LAN Patent Linkage Systems in APAC: Annexes

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Australia

Is there any similar system to harmonise the relationship between innovator and generic drugs?

While Australia does not maintain a patent linkage system,[1] it has implemented a similar (albeit significantly more tenuous) regime, which aims to provide potential notice of generic/biosimilar entry to innovator companies.

Section 26B(1) of the *Therapeutic Goods Act 1989* (Cth) (the federal legislation governing the safety and efficacy of pharmaceutical products and medical devices) was introduced to fulfil Australia's obligations under its 2005 free-trade agreement with the United States. The section requires a generic/biosimilar company applying for registration of its product on the Australian Register of Therapeutic Goods (**ARTG**), if relying on a patentee's evidence or information regarding safety or efficacy of the good (section 26B(1A)), to certify that either:

— it, acting in good faith, believes on reasonable grounds that marketing its therapeutic good would not infringe a valid claim of a patent that has been granted; or

— it has given the patentee notice of the application for ARTG registration.

As noted by the Therapeutic Goods Administration (**TGA**) (the government agency responsible for maintaining the ARTG and approving new medicines), the invariable practice of generic/biosimilar entrants is to provide a certificate stating that no valid claim is infringed, on the basis that the entrant believes any patent granted in relation to the product is invalid. As a result, generic/biosimilar entrants seldom provide formal notice to innovators.[2]

Further, even where a notification to a patentee under section 26B(1)(b) is provided, there is no requirement that the TGA decline marketing approval for the new product. By contrast, other patent linkage regimes, such as that in the US, permit a patentee to obtain a stay of marketing approval by commencing proceedings. In Australia, the onus is instead on the patentee to prevent market entry by seeking (and obtaining) a preliminary injunction, which will be discussed in more detail below.

Consequences of providing certificate or notice that no certificate is required

If the generic/biosimilar entrant is required to provide a certificate to the TGA secretary in accordance with section 26B(1) and the entrant does so, the entrant's therapeutic good(s) must be included in the Register and a certificate of registration must be provided to the entrant, without the Secretary assessing the veracity of the certificate provided. However, if the section 26B(1) certificate is false or misleading in a material particular, this constitutes an offence under section 26B(2), attracting a penalty of 1000 penalty units (currently equivalent to AUD 222,000). It is important to note that despite this offence existing, no one has been prosecuted under this offence.[3]

[1] In Australia, the regulator plays a more passive role than in other jurisdictions – it does not operate databases such as the Orange Book and Purple Book, which are maintained by the US FDA, with the former providing information about patents covering small molecule drugs, and the latter product information about approved licensed biologicals, though not concerning patents covering the biologicals.

[2] However, note that since January 2021, information concerning new medicines, new uses for existing medicines, and new combinations that have been accepted for evaluation are published on the TGA website, though not about biosimilar and generic medicines, or variations to existing medicines. The *Therapeutic Goods Act* did not require amending for the TGA to implement this change. Rather, the TGA could rely on section 61, conferring broad powers upon the TGA to release information about actions or decisions they have made.

[3] https://www.lawcouncil.asn.au/publicassets/1a7fdbda-e8a6-ea11-9434-005056be13b5/3825%20--%20Prescription%20medicines%20transparency%20measures.pdf

If no certificate is required since the entrant is not relying on evidence or information of the patentee to establish the safety or efficacy of the good (section 26B(1A)), the entrant is required to submit a written notice in an approved form to the TGA secretary stating that a section 26B(1) certificate is not required. As is the case for certificates under section 26B(1), if such a notice is provided, the Secretary must include the therapeutic good in the Register and provide the entrant with a certificate of registration, without verifying the correctness of the notice provided.

Provisions addressing patent infringement proceedings and preliminary injunctions

Section 26C – Certificates required in relation to patent infringement proceedings

Section 26C of the *Therapeutic Goods Act* is enlivened if the generic/biosimilar entrant has provided a certificate under either section 26B(1)(a) or section 26B(1)(b) and the patentee (or other person with standing) intends to commence patent infringement proceedings.

Section 26C provides that before the patentee can commence proceedings, they must give the TGA secretary and the generic/biosimilar entrant a signed certificate in an approved form that the proceedings are to be commenced in good faith, have reasonable prospects of success (as defined in section 26C(4)), and will be conducted without unreasonable delay.

If the patentee provides a certificate that is false or misleading in a material way, or breaches an undertaking in the certificate, the generic/biosimilar entrant can, with the permission of the court or Attorney-General, apply to a court for an order that the patentee pay to the Commonwealth a penalty of up to AUD10 million. The patentee may also be liable to compensate the Commonwealth or a State or Territory for damage sustained or costs incurred due to the granting of the interlocutory injunction in circumstances where the certificate provided under section 26C was false or misleading, or the patentee breached an undertaking.

Section 26D – Requirements for preliminary injunction

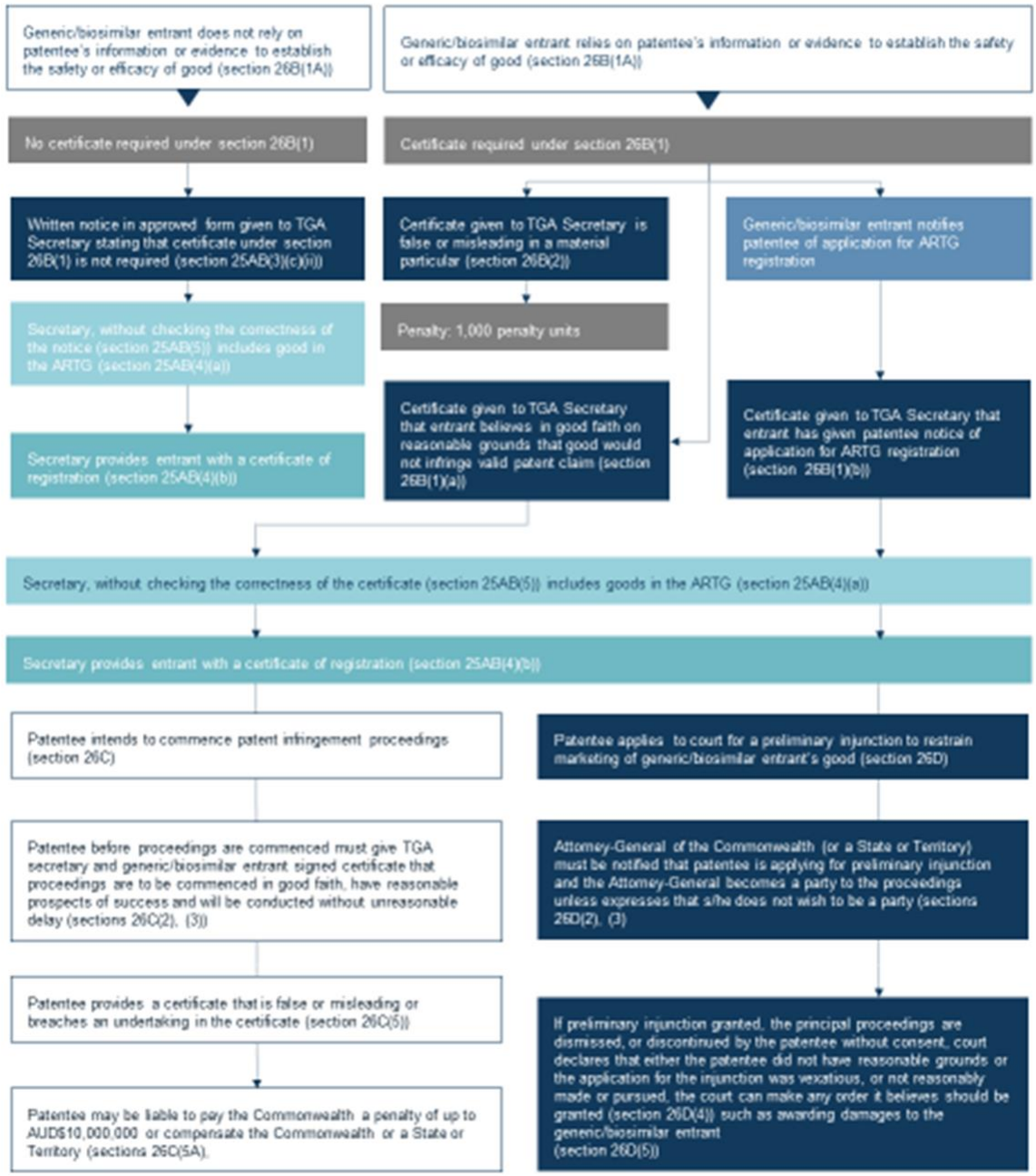
Section 26D is relevant if the generic/biosimilar entrant has given notice to a patentee in accordance with section 26B(1)(b) and the patentee (or exclusive licensee) applies to a court for a preliminary injunction to restrain the generic/biosimilar entrant from marketing their therapeutic good on the ground that this will constitute a patent infringement.

Section 26D provides that the patentee may not apply for preliminary injunctive relief unless they have first notified the Attorney-General of the Commonwealth, or a State or Territory. The result is that the Attorney-General of the Commonwealth is deemed to be a party to the proceeding unless the Attorney-General provides notice that he or she does not wish to be a party.

