generic drug development,** thereby facilitating generic drugs to enter the market.

**Therefore, patent linkage system needs to be designed in consideration of an appropriate balance between original and generic drugs,** and it is desirable to upgrade it step by step according to the economy's current state of the pharmaceutical industry, public health level, and patent system development, etc.

## Section One

### Competent Authorities and Patent Law Issues related to Patent Linkage System

**Q1.** What agency/authority is primarily responsible for examination on patent applications in your economy? And what is the legal basis for examination on patent applications?

Agency/Authority: [Japanese Patent Office \(JPO\)](#)

Legal Basis (law, act, legislation): [Patent Act](#)

Provide citation(s) or links to such materials:

(In Japanese) <https://elaws.e-gov.go.jp/document?lawid=334AC0000000121>

(In English) <https://www.japaneselawtranslation.go.jp/ja/laws/view/4097>

\* English version is not reflected the latest revision of the Patent Act in Japanese. But it doesn't matter because the latest revision is not related to the answer of this Survey Questionnaire.

**Q2.** What agency/authority is primarily responsible for marketing approval of drug/pharmaceutical in your economy? And what is the legal basis for marketing approval of drugs/pharmaceuticals?

Agency/Authority: [Ministry of Health, Labour and Welfare \(MHLW\)](#)

Legal Basis (law, act, legislation): [Act on Securing Quality, Efficacy and Safety of Products Including Pharmaceuticals and Medical Devices](#)

Provide citation(s) or links to such materials: <https://www.japaneselawtranslation.go.jp/ja/laws/view/3213>

**Q3.** Is it allowed for a patentee to extend the duration of his/her drug patent in your economy?

“Extension for the duration of drug patents means a framework that extends the duration of a drug patent for the period in which the patent could not be practiced due to the licensing process in consideration of the characteristics of drugs that require a long period of time in the licensing process.”

YES

NO

If the answer to Q3 above is “Yes”, please inform us of followings-

Legal Basis (law, act, legislation): [Article 67\(4\) of Patent Act](#)

Provide citation(s) or links to such materials:

[Article 67\(1\)](#) The term of a patent ends 20 years after the filing date of the patent application.

(4) If there is a period during which a person cannot work a patented invention due to the need to obtain a permission or other such disposition under the provisions of the law which is intended to ensure safety in the working of the patented invention or accomplish a similar objective, and which Cabinet Order prescribes as one that it requires considerable time to properly arrive at due to things such as the purpose of the disposition and the procedures that are involved, the patent term prescribed in paragraph (1) (inclusive of the term of any extension that has been added, if the patent term has been extended pursuant to paragraph (2); the same applies in the proviso to Article 67-5, paragraph (3), Article 68-2, and Article 107, paragraph (1)) may be extended, upon the filing of an application to register an extension, for a maximum of 5 years.

**Q4.** Is it allowed for a third party to practice/implement a patented invention for clinical trials, research, or experiments necessary for drug licensing in your economy?

“Exception for the practice of a patented invention for clinical trials, etc. means that the act of practicing a patented invention for research or experiments necessary for drug licensing procedures is allowed as an exception that does not constitute patent infringement.”

- YES  
 NO

If the answer to Q3 above is “YES”, please inform us of followings-

Legal Basis (law, act, legislation): [Article 69\(1\) of Patent Act](#)

Provide citation(s) or links to such materials:

[Article 69\(1\) A patent right is not effective against the working of the patented invention for experimental or research purposes.](#)

## **Section Two**

### **Introduction and Development of Patent Linkage System**

**Q5.** Has your economy introduced patent linkage system for preventing patent infringement in the process of marketing approval for drug/pharmaceutical?

- YES  
 NO

If the answer to Q5 above is “YES”, please inform us of followings-

The agency/authority primarily responsible for patent linkage system: [MHLW](#)

The date on which patent linkage system was introduced in your economy: [1994](#)

**Q6.** What are backgrounds to the introduction of patent linkage system in your economy? (Multiple replies are allowed where appropriate)

**Note:** If the answer to Q5 above is “NO”, you don’t have to respond to Q6.

- [Recognition of necessity for sui generis regimes in regard to patents for drugs/pharmaceuticals](#)
- Preemptive response to global standard to address patents for drugs/pharmaceuticals
- Conclusion/negotiation of bilateral free trade agreement (FTA)
- Ratification/accession/negotiation of multilateral free trade agreement such as CPTPP
- Other

If the answer to Q6 above is “Other”, please describe those backgrounds in detail:

**Q7.** Does your economy have any plan to introduce/implement patent linkage system?

**Note:** If the answer to Q5 above is “YES”, you don’t have to respond to Q7.

YES

NO

If the answer to Q7 above is “YES”, please describe those plans or works in progress in detail:

### **Section Three**

#### **Structure and Key Components of Patent Linkage System**

**Note:** If the answer to Q5 above is “NO”, you don’t have to respond to those Questions under Section Three.

**Q8.** Does your economy have a system for registration and management of drug patents?

“Registration and management of drug patents in patent linkage system refers to a procedure in which patent information related to a licensed drug is submitted to the competent authority for record and management in the list of drug patents.”

YES

NO

If the answer to Q8 above is “YES”, please inform us of followings-

Legal Basis (law, act, legislation):

[Handling of Drug Patent Information for Approval Reviews \(4 October, 1994\)](#)

[Handling of Drug Patents for Approval Reviews and Drug Price Listing of Generic Drugs \(5 June, 2009\)](#)

Provide citation(s) or links to such materials: [https://www.jpo.go.jp/resources/shingikai/sangyo-kouzou/shousai/saiseiiryu-wg/document/seisakubukai-05-shiryuu/sankou\\_2.pdf](https://www.jpo.go.jp/resources/shingikai/sangyo-kouzou/shousai/saiseiiryu-wg/document/seisakubukai-05-shiryuu/sankou_2.pdf) (only in Japanese)

The number of drug patents registered in the list of drug patents under patent linkage system: **UNDISCLOSED**

**Q9.** Does your economy have a system for notification to the patentee involved of the fact that any application for marketing approval of generic drugs has been filed?

“Notification in patent linkage system refers to a procedure in which a person applying for marketing approval of a generic drug notifies the owner of a (registered) patent related to the generic drug of the fact that the application for marketing approval has been filed.”

YES

NO

If the answer to Q9 above is “YES”, please inform us of followings-

Legal Basis (law, act, legislation):

Provide citation(s) or links to such materials:

The number of applications for marketing approval of (generic) drugs notified to the patentee under patent linkage system:

**Q10.** Does your economy have a system for prevention of marketing or reservation of licensing against generic drugs suspected of patent infringement in the marketing approval process of drugs?

“Prevention of marketing or reservation of licensing in patent linkage procedures means the competent authority’s measure to reserve licensing or prevent marketing of (generic) drugs applied for marketing approval upon the request of the patentee based on the notification mentioned in Q9.”

YES

NO

If the answer to Q10 above is “YES”, please inform us of followings-

Maximum term for such prevention of marketing or reservation of licensing: (months) [Depends on the pharmaceutical products](#)

Legal Basis (law, act, legislation): [Act on Securing Quality, Efficacy and Safety of Products Including Pharmaceuticals and Medical Devices](#)

[Handling of Drug Patent Information for Approval Reviews \(4 October, 1994\)](#)

[Handling of Drug Patents for Approval Reviews and Drug Price Listing of Generic Drugs \(5 June, 2009\)](#)

Provide citation(s) or links to such materials: [See above Q2 and Q8](#)

The number of requests by patentees to prevent marketing or reserve licensing of generic drugs under patent linkage system: [undisclosed](#)

The number of measures taken by the competent authority to prevent marketing or reserve licensing of generic drugs under patent linkage system: [undisclosed](#)

**Q11.** Does your economy have a system for exclusive marketing approval or generic exclusivity for a generic drug that succeeds in challenging the (registered) patent related to the generic drug?

“Exclusive marketing approval or generic exclusivity in patent linkage procedures means a market monopoly position that allows a person who wins a case against a (registered) patent to exclusively market his/her generic drug for a certain period of time.”

YES

NO

If the answer to Q11 above is “YES”, please inform us of followings-

Maximum term for such exclusive marketing approval or generic exclusivity: (months)

Legal Basis (law, act, legislation):

Provide citation(s) or links to such materials:

The number of applications for exclusive marketing approval or generic exclusivity under patent linkage system:

Average term allowed in practice for such exclusive marketing approval or generic exclusivity under patent linkage system: (months)

## **Section Four**

### **Obstacles in Introducing Patent Linkage System**

**Note:** If the answer to Q5 above is “YES”, you don’t have to respond to those Questions under Section Four.

**Q12.** Choose which one is the most advantageous point not to attempt on introduction of patent linkage system in your economy. (Multiple replies are allowed where appropriate)

- In aspect of pharmaceutical industry, consideration of pharmaceutical industry competitiveness
- In aspect of public health, improvement of public's access to medicines
- In aspect of social infrastructure, no additional cost required to complicate the current drug approval process
- In aspect of socio-political view, the resolution of political conflicts
- Other (please, describe details, if possible)

## (6) Mexico

### Survey Questionnaire

#### Survey on Status of Patent Linkage System in APEC member economies

##### Note:

1. Republic of Korea, joined by co-sponsors Japan; Mexico; and Chinese Taipei, is circulating this survey to gather information on introduction and development of Patent Linkage System in APEC member economies.
2. The intent of this survey is to collect information as to distinctions in patent linkage system among APEC member economies and to identify difficulties or obstacles experienced/faced by APEC member economies in introducing/implementing patent linkage system. For detailed information, those questions in this Survey Questionnaire are classified into four sections.

##### Information

Name of Economy: **MEXICO**

Contact Information:

Office/Agency: **Mexican Institute of Industrial Property / Instituto Mexicano de la Propiedad Industrial**

Position/Title: **Divisional Director of International Relations / Directora Divisional de Relaciones Internacionales**

##### Background

**Patent linkage system refers to the system that operates the patent system in conjunction with the approval system for drug/pharmaceutical.** Under the patent linkage system, if there is an application for marketing approval of a generic drug relying on the data of a drug patent, the drug authority must take measures to prevent patent infringement in the marketing approval process in consideration of the patent infringement of the generic drug.

**Patent linkage system was designed in the United States to strengthen patent protection for original drugs.** Where patent-related clarification, prohibition of marketing, and notification procedures to the patentee, etc. are required of generic drugs applied for approval, it has the advantage of strengthening the patent protection of the original drug.

**On the other hand, patent linkage system might have the advantage of shortening the clinical trial period and providing incentives for generic drug development,** thereby facilitating generic drugs to enter the market.

**Therefore, patent linkage system needs to be designed in consideration of an appropriate balance between original and generic drugs,** and it is desirable to upgrade it step by step according to the economy's current state of the pharmaceutical industry, public health level, and patent system development, etc.

## **Section One**

### **Competent Authorities and Patent Law Issues related to Patent Linkage System**

**Q1.** What agency/authority is primarily responsible for examination on patent applications in your economy? And what is the legal basis for examination on patent applications?

Agency/Authority: **Mexican Institute of Industrial Property / Instituto Mexicano de la Propiedad Industrial (IMPI)**  
Legal Basis (law, act, legislation): **Federal Law for the Protection of Industrial Property), and Regulations of the Industrial Property Law / Ley Federal de Propiedad Industrial (LFPI) y Reglamento de la Ley de la Propiedad Industrial**

Provide citation(s) or links to such materials:

[https://www.dof.gob.mx/nota\\_detalle.php?codigo=5596010&fecha=01/07/2020#gsc.tab=0](https://www.dof.gob.mx/nota_detalle.php?codigo=5596010&fecha=01/07/2020#gsc.tab=0)

[https://www.diputados.gob.mx/LevesBiblio/reglev/Reg\\_LPI\\_161216.pdf](https://www.diputados.gob.mx/LevesBiblio/reglev/Reg_LPI_161216.pdf)

**Q2.** What agency/authority is primarily responsible for marketing approval of drug/pharmaceutical in your economy? And what is the legal basis for marketing approval of drugs/pharmaceuticals?

Agency/Authority: **Federal Commission for the Protection against Sanitary Risks / Comisión Federal para la Protección contra Riesgos Sanitarios (COFEPRIS)**

Legal Basis (law, act, legislation): **General Health Law and Regulation of Health Supplies / Ley General de Salud y Reglamento de Insumos para la Salud**

Provide citation(s) or links to such materials: <https://www.diputados.gob.mx/LevesBiblio/pdf/LGS.pdf>

**Q3.** Is it allowed for a patentee to extend the duration of his/her drug patent in your economy?

“Extension for the duration of drug patents means a framework that extends the duration of a drug patent for the period in which the patent could not be practiced due to the licensing process in consideration of the characteristics of drugs that require a long period of time in the licensing process.”

YES **X**

NO

If the answer to Q3 above is “Yes”, please inform us of followings-

Legal Basis (law, act, legislation): **Federal Law for the Protection of Industrial Property, chapter VIII**

Provide citation(s) or links to such materials:

[https://www.dof.gob.mx/nota\\_detalle.php?codigo=5596010&fecha=01/07/2020#gsc.tab=0](https://www.dof.gob.mx/nota_detalle.php?codigo=5596010&fecha=01/07/2020#gsc.tab=0)

**In this regard, the Federal Law for the Protection of Industrial Property establishes that a complementary patent certificate will be granted only when there are unjustified delays in its processing, in accordance with the provisions of said Law. Otherwise, a complementary patent certificate will not be granted.**

**In this situation, a complementary certificate should NOT be understood as an EXTENSION of validity; it is a compensation mechanism that applies only to those patent applications that present an unjustified delay in their processing.**

**Q4.** Is it allowed for a third party to practice/implement a patented invention for clinical trials, research, or experiments necessary for drug licensing in your economy?

“Exception for the practice of a patented invention for clinical trials, etc. means that the act of practicing a patented invention for research or experiments necessary for drug licensing procedures is allowed as an exception that does not constitute patent infringement.”

- YES **X**  
 NO

If the answer to Q3 above is “YES”, please inform us of followings

Legal Basis (law, act, legislation): **Federal Law for the Protection of Industrial Property, article 57, section II**

Provide citation(s) or links to such materials:

[https://www.dof.gob.mx/nota\\_detalle.php?codigo=5596010&fecha=01/07/2020#gsc.tab=0](https://www.dof.gob.mx/nota_detalle.php?codigo=5596010&fecha=01/07/2020#gsc.tab=0)

## **Section Two**

### **Introduction and Development of Patent Linkage System**

**Q5.** Has your economy introduced patent linkage system for preventing patent infringement in the process of marketing approval for drug/pharmaceutical?

- YES **X**  
 NO

If the answer to Q5 above is “YES”, please inform us of followings-

The agency/authority primarily responsible for patent linkage system: **Mexican Institute of Industrial Property and the Commission for the Protection against Sanitary Risks**

The date on which patent linkage system was introduced in your economy: **since 2003.**

([https://www.dof.gob.mx/nota\\_detalle.php?codigo=690516&fecha=19/09/2003#gsc.tab=0](https://www.dof.gob.mx/nota_detalle.php?codigo=690516&fecha=19/09/2003#gsc.tab=0)

<https://amiif.org/evolucion-del-sistema-de-vinculacion-de-patentes-en-mexico/>)

**Q6.** What are backgrounds to the introduction of patent linkage system in your economy? (Multiple replies are allowed where appropriate)

**Note:** If the answer to Q5 above is “NO”, you don’t have to respond to Q6.

- Recognition of necessity for sui generis regimes in regard to patents for drugs/pharmaceuticals **X**  
 Preemptive response to global standard to address patents for drugs/pharmaceuticals **X**  
 Conclusion/negotiation of bilateral free trade agreement (FTA) **X**  
 Ratification/accession/negotiation of multilateral free trade agreement such as CPTPP  
 Other

If the answer to Q6 above is “Other”, please describe those backgrounds in detail:

**Q7.** Does your economy have any plan to introduce/implement patent linkage system?

**Note:** If the answer to Q5 above is “YES”, you don’t have to respond to Q7.

- YES **X**  
 NO

If the answer to Q7 above is “YES”, please describe those plans or works in progress in detail:

**To comply with the obligation of the Patent Linkage System related to medicines, the IMPI carries out the following actions:**

**1- Publication of the Industrial Property Gazette of current Patents that can be used in allopathic medicines, in accordance with article 162 of the LFPPI.**

**2- Attention to COFEPRIS-IMPI Intragovernmental Technical Cooperation Consultations on patents associated with allopathic medicines.**

### **Section Three**

#### **Structure and Key Components of Patent Linkage System**

**Note:** If the answer to Q5 above is “NO”, you don’t have to respond to those Questions under Section Three.

**Q8.** Does your economy have a system for registration and management of drug patents?

“Registration and management of drug patents in patent linkage system refers to a procedure in which patent information related to a licensed drug is submitted to the competent authority for record and management in the list of drug patents.”

- YES **X**  
 NO

If the answer to Q8 above is “YES”, please inform us of followings-

Legal Basis (law, act, legislation): **Federal Law for the Protection of Industrial Property, chapter II and Article 47 bis of the Regulation of the Industrial Property Law**

Provide citation(s) or links to such materials:

[https://www.dof.gob.mx/nota\\_detalle.php?codigo=5596010&fecha=01/07/2020#gsc.tab=0](https://www.dof.gob.mx/nota_detalle.php?codigo=5596010&fecha=01/07/2020#gsc.tab=0)

[https://www.diputados.gob.mx/LeyesBiblio/regley/Reg\\_LPI\\_161216.pdf](https://www.diputados.gob.mx/LeyesBiblio/regley/Reg_LPI_161216.pdf)

The number of drug patents registered in the list of drug patents under patent linkage system: **N/A**

**Q9.** Does your economy have a system for notification to the patentee involved of the fact that any application for marketing approval of generic drugs has been filed?