If a preliminary injunction is granted, the principal proceedings are dismissed, or discontinued by the patentee without the consent of other parties, and if the court declares that either the patentee did not have reasonable grounds, the application for the preliminary injunction was vexatious, or not reasonably made or pursued, the court can make any order it believes should be granted. Examples of orders the court can make are provided in section 26D(5) and include assessing and awarding damages to the generic/biosimilar entrant, the Commonwealth, or a State or Territory.

See **Figure 1** below illustrating the certification process under section 26B(1) and related provisions in the *Therapeutic Goods Act* for seeking regulatory approval from the TGA.

Figure 1: Consequences of providing a certificate or notice under Part 3-2 Division 2 *Therapeutic Goods Act*



Proposed changes to the law

Between March and June 2020, the TGA sought submissions from industry stakeholders concerning proposed changes to the *Therapeutic Goods Act* for the provision of earlier notification of generic and biosimilar medicine applications to patentees. The TGA proposed two options regarding implementation of an early notification scheme for generic/biosimilar therapeutic goods:

— Generic/biosimilar entrants which propose to use information or evidence submitted by a patentee/innovator in relation to an application for a product claimed by an extant patent would be required to provide a confidential notification to the patentee that their application has passed preliminary assessment; or

— Generic/biosimilar entrants which propose to use information or evidence submitted by a patentee/innovator must notify the innovator that its application has passed preliminary assessment, in all circumstance and regardless of whether the patent term has ended.

Surprisingly, on 9 October 2020, the TGA reported that the consultation process did not produce support for either of the above two proposals and proposed the following change:

'Applicants for **first** generic and **first** biosimilar medicines … will be required to notify the patent holder when their application is accepted for evaluation by the TGA, before the TGA commences the evaluation.'

The TGA outlined that 'the notification would be based on the existing arrangements under section 26B of the [*Therapeutic Goods Act*]' and that '[t]he existing notification scheme under section 26B of the Act will continue to apply to all other [i.e. second, third, etc.] applications for generic and biosimilar medicines'.

The TGA justified this change on the basis that it would enable patentees to be notified prior to the medicine being included on the ARTG and would therefore provide an opportunity for early negotiation and reduce the need for urgent litigation. Despite this measure being discussed in late 2020, it remains unimplemented nearly two years later, and details of its operation remain speculative.

China

Before the patent linkage system took effect in China, generic companies could submit simplified marketing applications to the drug administrative approval authority (the National Medical Products Administration, **NMPA**) with reference to the clinical data of the innovator drug. However, a generic company could only start clinical trials to collect the data required for the marketing application after the expiry of the patent of the innovator drug. Due to the administrative approval process and preparation for manufacturing, it could take years after the patent expiry date for the product to reach the market. During this waiting period, the innovator drug remained in exclusive possession of the market, which in effect extended the period of their patent protection.

When the Patent Law was amended for the third time in 2008, an exemption clause similar to the Bolar Exception was added. For the first time, this clause clarified that the activities related to generic drug manufacturers, such as conducting clinical trials for obtaining administrative approvals before the expiry date of a patent, will not be deemed as infringement to prior patent rights. As a result, generic drugs could be manufactured immediately and marketed as soon as the patent of an innovator drug expireed, consequently incentivising further generic drug development.

Since the amendment of the Patent Law, calls to reform the review and approval system of the domestic drug industry and the pressures of the international environment (e.g. China's economic growth and its burgeoning trade with the US in recent years) have made the establishment of a patent linkage system in China more and more urgent. The China-US Economic and Trade Agreement signed in 2020 mentions the establishment of a patent linkage system in China, including provisions on the notification obligations of administrative authorities and giving rights owners the ability to seek judicial or administrative remedies before a drug is marketed.

The new Patent Law, which came into effect on 1 June 2021, added a mechanism for resolving disputes arising from patent rights related to drugs for which registration is applied, formally establishing the patent linkage system in China. Subsequently, on 4 July 2021, the NMPA and the China National Intellectual Property Administration (**CNIPA**) jointly organised and issued the Implementation Measures for the Mechanism for Early Settlement of Drug Patent Disputes (for Trial Implementation) (**Implementation Measures**). On 4 July 2021, the Supreme People's Court promulgated 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 (**Provisions of SPC**). Following this, the CNIPA issued the Measures for the Administrative Adjudication of the Mechanism for Early Resolution of Drug Patent Disputes (**Administrative Adjudication Measures**). At this stage, the legal framework of the patent linkage system in China has been basically established.

Main content of the patent linkage system in China

Patent information registration platform

The Measures stipulate that the Centre for Drug Evaluation (**CDE**) will establish and maintain a patent information registration platform for drugs marketed in China. Drug marketing authorisation holders will register the patent information of the drugs to be marketed on the platform, which will be published and made available to the public. The information includes the name, dosage form, and specification of the drug; the name of the drug marketing authorisation holder; the number, name, holder, licensee, grant date, expiration date, status, type, and the drug corresponding claim of the relevant patent; and address, contact person and contact information. The drug marketing authorisation holder should register the information within 30 days after obtaining the drug registration certificate. When there is a change in information, the drug marketing authorisation holder should record it within 30 days after the effective date of the change.

The drug marketing authorisation applicant should submit a patent-status declaration against each relevant patent listed on the platform. The patent information recorded on the platform will be used as the basis for a generic company to fill the declaration. The declaration will be published and searchable on the platform.

Drug marketing authorisation holders and drug marketing authorisation applicants are responsible for the authenticity, accuracy and completeness of the provided information.

Drug patents which can be registered on the platform

The drug patents that can be registered on the platform include:

— for chemical drugs: compound patents of the active pharmaceutical ingredient, composition patents making up the active pharmaceutical ingredient, and patents directed for medical use;

— for biological drugs: patents of the sequence of biological products and patents directed for medical use; and

— for traditional Chinese medicines: composition patents, extraction patents, and patents directed for medical use.

According to the Policy Interpretation issued by the NMPA and the CNIPA, patents direct to intermediates, metabolism products, crystal forms, preparation methods, or detection methods cannot be registered on the platform.

Patent status declaration system for generic drug applicants

As discussed above, when a generic drug applicant submits an application for drug marketing authorisation, it must submit a declaration against each corresponding patent registered on the patent information registration platform and provide relevant supporting documents. The declaration is classified into four categories:

— Category I: there is no patent information related to the brand-name drug on the platform;

— Category II: the relevant patent of the brand-name drug registered on the platform has expired or has been declared invalid, or the generic drug applicant has been granted a license from the patentee to exploit the relevant patent;

— Category III: the platform records patents related to the brand-name drug, and the generic drug applicant undertakes that it will not market the generic drug before the expiration of the patent terms; and

— Category IV: the patent rights related to the brand-name drug registered on the platform must be declared invalid or the generic drug will not fall within the protection scope of the relevant patent rights.

Within ten days after the acceptance of the drug marketing authorisation application, the CDE will publish the drug application and the related declaration on the platform. The drug marketing authorisation applicant should inform the drug marketing authorisation holder of the declaration and the supporting documents by sending both a hard copy of those required documents and an email to the contact person of the brand-name drug company through the email address left on the platform. When the declaration is a Category IV declaration, the drug marketing authorisation applicant should provide a form comparing the technical solution of the generic drug and that of the brand-name drug, and also provide relevant technical materials to the innovator drug company.

Time limit for raising objections and the nine-month waiting period

Within 45 days from the publication of the drug marketing authorisation application with a Category IV declaration, the patentee or interested party can file a lawsuit before the people's court or an administrative adjudication request before the CNIPA. Within 15 business days after the acceptance of the case by the relevant authority, the patentee or interested party should submit a copy of the acceptance notice to the CDE and inform the generic drug applicant.

Upon the receipt of the acceptance notice, the NMPA will set a nine-month waiting period for chemical drugs only. The nine-month waiting period starts from the case acceptance date and will be set up only once. Drug marketing authorisation review will not be stopped during the waiting period.

If the patentee or interested party fails to file a lawsuit or request administrative adjudication within the prescribed time limit, the generic drug company may file a lawsuit or request an administrative ruling to confirm that the technical solution of the drug does not fall within the protection scope of the relevant patent.

First generic exclusivity

A market exclusivity period of 12 months will be awarded to the first generic chemical drug. During this period, the NMPA will not approve a generic drug of the same type for marketing, unless the patent was successfully challenged by multiple parties together. The exclusivity period will not exceed the term of the challenged patent. During the exclusivity period, the CDE will not stop reviewing applications. For other generic chemical drugs of the same type that receive a positive review result, the CDE will commence the approval process before the expiration date of the exclusivity period.

For clarification, “successfully challenge the patent” means the generic chemical drug applicant files a Category IV declaration, submits an invalidation request, and as a result, the patent right is invalidated so that the generic drug can be approved for marketing. Therefore, it appears that market exclusivity does not apply to biosimilars and traditional Chinese medicines with the same name and recipe.

Dispute resolution

According to the new Patent Law and the Implementation Measures, the early resolution mechanism for drug patent disputes is a "dual-track system" (i.e. the parties can resolve their disputes through both judicial and administrative procedures). Compared to other jurisdictions where only judicial proceedings are available to resolve drug patent disputes, this is a major feature of the early resolution mechanism for drug patent disputes in China. According to Article 1 of the Provisions of SPC, a first-instance case involving disputes over the confirmation of whether the matter falls within the scope of patent protection as filed by a party in accordance with Article 76 of the Patent Law will be subject to the jurisdiction of the Beijing Intellectual Property Court, meaning that a party who chooses the judicial proceeding should file a lawsuit with the Beijing IP Court. Meanwhile, according to Article 2 of the Administrative Adjudication Measures, the CNIPA will be responsible for the administrative adjudication described in Article 76 of the Patent Law and has set up an administrative adjudication committee for the mechanism for early resolution of drug patent disputes to organise and carry out the work related to administrative adjudication for early resolution of drug patent disputes, meaning the parties could also submit their requests to the CNIPA if they choose the administrative procedure.