“Notification in patent linkage system refers to a procedure in which a person applying for marketing approval of a generic drug notifies the owner of a (registered) patent related to the generic drug of the fact that the application for marketing approval has been filed.”

- YES  
 NO X

If the answer to Q9 above is “YES”, please inform us of followings-

Legal Basis (law, act, legislation):

Provide citation(s) or links to such materials:

The number of applications for marketing approval of (generic) drugs notified to the patentee under patent linkage system:

**Q10.** Does your economy have a system for prevention of marketing or reservation of licensing against generic drugs suspected of patent infringement in the marketing approval process of drugs?

“Prevention of marketing or reservation of licensing in patent linkage procedures means the competent authority’s measure to reserve licensing or prevent marketing of (generic) drugs applied for marketing approval upon the request of the patentee based on the notification mentioned in Q9.”

- YES X  
 NO

If the answer to Q10 above is “YES”, please inform us of followings-

Maximum term for such prevention of marketing or reservation of licensing: **IMPI determines no later than ten business days after receipt of the request, if current patent rights are invaded. If the IMPI concludes that there are patents in force on the substance or active ingredient of which the applicant is not the owner or licensee, it will inform the Health Authority so that it warns the applicant in order to demonstrate that he is the owner of the patent or that has the respective license, within a period of no less than five business days from the notification.**

Legal Basis (law, act, legislation): **Federal Law for the Protection of Industrial Property, article 162, paragraph 3 and Article 47 bis of the Regulation of the Industrial Property Law.**

Provide citation(s) or links to such materials:

[https://www.dof.gob.mx/nota\\_detalle.php?codigo=5596010&fecha=01/07/2020#gsc.tab=0](https://www.dof.gob.mx/nota_detalle.php?codigo=5596010&fecha=01/07/2020#gsc.tab=0)

[https://www.diputados.gob.mx/LeyesBiblio/regley/Reg\\_LPI\\_161216.pdf](https://www.diputados.gob.mx/LeyesBiblio/regley/Reg_LPI_161216.pdf)

The number of requests by patentees to prevent marketing or reserve licensing of generic drugs under patent linkage system: N/A

The number of measures taken by the competent authority to prevent marketing or reserve licensing of generic drugs under patent linkage system: N/A

**Q11.** Does your economy have a system for exclusive marketing approval or generic exclusivity for a generic drug that succeeds in challenging the (registered) patent related to the generic drug?

“Exclusive marketing approval or generic exclusivity in patent linkage procedures means a market monopoly position that allows a person who wins a case against a (registered) patent to exclusively market his/her generic drug for a certain period of time.”

- YES
- NO

**The IMPI is not the competent authority to answer this question**

If the answer to Q11 above is “YES”, please inform us of followings-

Maximum term for such exclusive marketing approval or generic exclusivity: (months)

Legal Basis (law, act, legislation):

Provide citation(s) or links to such materials:

The number of applications for exclusive marketing approval or generic exclusivity under patent linkage system:

Average term allowed in practice for such exclusive marketing approval or generic exclusivity under patent linkage system: (months)

**Section Four**

**Obstacles in Introducing Patent Linkage System**

**Note:** If the answer to Q5 above is “YES”, you don’t have to respond to those Questions under Section Four.

**Q12.** Choose which one is the most advantageous point not to attempt on introduction of patent linkage system in your economy. (Multiple replies are allowed where appropriate)

- In aspect of pharmaceutical industry, consideration of pharmaceutical industry competitiveness
- In aspect of public health, improvement of public's access to medicines
- In aspect of social infrastructure, no additional cost required to complicate the current drug approval process
- In aspect of socio-political view, the resolution of political conflicts
- Other (please, describe details, if possible) **X**

**In Mexico the patent linkage system already operates**

## (7) Peru

### Survey Questionnaire

#### Survey on Status of Patent Linkage System in APEC member economies

##### Note:

1. Republic of Korea, joined by co-sponsors Japan; Mexico; and Chinese Taipei, is circulating this survey to gather information on introduction and development of Patent Linkage System in APEC member economies.
2. The intent of this survey is to collect information as to distinctions in patent linkage system among APEC member economies and to identify difficulties or obstacles experienced/faced by APEC member economies in introducing/implementing patent linkage system. For detailed information, those questions in this Survey Questionnaire are classified into four sections.

##### Information

Name of Economy: PERU

Contact Information:

Office/Agency: National Institute for the Defense of Competition and  
The Protection of Intellectual Property – INDECOPI  
Position/Title: Patent Director

Office/Agency: National Institute for the Defense of Competition and  
The Protection of Intellectual Property – INDECOPI  
Position/Title: Technical Cooperation Head

##### Background

**Patent linkage system refers to the system that operates the patent system in conjunction with the approval system for drug/pharmaceutical.** Under the patent linkage system, if there is an application for marketing approval of a generic drug relying on the data of a drug patent, the drug authority must take measures to prevent patent infringement in the marketing approval process in consideration of the patent infringement of the generic drug.

**Patent linkage system was designed in the United States to strengthen patent protection for original drugs.** Where patent-related clarification, prohibition of marketing, and notification procedures to the patentee, etc. are required of generic drugs applied for approval, it has the advantage of strengthening the patent protection of the original drug.

**On the other hand, patent linkage system might have the advantage of shortening the clinical trial period and providing incentives for generic drug development,** thereby facilitating generic drugs to enter the market.

**Therefore, patent linkage system needs to be designed in consideration of an appropriate balance between original and generic drugs,** and it is desirable to upgrade it step by step according to the economy's current state of the pharmaceutical industry, public health level, and patent system development, etc.

## **Section One**

### **Competent Authorities and Patent Law Issues related to Patent Linkage System**

**Q1.** What agency/authority is primarily responsible for examination on patent applications in your economy? And what is the legal basis for examination on patent applications?

Agency/Authority: INDECOPI – Directorate of Inventions and New Technologies (DIN)

Legal Basis (law, act, legislation): Andean Community Decision 486, Common Intellectual Property Regime and Legislative Decree No. 1075

Provide citation(s) or links to such materials: <https://wipolex.wipo.int/en/legislation/details/9451>;  
<https://wipolex.wipo.int/es/text/506694>

**Q2.** What agency/authority is primarily responsible for marketing approval of drug/pharmaceutical in your economy? And what is the legal basis for marketing approval of drugs/pharmaceuticals?

Agency/Authority: Ministry of Health – Dirección General de Medicamentos, Insumos y Drogas- DIGEMID

Legal Basis (law, act, legislation):

Provide citation(s) or links to such materials: <https://www.digemid.minsa.gob.pe/UpLoad/UpLoaded/PDF/Ley29459.pdf>

**Q3.** Is it allowed for a patentee to extend the duration of his/her drug patent in your economy?

“Extension for the duration of drug patents means a framework that extends the duration of a drug patent for the period in which the patent could not be practiced due to the licensing process in consideration of the characteristics of drugs that require a long period of time in the licensing process.”

YES

NO

If the answer to Q3 above is “Yes”, please inform us of followings-

Legal Basis (law, act, legislation): Legislative Decree No. 1075 (articles 32 to 35)

Provide citation(s) or links to such materials: <https://wipolex.wipo.int/es/text/506694>

**Under Peruvian law, the extension of a patent does not include pharmaceutical products.**

**Q4.** Is it allowed for a third party to practice/implement a patented invention for clinical trials, research, or experiments necessary for drug licensing in your economy?

“Exception for the practice of a patented invention for clinical trials, etc. means that the act of practicing a patented invention for research or experiments necessary for drug licensing procedures is allowed as an exception that does not constitute patent infringement.”

YES

NO

If the answer to Q3 above is “YES”, please inform us of followings-

Legal Basis (law, act, legislation): **Legislative Decree No. 1075 (article 39)**

Provide citation(s) or links to such materials: <https://wipolex.wipo.int/es/text/506694>

## **Section Two**

### **Introduction and Development of Patent Linkage System**

**Q5.** Has your economy introduced patent linkage system for preventing patent infringement in the process of marketing approval for drug/pharmaceutical?

YES

NO

If the answer to Q5 above is “YES”, please inform us of followings-

The agency/authority primarily responsible for patent linkage system:

The date on which patent linkage system was introduced in your economy:

**Q6.** What are backgrounds to the introduction of patent linkage system in your economy? (Multiple replies are allowed where appropriate)

**Note:** If the answer to Q5 above is “NO”, you don’t have to respond to Q6.

Recognition of necessity for sui generis regimes in regard to patents for drugs/pharmaceuticals

Preemptive response to global standard to address patents for drugs/pharmaceuticals

Conclusion/negotiation of bilateral free trade agreement (FTA)

Ratification/accession/negotiation of multilateral free trade agreement such as CPTPP

Other

If the answer to Q6 above is “Other”, please describe those backgrounds in detail:

**Q7.** Does your economy have any plan to introduce/implement patent linkage system?

**Note:** If the answer to Q5 above is “YES”, you don’t have to respond to Q7.

YES

NO

If the answer to Q7 above is “YES”, please describe those plans or works in progress in detail:

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### **Section Three**

#### **Structure and Key Components of Patent Linkage System**

**Note:** If the answer to Q5 above is “NO”, you don’t have to respond to those Questions under Section Three.

**Q8.** Does your economy have a system for registration and management of drug patents?

“Registration and management of drug patents in patent linkage system refers to a procedure in which patent information related to a licensed drug is submitted to the competent authority for record and management in the list of drug patents.”

- YES  
 NO

If the answer to Q8 above is “YES”, please inform us of followings-

Legal Basis (law, act, legislation):

Provide citation(s) or links to such materials:

The number of drug patents registered in the list of drug patents under patent linkage system:

**Q9.** Does your economy have a system for notification to the patentee involved of the fact that any application for marketing approval of generic drugs has been filed?

“Notification in patent linkage system refers to a procedure in which a person applying for marketing approval of a generic drug notifies the owner of a (registered) patent related to the generic drug of the fact that the application for marketing approval has been filed.”

- YES  
 NO

If the answer to Q9 above is “YES”, please inform us of followings-

Legal Basis (law, act, legislation):

Provide citation(s) or links to such materials:

The number of applications for marketing approval of (generic) drugs notified to the patentee under patent linkage system:

**Q10.** Does your economy have a system for prevention of marketing or reservation of licensing against generic drugs suspected of patent infringement in the marketing approval process of drugs?

“Prevention of marketing or reservation of licensing in patent linkage procedures means the competent authority’s measure to reserve licensing or prevent marketing of (generic) drugs applied for marketing approval upon the request of the patentee based on the notification mentioned in Q9.”

- YES
- NO

If the answer to Q10 above is “YES”, please inform us of followings-

Maximum term for such prevention of marketing or reservation of licensing: (months)

Legal Basis (law, act, legislation):

Provide citation(s) or links to such materials:

The number of requests by patentees to prevent marketing or reserve licensing of generic drugs under patent linkage system:

The number of measures taken by the competent authority to prevent marketing or reserve licensing of generic drugs under patent linkage system:

**Q11.** Does your economy have a system for exclusive marketing approval or generic exclusivity for a generic drug that succeeds in challenging the (registered) patent related to the generic drug?

“Exclusive marketing approval or generic exclusivity in patent linkage procedures means a market monopoly position that allows a person who wins a case against a (registered) patent to exclusively market his/her generic drug for a certain period of time.”

- YES
- NO

If the answer to Q11 above is “YES”, please inform us of followings-

Maximum term for such exclusive marketing approval or generic exclusivity: (months)

Legal Basis (law, act, legislation):

Provide citation(s) or links to such materials:

The number of applications for exclusive marketing approval or generic exclusivity under patent linkage system:

Average term allowed in practice for such exclusive marketing approval or generic exclusivity under patent linkage system: (months)

#### **Section Four**

#### **Obstacles in Introducing Patent Linkage System**

**Note:** If the answer to Q5 above is “YES”, you don’t have to respond to those Questions under Section Four.

**Q12.** Choose which one is the most advantageous point not to attempt on introduction of patent linkage system in your economy. (Multiple replies are allowed where appropriate)

- In aspect of pharmaceutical industry, consideration of pharmaceutical industry competitiveness
- In aspect of public health, improvement of public's access to medicines
- In aspect of social infrastructure, no additional cost required to complicate the current drug approval process
- In aspect of socio-political view, the resolution of political conflicts
- Other (please, describe details, if possible)

## (8) Chinese Taipei

### Survey Questionnaire

#### Survey on Status of Patent Linkage System in APEC member economies

##### Note:

1. Republic of Korea, joined by co-sponsors Japan; Mexico; and Chinese Taipei, is circulating this survey to gather information on introduction and development of Patent Linkage System in APEC member economies.
2. The intent of this survey is to collect information as to distinctions in patent linkage system among APEC member economies and to identify difficulties or obstacles experienced/faced by APEC member economies in introducing/implementing patent linkage system. For detailed information, those questions in this Survey Questionnaire are classified into four sections.

##### Information

Name of Economy: Chinese Taipei

Contact Information:

Office/Agency: TIPO

Position/Title:

##### Background

**Patent linkage system refers to the system that operates the patent system in conjunction with the approval system for drug/pharmaceutical.** Under the patent linkage system, if there is an application for marketing approval of a generic drug relying on the data of a drug patent, the drug authority must take measures to prevent patent infringement in the marketing approval process in consideration of the patent infringement of the generic drug.

**Patent linkage system was designed in the United States to strengthen patent protection for original drugs.** Where patent-related clarification, prohibition of marketing, and notification procedures to the patentee, etc. are required of generic drugs applied for approval, it has the advantage of strengthening the patent protection of the original drug.

**On the other hand, patent linkage system might have the advantage of shortening the clinical trial period and providing incentives for generic drug development,** thereby facilitating generic drugs to enter the market.

**Therefore, patent linkage system needs to be designed in consideration of an appropriate balance between original and generic drugs,** and it is desirable to upgrade it step by step according to the economy's current state of the pharmaceutical industry, public health level, and patent system development, etc.

## **Section One**

### **Competent Authorities and Patent Law Issues related to Patent Linkage System**

**Q1.** What agency/authority is primarily responsible for examination on patent applications in your economy? And what is the legal basis for examination on patent applications?

Agency/Authority: TIPO, Ministry of Economic Affairs

Legal Basis (law, act, legislation): Patent Act

Provide citation(s) or links to such materials: <https://www.tipo.gov.tw/en/mp-2.html>

**Q2.** What agency/authority is primarily responsible for marketing approval of drug/pharmaceutical in your economy? And what is the legal basis for marketing approval of drugs/pharmaceuticals?

Agency/Authority: TFDA, Ministry of Health and Welfare

Legal Basis (law, act, legislation): Pharmaceutical Affairs Act

Provide citation(s) or links to such materials: Article 39 of Pharmaceutical Affairs Act

(<https://law.moj.gov.tw/ENG/LawClass/LawAll.aspx?pcode=L0030001>)

<https://www.fda.gov.tw/ENG/index.aspx>

**Q3.** Is it allowed for a patentee to extend the duration of his/her drug patent in your economy?

“Extension for the duration of drug patents means a framework that extends the duration of a drug patent for the period in which the patent could not be practiced due to the licensing process in consideration of the characteristics of drugs that require a long period of time in the licensing process.”

YES

NO

If the answer to Q3 above is “Yes”, please inform us of followings-

Legal Basis (law, act, legislation): Patent Act (Article 53)

Provide citation(s) or links to such materials: <https://law.moj.gov.tw/ENG/LawClass/LawAll.aspx?pcode=J0070007>

**Q4.** Is it allowed for a third party to practice/implement a patented invention for clinical trials, research, or experiments necessary for drug licensing in your economy?

“Exception for the practice of a patented invention for clinical trials, etc. means that the act of practicing a patented invention for research or experiments necessary for drug licensing procedures is allowed as an exception that does not constitute patent infringement.”

YES

NO

If the answer to Q3 above is “YES”, please inform us of followings-

Legal Basis (law, act, legislation): Patent Act (Article 60)

Provide citation(s) or links to such materials: <https://law.moj.gov.tw/ENG/LawClass/LawAll.aspx?pcode=J0070007>

## **Section Two**

### **Introduction and Development of Patent Linkage System**

**Q5.** Has your economy introduced patent linkage system for preventing patent infringement in the process of marketing approval for drug/pharmaceutical?

- YES  
 NO

If the answer to Q5 above is “YES”, please inform us of followings-

The agency/authority primarily responsible for patent linkage system: TFDA, Ministry of Health and Welfare

The date on which patent linkage system was introduced in your economy:

08/20/2019

**Q6.** What are backgrounds to the introduction of patent linkage system in your economy? (Multiple replies are allowed where appropriate)

**Note:** If the answer to Q5 above is “NO”, you don’t have to respond to Q6.

- Recognition of necessity for sui generis regimes in regard to patents for drugs/pharmaceuticals Preemptive response to global standard to address patents for drugs/pharmaceuticals  
 Conclusion/negotiation of bilateral free trade agreement (FTA)  
 Ratification/accesion/negotiation of multilateral free trade agreement such as CPTPP  
 Other

If the answer to Q6 above is “Other”, please describe those backgrounds in detail:

**Q7.** Does your economy have any plan to introduce/implement patent linkage system?

**Note:** If the answer to Q5 above is “YES”, you don’t have to respond to Q7.

- YES  
 NO

If the answer to Q7 above is “YES”, please describe those plans or works in progress in detail:

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### **Section Three**

#### **Structure and Key Components of Patent Linkage System**

**Note:** If the answer to Q5 above is “NO”, you don’t have to respond to those Questions under Section Three.

**Q8.** Does your economy have a system for registration and management of drug patents?

“Registration and management of drug patents in patent linkage system refers to a procedure in which patent information related to a licensed drug is submitted to the competent authority for record and management in the list of drug patents.”