In particular, according to Article 4.5 of the Administrative Adjudication Measures, a condition for the CNIPA’s acceptance of the party’s request for decision on a drug patent dispute is “the people's court has not filed a case on the drug patent dispute before”. On the contrary, however, the Beijing IP Court acceptance of drug patent disputes is not based on the premise, set by the Provisions of the SPC, that the CNIPA failed to file the same drug patent dispute. In other words, parallel processes in which administrative proceedings are instituted before judicial proceedings are possible, but judicial proceedings that are instituted before administrative proceedings are not. Undoubtedly, this restriction must be considered by the parties concerned when they choose judicial procedures or administrative procedures to resolve their disputes.

First case under the patent linkage system

On 15 April 2022, the Beijing IP Court announced the judgment on the dispute between Chugai Pharmaceutical Co., Ltd. (**Plaintiff**) and Wenzhou Haihe Pharmaceutical Co., Ltd. (**Defendant**) to confirm whether Generic drugs applied for registration by the Defendant fall into the scope of protection of the Plaintiff’s patent right. This is the first litigation case related to drug patent linkage system since the implementation of the new Patent Law.

Case timeline

— On 13 July 2021, the Plaintiff registered on the patent information registration platform for drugs marketed in China the Claim 1-7 of Chinese Patent No. 2005800098777.6.

— On 16 August 2021, the Defendant made a Category IV declaration on the patent information registration platform for drugs marketed in China, declaring that their generic drug didn't fall within the scope of protection of the Plaintiff's patent.

— In November 2021, the Plaintiff requested that the court confirm the Defendant's drug application infringes on the Plaintiff's patent rights and that the Defendant should cease its use of the Plaintiff's patent in any form.

— A nine-month waiting period started. The national drug evaluation institution will stop the administrative approval process until it receives the effective judgment, ruling, consent judgment or until the waiting period is over.

— On 30 December 2021, the CNIPA made the No.53498 invalidation decision, declaring the Plaintiff's patent invalid.

— On 15 April 2022, the Beijing IP Court made the first instance decision of this case.

Court decision

The Beijing IP Court held that the generic drug in question in this case did not fall within the protection scope of the patent right in question in this case, and ruled to dismiss the Plaintiff's litigation claims.

Case analysis

This case is the first case of patent linkage litigation in China since the implementation of the new Patent Law, thus the focus of this case is the implementation of the drug patent linkage system.

According to Article 1 of the Implementation Measures, the purpose of the patent linkage system is to protect the legitimate rights and interests of drug patentees, encourage research into new drugs, promote the development of high-level generic drugs, and establish an early settlement mechanism for drug patent disputes. The logic for achieving such a purpose lies in the fact that previously, when generic drugs were in the R&D stage, no infringement was created and the innovator drug companies had no way to intervene or learn about the development of generic drugs. If a patent infringement dispute arises between a generic drug and an innovator drug after it has been marketed, the innovator drug company may face a high loss of interest and litigation costs due to the long trial period and uncertainty of the case result. On the other hand, for generic drug companies, the generic drugs they have invested a lot of time and effort in developing will also face the risk of huge compensation, prohibition of production and sale if they are found to be infringing. The patent linkage system provides predictability and certainty for both the innovator and generic drug companies before the generic drug is marketed, avoiding the need to settle disputes after the generic drug has been marketed and causing substantial damage to both parties. As a result, the system will encourage both new drug research and promote the development of generic drugs.

As for this case, the time limit for the trial was short. The case was accepted and filed by the Beijing IP Court on 8 November 2021, and the court made its judgment on 15 April 2022, taking only over five months for the first trial, which was far shorter than that of a general patent infringement litigation. The five-month trial period also fell within the nine-month waiting period stipulated in the Implementation Measures. According to the Implementation Measures, if, after the waiting period, the NMPA has not received the effective judgment or written conciliation statement from the people's court, the generic registration application will be transferred to the administrative approval process in accordance with the procedures. Therefore, before the decision was handed down in this case, there was widespread concern in practice that the case might take longer than the nine-month waiting period given the volume of cases in the Beijing IP Court. However, at least for the time being, it appears that the trial in Beijing IP Court was very efficient.

Subsequent progress

After the court pronounced its judgment, the Plaintiff expressed it would file an appeal. According to Article 9 of the Implementation Measures, for applications for registration of chemical generic drugs that have passed the technical evaluation, the national drug evaluation institution will handle them accordingly in light of the effective judgment of the people's court or the administrative adjudication of the patent administrative department of the State Council. If an application is confirmed to not be covered by the relevant patent rights or the two parties reconcile, the application for registration of the relevant chemical generic drug will be transferred to the administrative approval process according to the procedures. In this case, the Plaintiff's appeal could delay the effective time of the judgment and the time that the generic drug enters into the administrative approval process, which will ensure that its exclusive market dominance will continue for a longer period of time. As for the invalidation decision relating to the patent in this case, after the CNIPA has made a decision on the examination of the request for announcement of patent invalidation, the decision will only take effect if the parties do not file a lawsuit with the people's court within three months or if the invalidation decision is not revoked by the administrative decision in force after the lawsuit is filed. Given this, we presume that the Plaintiff proceeded with the administrative proceedings against the invalidation decision. Otherwise, an appellate decision in this case would have less meaning.

India

India currently does not have any regulation, which recognises “patent linkage”. The Central Drugs Standard Control Organisation (CDSCO) headed by the Drug Controller General (DCGI) issues marketing approval for new drugs. New drug approval issuance is typically based on safety and therapeutic efficacy data and the approval status of the drug in other jurisdictions, without considering granted patent/pending patent applications covering such a drug. The patent system and the CDSCO in India are two separate and independent mechanisms created under different laws. The innovator on becoming aware of the launch of a generic version of a patented drug typically proceeds with patent enforcement in India mostly through litigation/courts.

A proposal was made by the DCGI in 2010 to incorporate the status of the patents of drugs in its marketing approval proposal. However, this proposal was abandoned pursuant to extreme opposition from the generic industry and public health groups.

There have been various attempts by innovator pharmaceutical companies to introduce patent linkage in India. These include strong lobbying through free trade agreements and court cases. A landmark case is the *Delhi High Court Decision in Bayer v. Cipla and Union of India* (Delhi High Court, LPA 443/2009, Judgment pronounced on: 9 February 2010). In the ruling, the court rejected Bayer’s plea to restrain the DCGI from granting a licence to Cipla to manufacture the patented drug. The court also clarified that there is no “patent linkage” regulation in India.

Indonesia

Currently Indonesia does not have a patent-linkage system. Registration for obtaining a distribution permit for generic drugs is administered by the Indonesian Drug and Food Agency (**BPOM**), whereby the Directorate of Intellectual Property (**DGIP**) administers patent registrations. There is no linkage or a system in place to connect between the generic medicine registration system and the patent registration system. Each is independently managed and operated by the respective institution.

At present, registration of generic medicine is regulated under the BPOM's regulation on Criteria and Procedure for Registration of Medicines (i.e. **BPOM's Regulation**), while patent registration is regulated under Law No. 13 of 2016 on Patent (i.e. the Patent Law). The Patent Law (Article 167 point b) includes a provision equivalent to the Bolar provision whereby an exemption to a patent infringement is provided for production of pharmaceutical products protected under a valid patent for five years prior to the expiration of the relevant patent for the purpose of obtaining the relevant distribution permit, which will then be distributed after the expiration date of the relevant patent. The BPOM's Regulation also stipulates a similar provision (Article 21), which states that "registration for first generic medicine with an active substance, which is still under protection of a valid patent, may be filed by a party who is not the patent owner within 5 (five) years prior to the expiration of the relevant patent". Furthermore, it is also stipulated that the distribution permit of such a generic medicine will only be issued after the relevant patent has expired.

Although the BPOM Regulation stipulates that some of the requirements that may need to be provided to support an application for a distribution permit of a generic medicine include patent search results from the DGIP and an independent patent assessment. However, it does not stipulate any provision requiring the BPOM to notify the corresponding patent owner of an application submitted by another party to register a generic medicine for obtaining a distribution permit for this product. Furthermore, it also does not provide any opportunity for a third party, including the owner of the relevant patent or innovator, to submit an opposition or objection against an ongoing application to register a generic medicine and/or to obtain the relevant distribution permit for such a generic medicine.

Notwithstanding the above, the BPOM Regulation does stipulate a provision regarding reassessment of the relevant medicine distribution permit (Article 62). A reassessment may be conducted by the BPOM if, based on monitoring, there is a change to the data and information on the efficacy, safety and quality of the relevant medicine. The result of a reassessment may, among other things, be in the form of withdrawal of the relevant medicine and/or suspension/revocation of the relevant distribution permit. However, the BPOM Regulation does not provide specific details on what constitutes "monitoring" in a reassessment case – namely, whether it is limited to the BPOM's independent monitoring or is based on a report from a third party, such as the relevant patent owner.