- YES  
 NO

If the answer to Q8 above is “YES”, please inform us of followings-

Legal Basis (law, act, legislation): Pharmaceutical Affairs Act

Provide citation(s) or links to such materials: Article 48-8 of Pharmaceutical Affairs Act

The number of drug patents registered in the list of drug patents under patent linkage system: 692

**Q9.** Does your economy have a system for notification to the patentee involved of the fact that any application for marketing approval of generic drugs has been filed?

“Notification in patent linkage system refers to a procedure in which a person applying for marketing approval of a generic drug notifies the owner of a (registered) patent related to the generic drug of the fact that the application for marketing approval has been filed.”

- YES  
 NO

If the answer to Q9 above is “YES”, please inform us of followings-

Legal Basis (law, act, legislation): Pharmaceutical Affairs Act

Provide citation(s) or links to such materials: Article 48-12 of Pharmaceutical Affairs

Act(<https://law.moj.gov.tw/ENG/LawClass/LawAll.aspx?pcode=L0030001>)

The number of applications for marketing approval of (generic) drugs notified to the patentee under patent linkage system: 20

**Q10.** Does your economy have a system for prevention of marketing or reservation of licensing against generic drugs suspected of patent infringement in the marketing approval process of drugs?

“Prevention of marketing or reservation of licensing in patent linkage procedures means the competent authority’s measure to reserve licensing or prevent marketing of (generic) drugs applied for marketing approval upon the request of the patentee based on the notification mentioned in Q9.”

- YES  
 NO

If the answer to Q10 above is “YES”, please inform us of followings-

Maximum term for such prevention of marketing or reservation of licensing: 12 (months)

Legal Basis (law, act, legislation): Pharmaceutical Affairs Act

Provide citation(s) or links to such materials: Article 48-13 of Pharmaceutical Affairs Act  
(<https://law.moj.gov.tw/ENG/LawClass/LawAll.aspx?pcode=L0030001>)

The number of requests by patentees to prevent marketing or reserve licensing of generic drugs under patent linkage system: 18

The number of measures taken by the competent authority to prevent marketing or reserve licensing of generic drugs under patent linkage system: 18

**Q11.** Does your economy have a system for exclusive marketing approval or generic exclusivity for a generic drug that succeeds in challenging the (registered) patent related to the generic drug?

“Exclusive marketing approval or generic exclusivity in patent linkage procedures means a market monopoly position that allows a person who wins a case against a (registered) patent to exclusively market his/her generic drug for a certain period of time.”

YES

NO

If the answer to Q11 above is “YES”, please inform us of followings-

Maximum term for such exclusive marketing approval or generic exclusivity: 12 (months)

Legal Basis (law, act, legislation): Pharmaceutical Affairs Act

Provide citation(s) or links to such materials: Article 48-16 of Pharmaceutical Affairs Act  
(<https://law.moj.gov.tw/ENG/LawClass/LawAll.aspx?pcode=L0030001>)

The number of applications for exclusive marketing approval or generic exclusivity under patent linkage system: 1

Average term allowed in practice for such exclusive marketing approval or generic exclusivity under patent linkage system: 12 (months)

#### **Section Four**

#### **Obstacles in Introducing Patent Linkage System**

**Note:** If the answer to Q5 above is “YES”, you don’t have to respond to those Questions under Section Four.

**Q12.** Choose which one is the most advantageous point not to attempt on introduction of patent linkage system in your economy. (Multiple replies are allowed where appropriate)

- In aspect of pharmaceutical industry, consideration of pharmaceutical industry competitiveness
- In aspect of public health, improvement of public's access to medicines
- In aspect of social infrastructure, no additional cost required to complicate the current drug approval process
- In aspect of socio-political view, the resolution of political conflicts
- Other (please, describe details, if possible)

## (9) Thailand

### Survey Questionnaire

#### Survey on Status of Patent Linkage System in APEC member economies

##### Note:

1. Republic of Korea, joined by co-sponsors Japan; Mexico; and Chinese Taipei, is circulating this survey together information on introduction and development of Patent Linkage System in APEC member economies.
2. The intent of this survey is to collect information as to distinctions in patent linkage system among APEC member economies and to identify difficulties or obstacles experienced/faced by APEC member economies in introducing/implementing patent linkage system. For detailed information, those questions in this Survey Questionnaire are classified into four sections.

##### Information

Name of Economy: Thailand

Contact Information:

Office/Agency: Department of Intellectual Property, Ministry of Commerce

Position/Title: Head of Regional Affairs, International Affairs Office

##### Background

**Patent linkage system refers to the system that operates the patent system in conjunction with the approval system for drug/pharmaceutical.** Under the patent linkage system, if there is an application for marketing approval of a generic drug relying on the data of a drug patent, the drug authority must take measures to prevent patent infringement in the marketing approval process in consideration of the patent infringement of the generic drug.

**Patent linkage system was designed in the United States to strengthen patent protection for original drugs.** Where patent-related clarification, prohibition of marketing, and notification procedures to the patentee, etc. are required of generic drugs applied for approval, it has the advantage of strengthening the patent protection of the original drug.

**On the other hand, patent linkage system might have the advantage of shortening the clinical trial period and providing incentives for generic drug development,** thereby facilitating generic drugs to enter the market.

**Therefore, patent linkage system needs to be designed in consideration of an appropriate balance between original and generic drugs,** and it is desirable to upgrade it step by step according to the economy's current state of the pharmaceutical industry, public health level, and patent system development, etc.

## **Section One**

### **Competent Authorities and Patent Law Issues related to Patent Linkage System**

**Q1.** What agency/authority is primarily responsible for examination on patent applications in your economy? And what is the legal basis for examination on patent applications?

Agency/Authority: Patent Office, Department of Intellectual Property, Ministry of Commerce

Legal Basis (law, act, legislation): Patent Act B.E.2522 and its amendments

Provide citation(s) or links to such materials: [www.ipthailand.go.th](http://www.ipthailand.go.th)

**Q2.** What agency/authority is primarily responsible for marketing approval of drug/pharmaceutical in your economy? And what is the legal basis for marketing approval of drugs/pharmaceuticals?

Agency/Authority: Food and Drug Administration, Ministry of Public Health

Legal Basis (law, act, legislation): Drug Act .E.2510 and its amendments

Provide citation(s) or links to such materials: <https://www.fda.moph.go.th>

**Q3.** Is it allowed for a patentee to extend the duration of his/her drug patent in your economy?

*“Extension for the duration of drug patents means a framework that extends the duration of a drug patent for the period in which the patent could not be practiced due to the licensing process in consideration of the characteristics of drugs that require a long period of time in the licensing process.”*

- YES  
 NO

If the answer to Q3 above is “Yes”, please inform us of followings-

Legal Basis (law, act, legislation):

Provide citation(s) or links to such materials:

**Q4.** Is it allowed for a third party to practice/implement a patented invention for clinical trials, research, or experiments necessary for drug licensing in your economy?

*“Exception for the practice of a patented invention for clinical trials, etc. means that the act of practicing a patented invention for research or experiments necessary for drug licensing procedures is allowed as an exception that does not constitute patent infringement.”*

- YES  
 NO

If the answer to Q4 above is “YES”, please inform us of followings-

Legal Basis (law, act, legislation): Patent Act B.E.2522 (Article 36.2 (4))

Provide citation(s) or links to such materials: [www.ipthailand.go.th](http://www.ipthailand.go.th)

## **Section Two**

### **Introduction and Development of Patent Linkage System**

**Q5.** Has your economy introduced patent linkage system for preventing patent infringement in the process of marketing approval for drug/pharmaceutical?

**YES**

**NO**

If the answer to Q5 above is “YES”, please inform us of followings-

The agency/authority primarily responsible for patent linkage system:

The date on which patent linkage system was introduced in your economy:

**Q6.** What are backgrounds to the introduction of patent linkage system in your economy? (Multiple replies are allowed where appropriate)

**Note:** If the answer to Q5 above is “NO”, you don’t have to respond to Q6.

- Recognition of necessity for sui generis regimes in regard to patents for drugs/pharmaceuticals Preemptive
- response to global standard to address patents for drugs/pharmaceuticals Conclusion/negotiation of bilateral free
- trade agreement (FTA)
  
- Ratification/accession/negotiation of multilateral free trade agreement such as CPTPP
  
- Other

If the answer to Q6 above is “Other”, please describe those backgrounds in detail:

**Q7.** Does your economy have any plan to introduce/implement patent linkage system?

**Note:** If the answer to Q5 above is “YES”, you don’t have to respond to Q7.

**YES**

**NO**

If the answer to Q7 above is “YES”, please describe those plans or works in progress in detail:

### **Section Three**

#### **Structure and Key Components of Patent Linkage System**

**Note:** If the answer to Q5 above is “NO”, you don’t have to respond to those Questions under Section Three.

**Q8.** Does your economy have a system for registration and management of drug patents?

*“Registration and management of drug patents in patent linkage system refers to a procedure in which patent information related to a licensed drug is submitted to the competent authority for record and management in the list of drug patents.”*

**YES**

**NO**

If the answer to Q8 above is “YES”, please inform us of followings-

Legal Basis (law, act, legislation):

Provide citation(s) or links to such materials:

The number of drug patents registered in the list of drug patents under patent linkage system:

**Q9.** Does your economy have a system for notification to the patentee involved of the fact that any application for marketing approval of generic drugs has been filed?