In the event an innovator or a patent owner becomes aware of a generic medicine that has obtained a distribution permit through the BPOM's list of approved/registered generic medicine, the innovator or owner usually refers objections to the Commercial Court by citing provisions on patent infringement under the Patent Law, since currently there are no other legal or regulatory systems that effectively prevent the distribution of a generic medicine suspected of infringing a patent that has not expired.

Japan

In Japan, generic drugs are put on the market through a two-step procedure: (i) obtaining an approval from the Ministry of Health, Labour and Welfare (**MHLW**) regarding manufacturing and selling of a pharmaceutical product under the Act on Quality, Efficacy and Safety Assurance of Pharmaceuticals and Medical Devices (**PMD Act**); and (ii) listing the product on the National Health Insurance drug price List (**NHI Drug Price List**), the list of pharmaceutical products that can be used for insured medical treatment. In each of these steps, the MHLW gathers information from original drug manufacturers and generic drug manufacturers regarding any conflict between the existing patents related to the original drugs and the generic drugs. If there is any conflict, the MHLW may, depending on the procedures in question, not grant approval or decide not to list the generic drug on the NHI Price List.

Generally speaking, these processes allow the MHLW to consider the existence of patent rights related to the original drug in the review and approval process for a generic drug in order to prevent any problems arising in stable supply of the generic drug because of patent infringement lawsuits after the marketing of the generic drug begins; and is thus, acknowledged as the Japanese patent linkage system. In fact, when Japan signed the Comprehensive and Progressive Agreement for Trans-Pacific Partnership (CPTPP), which requires the signatory states to implement a patent linkage set forth in Article 18.53 of the CTPPP, the Japanese government explained that the signing of the agreement will not affect the Japanese system because in Japan "this system is already in place. In other words, the TPP agreement does not require us to change our system."

The Japanese Patent Linkage system is not based on any written or statutory laws or regulations; rather the legal basis of this system is the MHLW's administrative directive. The Japanese patent linkage system was introduced by the MHLW's notification dated 4 October 1994 (**1994 Notification**), which covered only substance patents. However, on 5 June 2009, the MHLW issued a new notification, which partially revised the 1994 Notification to include use patents in the scope of the Japanese patent linkage system (**2009 Notification**, collectively with the 1994 Notification, **MHLW Notifications**).

Main content of the Japanese patent linkage system

Confirmation at the time of regulatory approval

Under the PMD Act, a person who intends to manufacture and sell a pharmaceutical product must obtain approval from the Minister of Health, Labour and Welfare (**HLW Minister**) for each pharmaceutical product (Article 14.1 of the PMD Act). The Pharmaceuticals and Medical Devices Agency (**PMDA**), an independent administrative agency commissioned by the HLW Minister, conducts the examination for approval and upon receiving notification of the results, the HLW Minister must consider the results and where appropriate grant approval (Article 14.1 and 14.2 of the PMD Act).

At this time, the presence or absence of patent right infringement between the original drug-related patents and the generic drug is checked, and the generic drug that is found to be infringing these patents will not be approved. Specifically, the MHLW Notifications state that a generic drug will not be approved if the manufacture of the active ingredient itself is not possible due to the existence of a substance patent for the active ingredient of the original drug, or if a patent exists on certain indications, dosage and administration of the original drug. In order to decide whether or not to grant approval for the generic drug, the MHLW collects relevant information from both the original drug manufacturer and the generic drug manufacturer:

— The "Drug Patent Information Report Form" is used to collect information from original drug manufacturers. The "Drug Patent Information Report Form" provides patent information on approved original drugs, which the MHLW requests that original drug manufacturers submit. Although submission of the Form is voluntary, most original drug manufacturers take the initiative in submitting the Form. The submitted Form is not publicly available and is used only as a MHLW internal document.

— The MHLW Notifications state that a person applying for approval of a pharmaceutical product with the same active ingredient (i.e. a generic drug manufacturer) must submit information on whether a substance patent or a usage patent exists for the active ingredient in question and, if so, “materials showing that the product can be manufactured or imported and sold promptly after approval.” Specifically, the following documents must be submitted in each of the following cases:

  - In the case of proving that the patent has lapsed, the closed patent register, patent details (patent number, name of patentee, patent term, etc.);
  - If the patent is invalid, a written decision of invalidation of the patent, a written court decision, etc. (patent details as reference material);
  - If the patentee or exclusive licensee's consent has been obtained, a contract, agreement, etc.

According to the MHLW Notifications, the existence of the original drug-related patent is determined on the scheduled approval date. Therefore, if the term of the patent expires on the scheduled approval date of the generic drug, the existence of the original drug related patent cannot be a reason not to grant approval. Furthermore, in practice, even if a request for a trial for invalidation is filed regarding the original drug-related patent and the Japan Patent Office issues a decision to invalidate this patent before the generic drug’s scheduled approval date and the invalidation decision is not yet final, the original drug-related patent is treated as non-existent, and thus the generic drug is approved.

Furthermore, the MHLW and PMDA do not collaborate with the JPO in the approval review of generic drugs. The specific process of how the existence of patents on original drugs is taken into account is not disclosed, and the details are not clear.

Confirmation at the time of NHI drug price listing

Under Japan's national health insurance system, even if a generic drug is approved for production and sale, physicians cannot prescribe the generic drug unless it is listed on the NHI Drug Price List by the MHLW.

In this regard, the MHLW Notifications state, “When listing a generic drug on the NHI drug price list, the parties concerned are required to make prior arrangements for items for which there were patent concerns, and only items for which a stable supply were deemed possible should be listed on the list.” In other words, after approval of a generic drug and prior to its listing on the NHI Drug Price List, the original drug manufacturer and the generic drug manufacturer discuss whether or not there are any patent issues with the approved generic drug, and both parties report the results of their discussions to the MHLW. This is intended to ensure that patents not subject to confirmation at the time of approval do not become an obstacle to the manufacture and sale of generic drugs.

The deadline for prior coordination is two months from the date of approval for the manufacture and sale of the generic drug. Even if prior coordination has not been completed by then and a patent dispute arises between the two parties, the MHLW allows the generic drug manufacturer to list the drug on the NHI drug price list and sell it, unless the generic drug manufacturer withdraws its application for listing on the NHI drug price list. In such cases, the MHLW requires the generic drug manufacturer to submit a memorandum of understanding that the supply of the drug will not be stopped even if the original drug manufacturer applies for an injunction due to a lawsuit, etc. If this document is submitted, the generic drug manufacturer is allowed to list the generic drug at its own risk.

Provisions Equivalent to Bolar Exception

Under the Japan Patent Act, there is no provision equivalent to the Bolar Exception. However, at the same time, the Japan Patent Act states that “the effect of the patent right shall not extend to the working of the patented invention for the purpose of testing or research” (Article 69(1) of the Patent Act). In relation to this article, the Supreme Court of Japan held that conducting various tests for the purpose of applying for approval to manufacture a generic drug and manufacturing drugs to be used for such tests during the patent term constitutes “use of the patented invention for the purpose of testing or research” and does not constitute infringement of the patent right.

Dispute resolution

As explained above, the Japanese patent linkage system is based on administrative directives rather than laws, and there is no legal system that directly regulates the procedures for appeal against the decision on patent infringement by the MHLW and PMDA. Therefore, any disagreement or dispute regarding the existence of patent infringement between the patent related to original drugs and generic drugs in Japan is to be resolved through consultation between the parties. However, several problems have been pointed out.

First, the MHLW and PMDA have not disclosed the process for determining whether or not a patent related to an original drug and a generic drug conflict with each other. Although it is legally possible for a generic drug manufacturer to file an administrative appeal against the MHLW's decision not to approve the generic drug, practically speaking, it is not easy for the generic drug manufacturer to take such legal action. On the other hand, an original drug manufacturer has no opportunity to learn whether an application for marketing approval has been filed for a generic drug that may infringe its patent right until the generic drug has been approved for marketing and has been made public.

Second, Japan's patent linkage system does not provide for disclosure of all patent information on substances, uses, and formulations of brand-name drugs, as is the case in the US with the Orange Book, and nor does it disclose which patent rights are referenced and what decisions are made by the MHLW. Therefore, there is a lack of transparency and predictability.

Third, after a generic drug is approved for production and sale, prior coordination between the manufacturers of the original drug and the generic drug is conducted before the drug is listed on the NHI Drug Price List. In practice, however, it is said that there are very few cases in which this prior coordination leads to any dispute resolution. This is because it is not expected that a third party will actively arbitrate patent disputes, and the NHI Drug Price List will be maintained based on the judgment of the generic drug manufacturer even if the conflict is not settled. However, this pre-adjustment is significant because it makes generic drug makers aware of the risk of future patent infringement lawsuits and encourages them to carefully consider marketing again just prior to the start of sales.

As discussed under Japan's patent linkage system, the MHLW and PMDA have exclusive authority to determine whether or not an original drug and a generic drug conflict with each other, which allows the parties involved in the case of a complicated issue to make preliminary adjustments. Although this unique two-step procedure has the above-mentioned issues, it contributes to avoiding unnecessary litigation and is welcomed by the parties concerned, according to some survey reports.

A case related to the patent linkage system

There are no cases related to the Japan’s patent linkage system because there is no appeal procedure.

The following case is related to a generic drug manufacturer that filed an application for approval of a generic drug (brand name: Allegra tablets, generic name: fexofenadine) even though the patent for the original drug existed and was still in its validity period. The outline of this case is as follows.

— Two generic drug manufacturers filed a request for an invalidation trial before the Japan Patent Office for a patent owned by the original drug manufacturer, and a decision was made to invalidate the patent.