*“Notification in patent linkage system refers to a procedure in which a person applying for marketing approval of a generic drug notifies the owner of a (registered) patent related to the generic drug of the fact that the application for marketing approval has been filed.”*

**YES**

**NO**

If the answer to Q9 above is “YES”, please inform us of followings-

Legal Basis (law, act, legislation):

Provide citation(s) or links to such materials:

The number of applications for marketing approval of (generic) drugs notified to the patentee under patent linkage system:

**Q10.** Does your economy have a system for prevention of marketing or reservation of licensing against generic drugs suspected of patent infringement in the marketing approval process of drugs?

*“Prevention of marketing or reservation of licensing in patent linkage procedures means the competent authority’s measure to reserve licensing or prevent marketing of (generic) drugs applied for marketing approval upon the request of the patentee based on the notification mentioned in Q9.”*

- YES**  
 **NO**

If the answer to Q10 above is “YES”, please inform us of followings-

Maximum term for such prevention of marketing or reservation of licensing: (months)

Legal Basis (law, act, legislation):

Provide citation(s) or links to such materials:

The number of requests by patentees to prevent marketing or reserve licensing of generic drugs under patent linkage system:

The number of measures taken by the competent authority to prevent marketing or reserve licensing of generic drugs under patent linkage system:

**Q11.** Does your economy have a system for exclusive marketing approval or generic exclusivity for a generic drug that succeeds in challenging the (registered) patent related to the generic drug?

*“Exclusive marketing approval or generic exclusivity in patent linkage procedures means a market monopoly position that allows a person who wins a case against a (registered) patent to exclusively market his/her generic drug for a certain period of time.”*

- YES**  
 **NO**

If the answer to Q11 above is “YES”, please inform us of followings-

Maximum term for such exclusive marketing approval or generic exclusivity: (months)

Legal Basis (law, act, legislation):

Provide citation(s) or links to such materials:

The number of applications for exclusive marketing approval or generic exclusivity under patent linkage system:

Average term allowed in practice for such exclusive marketing approval or generic exclusivity under patent linkage system: (months)

## **Section Four**

### **Obstacles in Introducing Patent Linkage System**

**Note:** If the answer to Q5 above is “YES”, you don’t have to respond to those Questions under Section Four.

**Q12.** Choose which one is the most advantageous point not to attempt on introduction of patent linkage system in your economy. (Multiple replies are allowed where appropriate)

- In aspect of pharmaceutical industry, consideration of pharmaceutical industry competitiveness
- In aspect of public health, improvement of public's access to medicines
- In aspect of social infrastructure, no additional cost required to complicate the current drug approval process
- In aspect of socio-political view, the resolution of political conflicts Other (please, describe details, if possible)

## (10) United States

### Survey Questionnaire

#### Survey on Status of Patent Linkage System in APEC member economies

##### Note:

1. Republic of Korea, joined by co-sponsors Japan; Mexico; and Chinese Taipei, is circulating this survey to gather information on introduction and development of Patent Linkage System in APEC member economies.
2. The intent of this survey is to collect information as to distinctions in patent linkage system among APEC member economies and to identify difficulties or obstacles experienced/faced by APEC member economies in introducing/implementing patent linkage system. For detailed information, those questions in this Survey Questionnaire are classified into four sections.

##### Information

Name of Economy: The United States

Contact Information:

Office/Agency: USTR

Position/Title: Senior Director for

Innovation and Intellectual Property

##### Background

**Patent linkage system refers to the system that operates the patent system in conjunction with the approval system for drug/pharmaceutical.** Under the patent linkage system, if there is an application for marketing approval of a generic drug relying on the data of a drug patent, the drug authority must take measures to prevent patent infringement in the marketing approval process in consideration of the patent infringement of the generic drug.

**Patent linkage system was designed in the United States to strengthen patent protection for original drugs.** Where patent-related clarification, prohibition of marketing, and notification procedures to the patentee, etc. are required of generic drugs applied for approval, it has the advantage of strengthening the patent protection of the original drug.

**On the other hand, patent linkage system might have the advantage of shortening the clinical trial period and providing incentives for generic drug development,** thereby facilitating generic drugs to enter the market.

**Therefore, patent linkage system needs to be designed in consideration of an appropriate balance between original and generic drugs,** and it is desirable to upgrade it step by step according to the economy's current state of the pharmaceutical industry, public health level, and patent system development, etc.

## General Comments

The United States does not agree with certain aspects of the characterization of the patent linkage system in the Background section as it relates to statutory and regulatory requirements in the United States. The United States also does not agree with certain definitions or phrasing in the survey questions but attempted to provide relevant responses. In our responses, we have attempted to answer with respect to pharmaceutical products generally, even though some questions used the phrasing “generic drugs,” which has a specific meaning under the US law.

## Section One

### Competent Authorities and Patent Law Issues related to Patent Linkage System

**Q1.** What agency/authority is primarily responsible for examination on patent applications in your economy? And what is the legal basis for examination on patent applications?

Agency/Authority: the US Patent and Trademark Office

Legal Basis (law, act, legislation): law and regulations

Provide citation(s) or links to such materials: 35 U.S.C. § 1-3; 35 U.S.C. § 131; 37 C.F.R. 1.101-110

**Q2.** What agency/authority is primarily responsible for marketing approval of drug/pharmaceutical in your economy? And what is the legal basis for marketing approval of drugs/pharmaceuticals?

Agency/Authority: the [US Food and Drug Administration \(FDA\)](#)

Legal Basis (law, act, legislation): [Federal Food, Drug, and Cosmetic Act \(FD&C Act\)](#) and the [Public Health Service Act \(PHS Act\)](#)

Provide citation(s) or links to such materials: [21 U.S.C. 355 et seq.](#) and [42 U.S.C. 262.](#)

FDA’s responses below are limited to drug products approved under the FD&C Act and do not address biological products licensed under the PHS Act.

**Q3.** Is it allowed for a patentee to extend the duration of his/her drug patent in your economy?

“Extension for the duration of drug patents means a framework that extends the duration of a drug patent for the period in which the patent could not be practiced due to the licensing process in consideration of the characteristics of drugs that require a long period of time in the licensing process.”

YES

NO

If the answer to Q3 above is “Yes”, please inform us of followings-

Legal Basis (law, act, legislation): Drug Price Competition and Patent Term Restoration Act of 1984 (Pub. L. 98-417)

Provide citation(s) or links to such materials: 35 U.S.C. § 156; 37 C.F.R. 1.710-1.791

**Q4.** Is it allowed for a third party to practice/implement a patented invention for clinical trials, research, or experiments necessary for drug licensing in your economy?

“Exception for the practice of a patented invention for clinical trials, etc. means that the act of practicing a patented invention for research or experiments necessary for drug licensing procedures is allowed as an exception that does not constitute patent infringement.”

YES

NO

If the answer to Q3 above is “YES”, please inform us of followings-

Legal Basis (law, act, legislation): [law](#)

Provide citation(s) or links to such materials: [35 U.S.C. § 271\(e\)\(1\)](#)

## **Section Two**

### **Introduction and Development of Patent Linkage System**

**Q5.** Has your economy introduced patent linkage system for preventing patent infringement in the process of marketing approval for drug/pharmaceutical?

- YES  
 NO

If the answer to Q5 above is “YES”, please inform us of followings-

The agency/authority primarily responsible for patent linkage system: [FDA](#)

The date on which patent linkage system was introduced in your economy: [1984](#).

**Q6.** What are backgrounds to the introduction of patent linkage system in your economy? (Multiple replies are allowed where appropriate)

**Note:** If the answer to Q5 above is “NO”, you don’t have to respond to Q6.

- Recognition of necessity for sui generis regimes in regard to patents for drugs/pharmaceuticals  
 Preemptive response to global standard to address patents for drugs/pharmaceuticals  
 Conclusion/negotiation of bilateral free trade agreement (FTA)  
 Ratification/accession/negotiation of multilateral free trade agreement such as CPTPP  
 Other

If the answer to Q6 above is “Other”, please describe those backgrounds in detail:

Through amendments to both the patent law and the food and drug law, the Hatch-Waxman Act established several practices intended to facilitate the marketing of generic pharmaceuticals while providing brand name firms with incentives to innovate.

The US system uses different mechanisms for biologics and biosimilars to address similar policy goals. The US system provides notice, adequate time, and opportunity, as well as procedures and remedies for the timely resolution of patent disputes related to biologics and biosimilars. Relevant provisions are found in the Biologics Price Competition and Innovation Act of 2009 and codified at 42 U.S.C. § 262(l), as well as in the Biological Product Patent Transparency (BPPT) section of the Consolidated Appropriations Act of 2021.

**Q7.** Does your economy have any plan to introduce/implement patent linkage system?

**Note:** If the answer to Q5 above is “YES”, you don’t have to respond to Q7.

- YES  
 NO

If the answer to Q7 above is “YES”, please describe those plans or works in progress in detail:

### **Section Three**

#### **Structure and Key Components of Patent Linkage System**

**Note:** If the answer to Q5 above is “NO”, you don’t have to respond to those Questions under Section Three.

**Q8.** Does your economy have a system for registration and management of drug patents?

“Registration and management of drug patents in patent linkage system refers to a procedure in which patent information related to a licensed drug is submitted to the competent authority for record and management in the list of drug patents.”

- YES  
 NO

If the answer to Q8 above is “YES”, please inform us of followings-

Legal Basis (law, act, legislation): [FD&C Act](#); [PHS Act](#)

Provide citation(s) or links to such materials: [21 U.S.C. 355\(b\)\(1\)\(A\)\(viii\), \(c\)\(2\); section 351\(k\)\(9\)\(A\)\(iii\) of the PHS Act](#)

The number of drug patents registered in the list of drug patents under patent linkage system: [FDA’s publication Approved Drug Products With Therapeutic Equivalence Evaluations \(commonly known as the Orange Book\)](#) provides patent information concerning approved drug products and is publicly available on our web site at <https://www.fda.gov/drugs/drug-approvals-and-databases/approved-drug-products-therapeutic-equivalence-evaluations-orange-book>. With respect to biological products, the Biological Product Patent Transparency (BPPT) section of the Consolidated Appropriations Act of 2021 requires FDA to publish patent lists provided by reference product sponsors (i.e., a holder of a biologics license application (BLA) licensed under section 351(a) of the PHS Act) to FDA for certain licensed biological products. This publication is known as FDA’s “Purple Book” and related obligations for sponsors of biological products are described in Section 351(k)(9)(A)(iii) of the PHS Act.

**Q9.** Does your economy have a system for notification to the patentee involved of the fact that any application for marketing approval of generic drugs has been filed?

“Notification in patent linkage system refers to a procedure in which a person applying for marketing approval of a generic drug notifies the owner of a (registered) patent related to the generic drug of the fact that the application for marketing approval has been filed.”

- YES  
 NO

If the answer to Q9 above is “YES”, please inform us of followings-

Legal Basis (law, act, legislation): [FD&C Act](#); [PHS Act](#)

Provide citation(s) or links to such materials: [21 U.S.C. 355\(b\)\(3\) and \(j\)\(2\)\(B\); 42 U.S.C. 262\(l\)](#)

The number of applications for marketing approval of (generic) drugs notified to the patentee under patent linkage system: [We do not have this information readily available at this time.](#)

**Note:** The US system uses different mechanisms for biologics and biosimilars to address similar policy goals. The US system still provides notice, adequate time, and opportunity, as well as procedures and remedies for the timely resolution of patent disputes related to biologics and biosimilars.

**Q10.** Does your economy have a system for prevention of marketing or reservation of licensing against generic drugs suspected of patent infringement in the marketing approval process of drugs?

“Prevention of marketing or reservation of licensing in patent linkage procedures means the competent authority’s measure to reserve licensing or prevent marketing of (generic) drugs applied for marketing approval upon the request of the patentee based on the notification mentioned in Q9.”

- YES  
 NO

If the answer to Q10 above is “YES”, please inform us of followings-

Maximum term for such prevention of marketing or reservation of licensing: (months) For drug products (which are generally small molecule), in general, 30 months beginning on the date of the receipt of the notice, if an action is brought for infringement of the patent that is the subject of the notice before the expiration of 45 days after the date on which the notice is received, or 7.5 years from the date of the approval of the drug that the generic drug relies upon, if an action for patent infringement is commenced during the one-year period beginning 48 months after the date of the approval of that drug and the drug is a new chemical entity.

For biological products, the significantly longer (12 years) data protection period allows time and opportunity before marketing approval to litigate without the need for a stay in the marketing approval process. However, there is still notice, adequate time, and opportunity, as well as procedures and remedies for the timely resolution of patent disputes.

Legal Basis (law, act, legislation): [FD&C Act](#); [PHS Act](#)

Provide citation(s) or links to such materials: [21 U.S.C. 355\(c\)\(3\)\(C\)](#), [\(E\)\(ii\)](#); [21 U.S.C. 355\(j\)\(5\)\(B\)\(iii\)](#), [\(F\)\(ii\)](#); [42 U.S.C. 262\(l\)](#)

The number of requests by patentees to prevent marketing or reserve licensing of generic drugs under patent linkage system: [We do not have this information readily available at this time; however, we have attached a Report to Congress from fiscal year 2020, which may have pertinent information.](#)

The number of measures taken by the competent authority to prevent marketing or reserve licensing of generic drugs under patent linkage system: [We do not have this information readily available at this time.](#)

**Q11.** Does your economy have a system for exclusive marketing approval or generic exclusivity for a generic drug that succeeds in challenging the (registered) patent related to the generic drug?

“Exclusive marketing approval or generic exclusivity in patent linkage procedures means a market monopoly position that allows a person who wins a case against a (registered) patent to exclusively market his/her generic drug for a certain period of time.”

- YES (note: [this exclusivity is not dependent on the outcome of the patent litigation](#))  
 NO

If the answer to Q11 above is “YES”, please inform us of followings-

Maximum term for such exclusive marketing approval or generic exclusivity: (months) [180 days](#)

Legal Basis (law, act, legislation): [FD&C Act](#)

Provide citation(s) or links to such materials: 21 U.S.C. 355(j)(5)(B)(iv)

The number of applications for exclusive marketing approval or generic exclusivity under patent linkage system: We do not have this information readily available at this time, but we have provided a link to FDA's website containing the Paragraph IV Certifications List, which may have pertinent information: <https://www.fda.gov/drugs/abbreviated-new-drug-application-anda/patent-certifications-and-suitability-petitions#List>.

Average term allowed in practice for such exclusive marketing approval or generic exclusivity under patent linkage system: (months) We do not have this information readily available at this time, but we have provided a link to FDA's website containing the Paragraph IV Certifications List, which may have pertinent information: <https://www.fda.gov/drugs/abbreviated-new-drug-application-anda/patent-certifications-and-suitability-petitions#List>

#### **Section Four**

#### **Obstacles in Introducing Patent Linkage System**

**Note:** If the answer to Q5 above is “YES”, you don’t have to respond to those Questions under Section Four.

**Q12.** Choose which one is the most advantageous point not to attempt on introduction of patent linkage system in your economy. (Multiple replies are allowed where appropriate)

- In aspect of pharmaceutical industry, consideration of pharmaceutical industry competitiveness
- In aspect of public health, improvement of public's access to medicines
- In aspect of social infrastructure, no additional cost required to complicate the current drug approval process
- In aspect of socio-political view, the resolution of political conflicts
- Other (please, describe details, if possible)

## (11) Viet Nam

### Survey Questionnaire

#### Survey on Status of Patent Linkage System in APEC member economies

##### Note:

1. Republic of Korea, joined by co-sponsors Japan; Mexico; and Chinese Taipei, is circulating this survey to gather information on introduction and development of Patent Linkage System in APEC member economies.
2. The intent of this survey is to collect information as to distinctions in patent linkage system among APEC member economies and to identify difficulties or obstacles experienced/faced by APEC member economies in introducing/implementing patent linkage system. For detailed information, those questions in this Survey Questionnaire are classified into four sections.

##### Information

Name of Economy: **Viet Nam**

Contact Information:

Office/Agency: **Intellectual Property Office of Viet Nam**

Position/Title: **Legal Official**

##### Background

**Patent linkage system refers to the system that operates the patent system in conjunction with the approval system for drug/pharmaceutical.** Under the patent linkage system, if there is an application for marketing approval of a generic drug relying on the data of a drug patent, the drug authority must take measures to prevent patent infringement in the marketing approval process in consideration of the patent infringement of the generic drug.

**Patent linkage system was designed in the United States to strengthen patent protection for original drugs.** Where patent-related clarification, prohibition of marketing, and notification procedures to the patentee, etc. are required of generic drugs applied for approval, it has the advantage of strengthening the patent protection of the original drug.

**On the other hand, patent linkage system might have the advantage of shortening the clinical trial period and providing incentives for generic drug development,** thereby facilitating generic drugs to enter the market.

**Therefore, patent linkage system needs to be designed in consideration of an appropriate balance between original and generic drugs,** and it is desirable to upgrade it step by step according to the economy's current state of the pharmaceutical industry, public health level, and patent system development, etc.

## Section One

### Competent Authorities and Patent Law Issues related to Patent Linkage System

**Q1.** What agency/authority is primarily responsible for examination on patent applications in your economy? And what is the legal basis for examination on patent applications?