— Thereafter, the original drug manufacturer filed a lawsuit to revoke the invalidation trial decision, and as a result of the settlement, the patent in question was allowed to continue to exist.

— The following month, however, it was announced that three completely different generic drug manufacturers had received approval to manufacture and market a generic version of fexofenadine.

— In response, the original drug maker filed a patent infringement lawsuit, but two of the three companies filed an application for inclusion in the NHI Drug Price List, claiming invalidation of the patent, and began marketing the generic drug ahead of the other generic drug makers.

— Subsequently, all requests for invalidation trials against the subject patents were withdrawn, and the patent infringement lawsuits were settled.

It is unclear what information and decision-making process the MHLW and PMDA used to determine the validity of the subject patent, but it is possible that the decision was influenced by the fact that the patent had once received an invalidation decision by the Japan Patent Office. However, even if an invalidation decision is made once, there is a possibility that a reverse decision will be made in a lawsuit to revoke the Japan Patent Office's decision, or that the patent will continue to exist as a result of a settlement, as in this case. In this regard, there is uncertainty in the system whereby the MHLW and PMDA make decisions on whether or not there is patent infringement during the pendency of invalidation trials and revocation actions. However, this is an interesting case because it shows that generic drug makers may ultimately decide to market a generic drug after accepting the risk of patent infringement lawsuits as part of their strategy.

Korea

The Korea-US Free Trade Agreement, which was signed in 2007 and came into force on 15 March 2012, introduced a drug approval-patent linkage system to Korea.[4] Before the patent linkage system was introduced, the Ministry of Food and Drug Safety (**MFDS**; the Korean equivalent of the US FDA) reviewed the drug approval issue based on a drug's safety and efficacy data without considering any issues relating to patent rights covering the product. While the then-existing Enforcement Rules on the Pharmaceutical Affairs Act prohibited a drug manufacturer from manufacturing a drug product that infringes patents of another,[5] drug approval was not directly related to – or did not hinge on – whether or not the relevant drug product infringes patents of another. From 2012, however, the linkage system created a bridge between the drug approval process and related patent rights.

The system was implemented in two phases. On 15 March 2012, the first phase introduced (a) patent listing under which marketing approval holders (i.e. a **MA Holder**) are allowed to publicly list patents covering their approved drugs, and (b) the notification process under which MA Holders were notified if any subsequent drug manufacturer intends to seek approval for its new drug product relying on the safety and efficacy data of the approved drug. Three years thereafter, on 15 March 2015, the second phase implemented (c) a statutory stay on regulatory approval of an abbreviated new drug application (**ANDA**) filed by a subsequent drug manufacturer relying on the safety and efficacy data of the approved drug, and (d) marketing exclusivity granted for first follow-on drug products.

The MFDS is the main government entity that administers the patent linkage system, and the Pharmaceutical Affairs Act[6] provides the legal framework for the patent linkage system.

Main content of the patent linkage system in Korea

Korea's drug approval-patent linkage system consists largely of four parts: (a) patent listing; (b) a notification process; (c) a statutory stay of ANDA approval; and (d) marketing exclusivity for first generics.

Patent Listing

Patent listing encourages brand-name companies to identify to the MFDS patents that cover their brand-name drug products.

Only those companies that have obtained marketing approval or amended marketing approval (collectively referred to here as the **MAs**) to manufacture or sell an original drug product can submit to the MFDS a list of patents that covers such a drug product for listing in the drug product-patent list.[7] This drug product-patent list is commonly known as the Green List. If an MA Holder is not an owner or registered exclusive licensee[8] (collectively referred to here as the **Patent Owner**) of the patents submitted for listing, the MA Holder must first obtain consent from the Patent Owner.[9]

MA Holders are allowed to submit patent information for listing within 30 days from receipt of marketing approval or from the patent issue date.[10]

MA Holders can only submit the following drug patents for listing:

— a drug patent covering the drug substance, dosage form, composition, or pharmaceutical use;

[4] Korea-US Free Trade Agreement, art. 18.9.
[5] Enforcement Rules on the Pharmaceutical Affairs Act, Ministry of Health and Welfare Decree No. 52, May 6, 2011, art. 43(7).
[6] The unofficial translation of the Pharmaceutical Affairs Act provided by the Korea Legislation Research Institute is available at: https://www.law.go.kr/LSW//lsInfoP.do?lsiSeq=228237&chrClsCd=010203&urlMode=engLsInfoR&viewCls=engLsInfoR#0000.
[7] Pharmaceutical Affairs Act, Act No. 18307, July 20, 2021, art. 50-2(1).
[8] A registered exclusive licensee means a licensee that has entered into an exclusive patent licence agreement with a licensor, and has registered this exclusive patent licence with the Korean Intellectual Property Office ("**KIPO**").
[9] Pharmaceutical Affairs Act, Act No. 18307, July 20, 2021, art. 50-2(2).
[10] *Id*.

— a drug patent directly covering the drug product for which an MA is granted;

— the patent application for the drug patent was filed before the MA date;

— the drug patent has not expired, been declared invalid, or been abandoned; and

— the MA of the drug product must be valid.[11]

If an MA Holder submits patents eligible for listing in a timely fashion, the MFDS will list the patents on the Green List, and will publish the submitted patent information on its online database known as the Integrated Medicine Information System.[12]

Notification system

An ANDA applicant seeking marketing approval of a new drug based on the efficacy and safety data of an approved drug listed in the Green List (i.e. "**Generic Drugs**") must notify both the Patent Owner and the MA Holder of the listed drug product.[13] This can be done by sending a notice letter. A notice letter must contain, among other things, the ANDA Applicant's invalidity or non-infringement arguments.[14]

Even if an ANDA Applicant seeks MA for a drug product that contains a different amount of the same active ingredients or has a different dosage form than the listed drug product, the ANDA Applicant is still required to provide the notification so long as it seeks to rely on the safety and efficacy data of the listed drug product. An ANDA Applicant will be exempt from this notification obligation if:

— the listed patent has expired;

— the ANDA Applicant seeks MA to sell its Generic Drug after the listed patent expires;

— both the Patent Owner and the MA Holder of the listed drug product have consented to waive the ANDA Applicant's notification obligation; or

— the listed patent is not related to the efficacy or effects of the Generic Drug.[15]

The ANDA Applicant has 20 days to send the notice letter from the date of application for MA.[16] If the ANDA Applicant fails to provide the notice letter in a timely fashion, then the date of application for MA will be postponed to the date on which the notice letter was sent.[17] If the ANDA Applicant fails to provide the notice letter at all, the MFDS is not allowed to grant MA.[18]

In addition, an ANDA Applicant must provide in its ANDA one of the following certifications:[19]

— it is statutorily exempt from the notification obligation; or

— in its opinion and to its knowledge, the listed patent is invalid, unenforceable, or will not be infringed by the Generic Drug.

Statutory stay

Once the Patent Owner of the listed patents receives the notice letter, it may apply to the MFDS for a statutory stay on regulatory approval of the ANDA identified in the notice letter.[20] The application must be made within 45 days from receipt of the notice letter.[21] Within this 45-day window and prior to applying for a stay, the Patent Owner must file either a patent infringement lawsuit seeking an injunction or a patent scope confirmation trial[22].[23]

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[11] *Id*. art. 50-2(4).
[12] MFDS, INTEGRATED MEDICINE INFORMATION SYSTEM, https://nedrug.mfds.go.kr/searchBioeq.
[13] Pharmaceutical Affairs Act, Act No. 18307, July 20, 2021, arts. 50-4(1).
[14] *Id*.; Enforcement Rules on the Safety of Pharmaceuticals, etc., Prime Minister Decree No. 1820, 21 July 2022, art. 62-5(1).
[15] Pharmaceutical Affairs Act, Act No. 18307, July 20, 2021, art. 50-4(1).
[16] *Id*. art. 50-4(4).
[17] *Id*.
[18] *Id*. art. 50-4(6).
[19] *Id*. art. 31(12).
[20] *Id*. art. 50-5(1).
[21] *Id*.
[22] A patent scope confirmation action is an administrative proceeding filed at the Korean Intellectual Property Trial and Appeal Board ("**KIPTAB**") of the KIPO to confirm whether an accused product or process is within or outside the scope of a patent.
[23] Pharmaceutical Affairs Act, Act No. 18307, July 20, 2021, art. 50-5(2).

Upon receiving the application for a statutory stay, the MFDS is required to stay or delay market entry of the Generic Drug for a maximum of nine months from the Patent Owner's receipt of the notice letter from the ANDA Applicant.[24] However, the following exceptions may apply:

— the Patent Owner has failed to apply for a stay within 45 days from its receipt of the notice letter;

— the Patent Owner has applied for a stay based on an expired or abandoned patent;

— the Patent Owner has applied for a stay before initiating a patent infringement lawsuit or a patent scope confirmation trial;

— the patent was listed on the Green List in a fraudulent or otherwise wrongful manner;

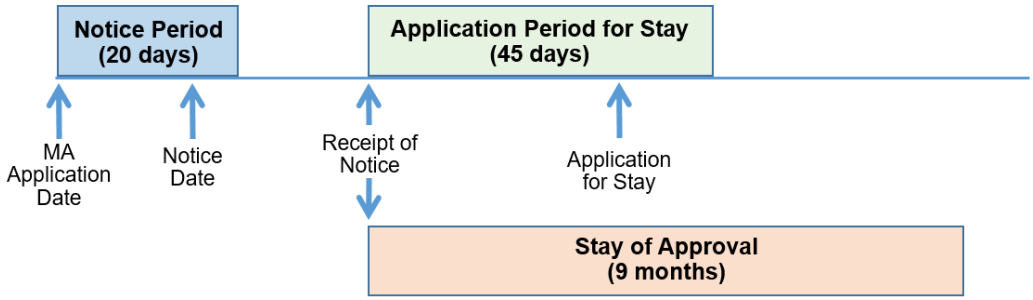
— the notice letter contains two or more Generic Drugs, and with respect to the equivalent drug products[25] among such Generic Drugs, the Patent Owner has selectively applied for a stay of only some of the equivalent drugs;[26]

— there already exists an approved Generic Drug that is equivalent to Generic Drug product for which a stay is sought;

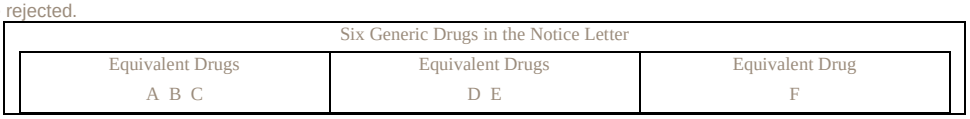
— the KIPTAB or a court has rendered a decision that the listed patent is invalid or the Generic Drug for which a stay is sought falls outside the scope of the listed patent; or

— the listed patent is subject to compulsory licensing.[27]

It is important to note that the maximum nine-month stay starts from Patent Owner's receipt of the notice letter, rather than from the date the Patent Owner applies for a statutory stay.



[24] *Id*. art. 50-6(1).
[25] The drug products are considered the equivalent drug products if they share the same active ingredient (including the amount thereof), dose, dosage, dosage form, efficacy, and effects. *Id*. art. 50-6(1)(5).
[26] For example, if the notice letter lists six Generic Drugs, A, B, C, D, E, and F, where A, B, and C are equivalent drugs, and D and E are equivalent drugs, a patent owner must apply for a stay with respect to A, B, and C, and/or D and E, and/or F. Any application for a stay that lists less than what is described above will be rejected.



Statutory Stay Applied by Patent Owner	Statutory Stay Granted by MFDS	Explanation
A, B, D, E	D, E	A stay with respect to A and B is not granted because the patent owner partially applied for a stay only for A and B, and failed to include C, which is an equivalent drug of A and B. A stay with respect to D and E is granted because the patent owner applied for a stay with respect to all equivalent drugs, D and E.
D, E	D, E	A stay with respect to D and E is granted because the patent owner applied for a stay with respect to all equivalent drugs, D and E.
F	F	A stay with respect to F is granted because the patent owner applied for a stay with respect to all equivalent drug, F.

[27] Pharmaceutical Affairs Act, Act No. 18307, July 20, 2021, art. 50-6(1).

Marketing exclusivity

An ANDA Applicant required to provide the notice letter may apply for – and the MFDS will grant to the ANDA Applicant – marketing exclusivity to exclusively sell its follow-on drug before the sale of other follow-on Generic Drugs if:

— the applicant is the first applicant that filed an ANDA;

— the applicant has obtained a favourable decision with respect to its challenges of the Patent Owner's patents (excluding those who have obtained a favorable decision after nine months from Patent Owner's receipt of the notice letter); and

— the applicant is the ANDA Applicant that (a) first challenged the Patent Owner's patent, (b) challenged the Patent Owner's patent within 14 days from the date of the first challenge, or (c) first obtained a favourable decision.[28]

An ANDA Applicant's challenges to a Patent Owner's patent may include the invalidity of the patent or patent term extension, or seeking confirmation of patent scope.[29]

The period for marketing exclusivity is nine months from the marketing approval date, unless the respective marketing approval for the listed patent expires earlier.[30] Also, an additional 2 month period may be available to compensate for delayed marketing due to the national health insurance reimbursement process. During this nine-month period, the MFDS will prohibit the sale of equivalent Generic Drugs that received marketing exclusivity and drug products having the same active ingredient with that of the drug products listed in the Green List.[31]

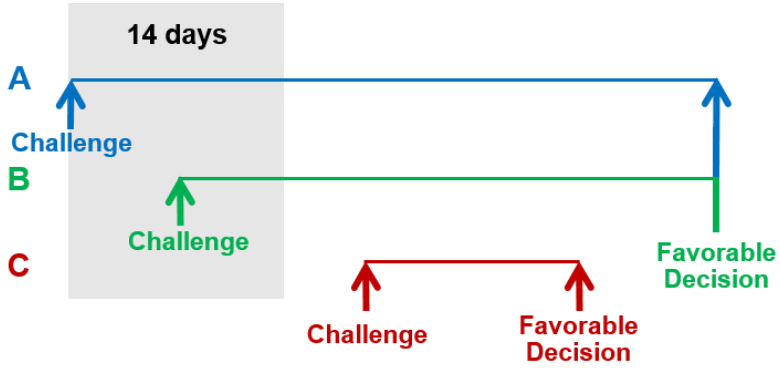
Dispute resolution

There are two main venues for patent disputes in Korea: a judicial proceeding and an administrative proceeding.

A judicial proceeding refers to a civil patent lawsuit where a plaintiff may seek monetary damages, injunctive relief, and a declaratory judgment from a judicial court. For example, in the context of the patent linkage system, an ANDA Applicant may file a civil patent lawsuit seeking declaratory judgment that the patent at issue is invalid or the patent term has been unlawfully extended. Patent lawsuits can be filed in any district court throughout the country, but the Korean Patent Court has exclusive appellate jurisdiction.

An administrative proceeding refers to a patent scope confirmation trial, which is filed at the Korean Intellectual Property Trial and Appeal Board of KIPO. The purpose of the trial is to confirm whether an accused product or process is within or outside the scope of a patent. Alleged infringers often file a patent scope confirmation trial to expeditiously obtain a decision that the accused products or process does not fall

[28] *Id*. art. 50-8(1).
Regarding the third requirement, for example, in the following case, A, B, and C will all be eligible to apply for marketing exclusivity because A first challenged the patent owner's patent, B challenged the patent owner's patent within 14 days from the date of the first challenge, and C first obtained a favorable decision.



[29] *Id*. art. 50-7(2).
[30] *Id*. arts. 50-9(2), 50-10(1).
[31] *Id*. art. 50-9(1).

within the scope of a patent. Importantly, the decision issued in a patent scope confirmation trial has no binding authority on Korean civil courts, as the decision is only binding on the parties. Therefore, the decision at best can be used as strong persuasive evidence in a related court proceeding or, in the context of the patent linkage system, used to meet the statutory requirements.

Representative case under the patent linkage system

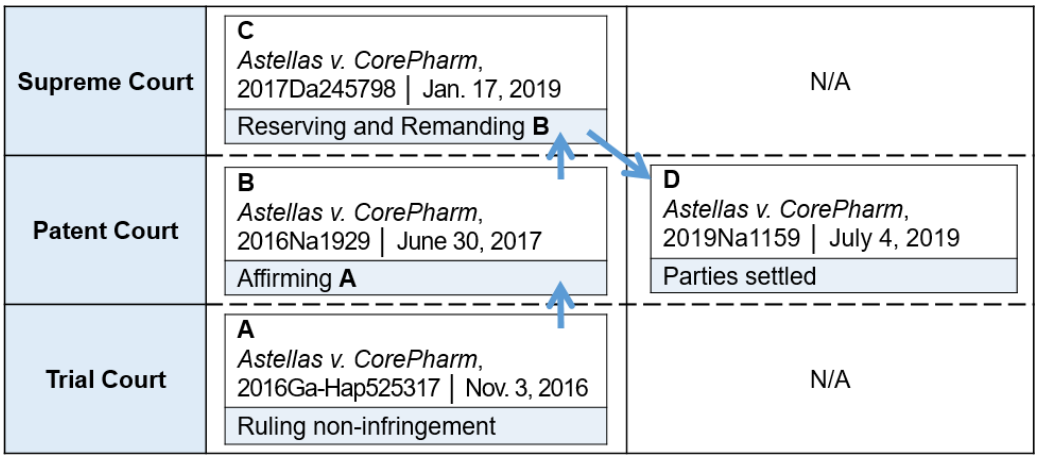
Traditionally, many Korean pharmaceutical companies have been generic manufacturers, as – in addition to the difficulties of inventing new drugs – the Korean Patent Act did not grant patent protection for inventions covering drug substances until 1986. Korean generic makers often changed the salt form of the original drug to create generic versions. This practice, however, came to a halt after the Korean Supreme Court held in the *Astellas v. CorePharm* case that a generic drug with a different salt form may still infringe an extended original drug patent.

Facts

Astellas Pharma Inc. is the patent owner of Korean Patent No. 386,487 (i.e. the "**KR '487 Patent**") that discloses a pharmaceutical composition for the treatment of an overactive bladder. The specification of the KR '487 Patent disclosed that the active ingredient solifenacin can form salts with – in addition to ammonium salts – other organic acids, including succinic acid and fumaric acid. Astellas obtained MA for its drug product Vesicare (solifenacin succinic acid) covered by the KR '487 Patent. On 21 August 2007, pursuant to Astellas' application for patent term extension, KIPO extended the patent term of the KR '487 Patent for one year six months and 16 days corresponding to the time Astellas took to obtain the MA for Vesicare.