Agency/Authority: Intellectual Property Office of **Viet Nam**

Legal Basis (law, act, legislation): Law on Intellectual Property; Circular No. 01/2007/TT-BKHCN of 14 February, 2007, guiding the implementation of the government's Decree No. 103/2006/ND-CP of 22 September, 2006, detailing and guiding the implementation of a number of articles of the Law on Intellectual Property regarding industrial property

Provide citation(s) or links to such materials:

[https://ipvietnam.gov.vn/vi\\_VN/web/guest/bo-luat-luat](https://ipvietnam.gov.vn/vi_VN/web/guest/bo-luat-luat)

(<https://ipvietnam.gov.vn/documents/20182/1226838/5.1.+Luat+So+huu+tri+tue+2005.pdf/25549ba4-86cc-41e9-b8cc-02c562c1934d>) ;

[https://ipvietnam.gov.vn/vi\\_VN/web/guest/thong-tu](https://ipvietnam.gov.vn/vi_VN/web/guest/thong-tu)

(<https://ipvietnam.gov.vn/documents/20182/1227912/8.1.+Th%C3%B4ng+t%C6%B0+s%E1%BB%91+01.2007.TT.BKHCN.pdf/52867dd8-3191-481a-8ec8-117bb0b25fc0>)

**Q2.** What agency/authority is primarily responsible for marketing approval of drug/pharmaceutical in your economy? And what is the legal basis for marketing approval of drugs/pharmaceuticals?

Agency/Authority: Drug Administration of **Viet Nam** (of Ministry of Health)

Legal Basis (law, act, legislation): Law on Pharmacy; Circular No. 32/2018/TT-BYT of November 12, 2018, marketing authorization of drugs and medicinal ingredients.

Provide citation(s) or links to such materials: <https://dav.gov.vn/info-document-221.html> ; <https://dav.gov.vn/info-document-248.html>

**Q3.** Is it allowed for a patentee to extend the duration of his/her drug patent in your economy?

“Extension for the duration of drug patents means a framework that extends the duration of a drug patent for the period in which the patent could not be practiced due to the licensing process in consideration of the characteristics of drugs that require a long period of time in the licensing process.”

YES

NO

If the answer to Q3 above is “Yes”, please inform us of followings-

Legal Basis (law, act, legislation):

Provide citation(s) or links to such materials:

**Q4.** Is it allowed for a third party to practice/implement a patented invention for clinical trials, research, or experiments necessary for drug licensing in your economy?

“Exception for the practice of a patented invention for clinical trials, etc. means that the act of practicing a patented invention for research or experiments necessary for drug licensing procedures is allowed as an exception that does not constitute patent infringement.”

- YES  
 NO

If the answer to Q3 above is “YES”, please inform us of followings-

Legal Basis (law, act, legislation): Law on Intellectual Property

Provide citation(s) or links to such materials:

**“Article 125. Right to prevent others from using industrial property objects**

2. Owners of industrial property objects as well as organizations and individuals granted the right to use or the right to manage geographical indications shall not have the right to prevent others from performing the following acts:

(a) Using inventions, industrial designs or layout designs in service of their personal needs or for non-commercial purposes, or for purposes of evaluation, analysis, research, teaching, testing, trial production or information collection for carrying out procedures of application for licences for production, importation or circulation of products;”

[https://ipvietnam.gov.vn/vi\\_VN/web/guest/bo-luat-luat](https://ipvietnam.gov.vn/vi_VN/web/guest/bo-luat-luat)

<https://ipvietnam.gov.vn/documents/20182/1226838/5.1.+Luat+So+huu+tri+tue+2005.pdf/25549ba4-86cc-41e9-b8cc-02c562c1934d>

## Section Two

### Introduction and Development of Patent Linkage System

**Q5.** Has your economy introduced patent linkage system for preventing patent infringement in the process of marketing approval for drug/pharmaceutical?

- YES  
 NO

If the answer to Q5 above is “YES”, please inform us of followings-

The agency/authority primarily responsible for patent linkage system: Drug Administration of **Viet Nam** (of Ministry of Health)

The date on which patent linkage system was introduced in your economy: The Law amending and supplementing a number of articles of the law on intellectual property (Act No. 07/2022/QH145), which was promulgated on 16 June, 2022, will come into effect on 1<sup>st</sup> January 2023 (Article 128)

**Q6.** What are backgrounds to the introduction of patent linkage system in your economy? (Multiple replies are allowed where appropriate)

**Note:** If the answer to Q5 above is “NO”, you don’t have to respond to Q6.

- Recognition of necessity for sui generis regimes in regard to patents for drugs/pharmaceuticals  
 Preemptive response to global standard to address patents for drugs/pharmaceuticals  
 Conclusion/negotiation of bilateral free trade agreement (FTA)  
    **Ratification/accession/negotiation of multilateral free trade agreement such as CPTPP**  
 Other

If the answer to Q6 above is “Other”, please describe those backgrounds in detail:

**Q7.** Does your economy have any plan to introduce/implement patent linkage system?

**Note:** If the answer to Q5 above is “YES”, you don’t have to respond to Q7.

- YES  
 NO

If the answer to Q7 above is “YES”, please describe those plans or works in progress in detail:

### Section Three

#### Structure and Key Components of Patent Linkage System

**Note:** If the answer to Q5 above is “NO”, you don’t have to respond to those Questions under Section Three.

**Q8.** Does your economy have a system for registration and management of drug patents?

“Registration and management of drug patents in patent linkage system refers to a procedure in which patent information related to a licensed drug is submitted to the competent authority for record and management in the list of drug patents.”

YES

NO

If the answer to Q8 above is “YES”, please inform us of followings-

Legal Basis (law, act, legislation):

Provide citation(s) or links to such materials:

The number of drug patents registered in the list of drug patents under patent linkage system:

**Q9.** Does your economy have a system for notification to the patentee involved of the fact that any application for marketing approval of generic drugs has been filed?

“Notification in patent linkage system refers to a procedure in which a person applying for marketing approval of a generic drug notifies the owner of a (registered) patent related to the generic drug of the fact that the application for marketing approval has been filed.”

YES

NO

If the answer to Q9 above is “YES”, please inform us of followings-

Legal Basis (law, act, legislation): The Law amending and supplementing a number of articles of the law on intellectual property (Act No. 07/2022/QH145), which was promulgated on 16 June, 2022, **will come into effect on 1<sup>st</sup> January 2023** (Article 128)

Provide citation(s) or links to such materials:

“Article 128.

3.If the competent authority permits the later applicant, other than the applicant originally submitting the safety and efficacy information, to rely on evidence of prior marketing approval of a product or information concerning the safety and efficacy of a product that was previously approved, in applying for marketing approval of a generic drug, the competent authority shall publish, on their web portal or website, information of the later application within five months before the drug in such later application is approved for marketing, unless the marketing approval needs to be granted earlier in accordance with other relevant laws.”

<https://ipvietnam.gov.vn/documents/20195/1326404/Luat+sua+doi%2C+bo+sung+mot+so+dieu+cua+Luat+So+huu+tri+tue.pdf/e4fc7dc2-2e7b-4a6a-99d6-7a9ae7caf90f>

The number of applications for marketing approval of (generic) drugs notified to the patentee under patent linkage system: 0

**Q10.** Does your economy have a system for prevention of marketing or reservation of licensing against generic drugs suspected of patent infringement in the marketing approval process of drugs?

“Prevention of marketing or reservation of licensing in patent linkage procedures means the competent authority’s measure to reserve licensing or prevent marketing of (generic) drugs applied for marketing approval upon the request of the patentee based on the notification mentioned in Q9.”

YES

NO

If the answer to Q10 above is “YES”, please inform us of followings-

Maximum term for such prevention of marketing or reservation of licensing: (months)

Legal Basis (law, act, legislation):

Provide citation(s) or links to such materials:

The number of requests by patentees to prevent marketing or reserve licensing of generic drugs under patent linkage system:

The number of measures taken by the competent authority to prevent marketing or reserve licensing of generic drugs under patent linkage system:

**Q11.** Does your economy have a system for exclusive marketing approval or generic exclusivity for a generic drug that succeeds in challenging the (registered) patent related to the generic drug?

“Exclusive marketing approval or generic exclusivity in patent linkage procedures means a market monopoly position that allows a person who wins a case against a (registered) patent to exclusively market his/her generic drug for a certain period of time.”

YES

NO

If the answer to Q11 above is “YES”, please inform us of followings-

Maximum term for such exclusive marketing approval or generic exclusivity: (months)

Legal Basis (law, act, legislation):

Provide citation(s) or links to such materials:

The number of applications for exclusive marketing approval or generic exclusivity under patent linkage system:

Average term allowed in practice for such exclusive marketing approval or generic exclusivity under patent linkage system: (months)

## **Section Four**

### **Obstacles in Introducing Patent Linkage System**

**Note:** If the answer to Q5 above is “YES”, you don’t have to respond to those Questions under Section Four.

**Q12.** Choose which one is the most advantageous point not to attempt on introduction of patent linkage system in your economy. (Multiple replies are allowed where appropriate)

- In aspect of pharmaceutical industry, consideration of pharmaceutical industry competitiveness
- In aspect of public health, improvement of public's access to medicines
- In aspect of social infrastructure, no additional cost required to complicate the current drug approval process
- In aspect of socio-political view, the resolution of political conflicts
- Other (please, describe details, if possible)