During the extended patent term, CorePharm Co., Ltd. obtained MA for the generic version of Vesicare named A-Care. A-Care has the same active ingredient as Vesicare (i.e. solifenacin), but formed a salt with fumaric acid instead of succinic acid. Astellas later filed a patent infringement lawsuit against CorePharm alleging that CorePharm's A-Care infringes the KR '487 Patent.

The procedural history of the patent dispute is as follows:



Decision

The Seoul Central District Court dismissed Astellas' complaint holding that A-Care did not infringe the extended KR '487 Patent because the term extension was limited to the first commercial use of the drug product (i.e. solifenacin succinic acid). The Patent Court affirmed the holding of the lower court.

The Supreme Court, however, reversed the Patent Court's decision. The Supreme Court held that CorePharm's A-Care infringed the KR '487 Patent and vacated the Patent Court's decision.

The Court found that an accused drug product having a different salt form may fall within the scope of an extended original drug patent if: (a) a person having ordinary skill in the art can easily invent the accused drug product by replacing the salt form of the original drug product with another pharmaceutically acceptable salt form; and (b) the pharmacological mechanism of an active ingredient or the method use of the accused

drug is substantially similar to that of the original drug. Based on the foregoing, the Court held that CorePharm's A-Care infringed the KR '487 Patent despite the difference in salt forms because (a) the disclosure in the specification of the KR '487 Patent suggests that a person skilled in the art can easily replace succinic acid to fumaric acid, and (b) the pharmacological mechanism of CorePharm's A-Care is identical to that of Astellas' Vesicare.

Implication and significance

The Supreme Court decision not only had a sweeping effect on the drug manufacturing industry but also significantly changed the patent litigation landscape. Clearly, generic design arounds have become more challenging to devise. Generic manufacturers became unable to rely on the method of simply changing the salt form of an original drug before the expiration of the extended patent term of the patent covering the original drug. Alternatively, generic makers now focus on discovering indications not covered by the original drug patent or changing the crystalline form of the original drug product.

As for the litigation landscape, although many generic makers received a favourable decision from the KIPTAB or a court prior to the Supreme Court decision in the *Astellas v. CorePharm* case, they thereafter voluntarily withdrew the appeal and agreed to settle the patent disputes with the original makers. More original makers filed a patent infringement lawsuit against generic makers asserting that a generic version with a different salt form infringes the original drug product.

Singapore

In 2004, Singapore adopted the patent linkage scheme to meet its obligations under the US-Singapore Free Trade Agreement (**USSFTA**). Art 16.8(4) of the USSFTA specified that "[W]ith respect to any pharmaceutical product that is subject to a patent…(b) the Party shall provide that the patent owner shall be notified of the identity of any third-party 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."[32]

To fulfil the requirements of the USSFTA, Singapore amended the Singapore Medicines Act 1975 (**MA**) to include s12A[33], which provided that the applicant for a product needs to declare whether a patent is in force in respect of the medicinal product for which the application is made, and where such a patent exists, whether it believes that its product infringes the patent and whether the patent is invalid. Where the applicant declares that it does not believe the drug to be infringing or that it believes the patent to be invalid, the issuing authority may require a notification to be sent to the patent holder to give the patent holder an opportunity to obtain a court order against the generic drug company's launch of the drug.

On 1 November 2016, the MA was integrated into the Health Products (Therapeutic Products) Regulations 2016 (**HPTPR**). Reg 23 of the HPTPR provides that a manufacturer of generic drugs wishing to obtain marketing approval must declare all valid patents relating to the product they wish to duplicate and sell.[34] This declaration is to be made to the Singapore Health Sciences Authority (**HSA**), which oversees the marketing approval process for drugs.

Main content of the patent linkage system in Singapore

Patent status declaration system for generic drug applicants

Therapeutic products are regulated under the Health Products Act (2008 Rev Ed) and the HPTPR. All therapeutic products must be registered before they can be supplied in Singapore. Under reg 23 of the HPTPR, a generic drug manufacturer must make a declaration to the HSA of any existing patents "in respect of the therapeutic product",[35] as well as whether the generic applicant is the same as the patent holder. If the applicant is not also the patent holder, they must declare that:

— the patent owner has given consent (to the launch of the generic version);

— the patent is invalid; or

— the patent will not be infringed by acts relating to the therapeutic product.

The application for registration to the HSA can be classified into four categories:

— Category A1: where there is no existing patent that relates to the therapeutic product;

— Category A2: where there is an existing patent in relation to the therapeutic product and the applicant is either the holder of the patent, or if the applicant is not the holder of the patent, the holder has consented to the grant of the registration;

— Category A3: where there is an existing patent in relation to the therapeutic product, the applicant is not the holder of the patent, and the holder has not consented to the grant of registration, and the applicant seeks a grant of registration after the expiry of the patent. Such an application can only be made a maximum of 18 months prior to the expiry of the patent; and

[32] US-Singapore Free Trade Agreement (6 May 2003) Art 16.8.4(b)-(c).
[33] Medicines Act 1975 (2020 Rev Ed) s12A.
[34] Health Products (Therapeutic Products) Regulations 2016 (S 329/2016) reg 23(1)-23(7).
[35] HPTPR reg 23(1).

— Category B: where there is an existing patent in relation to the therapeutic product, the applicant is not the holder of the patent and the holder has not consented to the grant of registration, but the applicant believes that the patent is invalid or will not be infringed by the performing of the act for which the registration is sought.[36]

In the case of a Category A application, the market approval process will continue unhindered. In the case of a Category B application, the HSA will require the applicant to issue a notice to the patent holder, informing them of the market approval application.

Time limit for raising objections and waiting period

Once the notice has been issued, the patentee will have 45 days to apply to the Court to block the approval or procure a declaration that the patent is in fact valid and will be infringed by the performing of the act for which the generic manufacturer seeks registration. Following such an application, the registration process will be suspended for up to 30 months to give the Court time to review the application and provide the injunction or declaration if necessary. If a Court decision is not made within 30 months, the market approval process will resume while the generic company awaits the verdict. If the Court rules in favour of the generic company, the company can apply to the Court to rescind the stay of proceedings. However, if the judgment is in favour of the patent holder, the generic manufacturer will need to reapply for registration closer to the expiry date of the original product. On the other hand, if the patentee does not make an application within 45 days, the market approval process for the generic product will resume unhindered.

False declarations

Making false declarations under reg 23 of the HPTPR could cause one's registration to be cancelled or cause the declarant to be liable for an offence.

Under reg 24 of the HPTPR, a person's therapeutic product registration can be cancelled if it has been determined that (1) the act authorised by the registration infringes a registered patent, or (2) a court has determined that the declaration made under reg 23(2) contains a false or misleading statement in a material respect, or omits to disclose any matter that is material to the application. Separately, under reg 25 of the HPTPR, a party that produces a false declaration can be liable to a fine not exceeding SGD 20,000, or imprisonment not exceeding 12 months, or both. The offence of making a false declaration is committed when a person "(a) makes any statement or furnishes any document which the person knows or has reason to believe is false in a material particular; or (b) by the intentional suppression of any material fact, furnishes information which is misleading".

Period of exclusivity

As per reg 29 of the HPTPR, once information relating to the safety and efficacy of a therapeutic product has been provided to the HSA and has been registered, the registrant will enjoy a five-year period of exclusivity during which other similar therapeutic products cannot be registered and marketed in Singapore (unless the earlier registrant has consented to it).

Dispute resolution mechanisms

Disputes relating to the patent-linkage systems have typically been adjudicated by the Singapore Courts.[37]

Separately, the Intellectual Property Office of Singapore (**IPOS**) has initiated several schemes that are aimed at a more efficient protection of IP rights, in line with its objective of positioning Singapore as a global IP hub. In particular, the IPOS Revised Enhanced Mediation Promotion Scheme (REMPS) provides funding of up to SGD 10,000 (or SGD 14,000 if the dispute concerns foreign IP rights as well) for parties, which choose to resolve disputes through mediation rather than litigation.[38]

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[36] Health Sciences Authority, *Guidance on therapeutic product registration in Singapore* (1 June 2022) at p16.
[37] See: *AstraZeneca AB (SE) v Sanofi-Aventis Singapore Pte Ltd* [2012] SGHC 16; *AstraZeneca AB (SE) v Sanofi-Aventis Singapore Pte Ltd* [2013] SGHCR 7.
[38] Intellectual Property Office of Singapore, 'Revised Enhanced Mediation Promotion Scheme (REMPS)' (23 March 2022) remps-information-sheet.pdf (ipos.gov.sg) accessed 4 August 2022.
Ministry of Law Singapore, 'New Legislation to Enhance Intellectual Property Dispute Resolution' (5 April 2022) New Legislation to Enhance Intellectual Property Dispute Resolution (mlaw.gov.sg) accessed 4 August 2022.

Additionally, the Supreme Court of Judicature (Intellectual Property) Rules 2022 (SCJIPR) that came into effect on 1 April 2022 introduced a new Simplified Process for Certain Intellectual Property Claims (**Simplified Process**), along with the existing "normal" process. Hence, this has established a two-track system of IP dispute resolution. The primary objective of the Simplified Process is to reduce the time taken and cost incurred to settle disputes, which will especially benefit parties that have limited access to legal and financial resources.

Despite the presence of these dispute resolution mechanisms, given the complexity of a patent linkage dispute, it is likely that such disputes would still be adjudicated through the normal court processes in Singapore.

A representative case of the patent linkage system

On 27 August 2020, the Court of Appeal in *Zyfas Medical Co vs Millennium Pharmaceuticals, Inc* [2020] SGCA 84 delivered its judgment on, *inter alia*, whether existing patents "in respect of the therapeutic product" include process patents. This case reaffirmed the SGCA's holding in *Millennium Pharmaceuticals, Inc v Drug Houses of Australia Pte Ltd* [2019] SGCA 31 (**DHA**) that process patents also need to be declared in an application to the HSA. It further held that process patents must be declared as long as the active ingredient in the product could have been made using the patented process.

Case description: On 2 February 2018, the Appellant, Zyfas Medical Co, a distributor of generic pharmaceutical products applied to the HSA to register an anti-cancer drug called "Myborte". After Zyfas's application obtained approval, the Respondent, Millennium Pharmaceuticals (**MP**), Inc. discovered this and requested a copy of the declaration that was made by Zyfas during the application process. Zyfas claimed that no declaration was required in relation to MP's patents. MP subsequently filed an application to the court seeking a declaration that that Zyfas had made a false declaration under reg 23(2) of the HPTPR (i.e. it contained a false or misleading statement or omitted certain relevant information).

Zyfas conceded to the SGHC that (1) MP had process patents that were in force regarding the therapeutic product and had to be declared under reg 23(2)(a) of the HPTPR; and (2) the existence of the process patents was a matter material to its application for registration. Its sole argument was that it did not knowingly or intentionally omit to declare material information because it had applied to register Myborte before the decision for DHA had been released, and did not know that process patents had to be declared at that time. The SGHC concluded that there was no provision in reg 24(1)(a)(ii) that required the mental elements of knowledge or intention to be fulfilled before a declaration was required to be made. Therefore, it issued a declaration stating that Zyfas' declaration under reg 23(2) omitted to disclose matter that was material for its application for registration of its therapeutic product. Zyfas appealed to the Singapore Court of Appeal (**SGCA**).

On appeal, Zyfas abandoned its argument that an omission had to be a knowing or intentional one, and instead raised a new point to say that process patents did not fall within the scope of reg 23(2)(a) since it covered only product patents. Notwithstanding the decision in DHA, the SGCA allowed this argument to be made on appeal under special circumstances, one of the considerations being that this was a question of law, which would impact the work of the HSA in implementing the HPTPR.

Court decision and case analysis

Ultimately, the SGCA undertook a broad interpretation of reg 23 of the HPTPR and held that process patents would be included within its scope, and such an interpretation "would be consonant with the legislative purpose of reg 23 as it was intended to give notice and protection to proprietors of relevant patents, whether they are product or process patents."[39] In simple terms, it dismissed the Appellant's claim and held that the ambit of reg 23 includes process patents.

Additionally, the SGCA stated at [42] that a process patent would relate to the therapeutic product as long as it is "logically possible" that the "active ingredient in that product could have been made using the patented

[39] *Zyfas* at [48].

process", and as such, needed to be declared.[40] This is despite Zyfas's claim that the therapeutic product did not in fact use the processes patented by MP. The SGCA stated that the proper procedure was for Zyfas to declare the existence of the process patents, and to further declare that it was not the proprietor of the patents but that the patents would not be infringed by carrying out the act for which the registration of the therapeutic product is sought, if Zyfas had genuinely believed that there was no infringement. It would then be up to the HSA to decide whether to require the requisite notice to be served on the proprietor.

Separately, the SGCA also took the opportunity to confirm the SGHC's conclusion that reg 24(1)(a)(ii) of the HPTPR did not require that a false or misleading statement or an omission to disclose a material matter must be made knowingly or intentionally. However, if such knowledge or intention was found in any particular case, an offence under reg 25(a) or (b) would be disclosed and the maker of the declaration would be subject to the criminal sanctions spelled out in that regulation (as opposed to where there is no knowledge or intention, in which case the consequence is merely that the registration may be cancelled).

This decision places the burden on generic manufacturers to take into account any patents that may appear to be connected to the product. In the first place, generic manufacturers have little guidance as to what the strength of the connection must be between existing patents and therapeutic products. In particular, it is unclear what the phrase "in respect of the therapeutic product"[41] means, which leaves open the possibility that even a remote connection between a therapeutic product and a valid patent may need to be revealed in a declaration. Additionally, there are a multitude of ways in which an active pharmaceutical ingredient could have been made, all of which may be the subject of claims in process patents on the Singapore patent register. This places a heavy burden on applicants to search through the Singapore patent register in order to identify relevant patents, and applicants potentially may have to file an onerous number of declarations upon identifying all potentially relevant patents. Hence, the courts could have given more clarity as to what constitutes relevant patents that need to be declared.

Ultimately, this case marks a significant step in favour of patent holders by placing a substantial burden on generic manufacturers to declare process patents that may be related to the therapeutic product they wish to sell. However, this may have potential negative implications on the industry as a whole, since generic manufacturers may be dissuaded from producing more affordable and easily accessible therapeutic products, which is particularly problematic in the case of medicinal and pharmaceutical products. Ideally, there should be a review of the relevant legislation to ensure a more equal balance between proprietors of brand name drugs versus manufacturers of generic products.

[40] *Ibid* at [42].
[41] HPTPR reg 23(1).

Thailand

Thailand does not have a “patent linkage” system like in the US, in which the US FDA will not grant marketing approval to a generic product that infringes a valid patent. Currently, the Thai FDA requires the submission of patent information as part of the marketing approval process (pursuant to the recent implementation of the Drug Act Amendment No. 6 (2019), which mandates declaration of published patent/petty-patent applications), and the Thai FDA keeps a database of patents on approved pharmaceutical products. However, the status of an existing application does not prevent or delay approval of a generic product by the Thai FDA. At present, the drug regulatory system in Thailand still operates independently of the patent system. The Thai FDA continues to grant marketing approval for generic drugs based on the Bolar provision (Section 36, paragraph 2, subparagraph 4) of the Thai Patent Act, which exempts from patent infringement “any act connected with an application for drug registration, wherein the applicant intends to produce, sell, or import patented medical products after the expiration of the patent”. As a result, generic pharmaceutical companies are not obliged to notify innovator companies about their submission of a drug marketing authorisation dossier. Under these circumstances, the innovator is aware of the launch of a generic version, but prefers to proceed with patent enforcement in Thailand mostly via litigation (i.e. court action). There is no other legal or regulatory mechanism that effectively prevents the marketing of an infringing product during the term of the patent for the original product.

There is also the issue of patent restoration and extension. The patent term in Thailand was 15 years, but in 1992 this term was extended to 20 years from the date a patent application is filed. This change in the patent term aligns Thai law with Article 33 of the TRIPS Agreement. Unlike the laws of the US, EU, Japan, South Korea and China, the duration of exclusive rights conferred by Thai law is uniform, irrespective of the type of invention. The Thai Patent Act does not recognise a restoration of a portion of the patent term for pharmaceutical inventions during which the patentee is unable to sell or market a product while awaiting marketing authorisation.

The Comprehensive and Progressive Agreement for Trans-Pacific Partnership (CPTPP) has been in the spotlight since this agreement may impact the establishment of a patent-linkage system in Thailand. Thailand may be required to introduce a patent-linkage system as part of a premarket regulatory review similar to those implemented in other CPTPP members. Nonetheless, there has not been much progress regarding Thailand's entry into the CPTPP. Even if the opportunity to update the Thai system according to the CPTPP has been lost or delayed, the reality is that Thailand is still capable of becoming a major player in the regional biotechnology sector. However, firm recognition of the need for and the role played by IP must be forthcoming. In addition, drug regulations must be strengthened and brought in line with international best practices and procedures.

Vietnam

Vietnam does not have a “direct patent linkage” system. The Drug Administrative of Vietnam (DAV) under the Ministry of Health still grants marketing approval for any generic product that would be covered by a valid patent. The DAV does not check or review any relevant patent information as part of the marketing approval process. At present, we do not notice any relationship between the drug regulatory system and the patent system in Vietnam. Vietnam extends the Bolar Exception to any product requiring regulatory approval (Article 125.2.a of the IP law), accordingly “patent owners would not have the right to prevent others from performing the following acts:

> Using inventions 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 requesting for regulatory licences for production, importation or circulation of products;”

Thus, the DAV may still grant marketing approval for generic drugs based on the Bolar provision without any obligation of the DAV or the generic pharmaceutical companies to notify innovator companies about any drug marketing authorisation generic dossier. In practice, via their local marketing team, the innovator often proactively learns about the launch of a generic version. However, the innovator would need to proceed with patent enforcement via either Court or Inspectorate of The Ministry of Science and Technology. There is no other regulatory mechanism provided by the Ministry of Health that effectively prevents the marketing authorisation granting of an infringing product during the term of a patent.

Under the Comprehensive and Progressive Agreement for Trans-Pacific Partnership (CPTPP), from January 2022, Vietnam was required to apply a system of pharmaceutical patent linkage.

Accordingly, prior to marketing any generic drug in Vietnam, Vietnam authorities must provide information or notify the original drug’s patent holder of the generic drug’s MA.

Alternatively, Vietnam may adopt a regime to prevent the issuance of a MA to generic drugs covered in the protection scope of a valid patent.

Currently, the DAV publishes the information of the newly granted MA so that any party can search for generic’s MA information. Thus, we interpret that the patent linkage commitment under the CPTPP may be considered appropriate with the current domestic regime in Vietnam.

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