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Introduction

The concept of patent linkage is a contentious issue in the healthcare industry as it concerns the involvement of drug authorities with patent infringement considerations. In this Global Guide to Patent Linkage, covering 36 key jurisdictions, Baker McKenzie and the Association of International Pharmaceutical Manufacturers (AIPM) explore which legal regimes adopt patent linkage doctrines and how these work. In the absence of patent linkage provisions, we explore what enforcement options are open to a patent owner to prevent approval of a generic or biosimilar or its entry into the market.

The Guide includes a sophisticated description of patent enforcement practices in different jurisdictions based on in-depth knowledge of the Baker McKenzie team, to reflect the current situation in each specific jurisdiction. We hope you find this guide useful. Should you have further queries, please do not hesitate to contact the authors for each country chapter directly.
**What is patent linkage?**

Patent linkage is generally understood to be the practice of linking the granting of marketing approval or any other regulatory approval for a generic or biosimilar medicinal product to the status of a patent for the originator reference product. Consequently, if there is a valid patent covering the drug which is the subject of a new drug approval, the drug authority, depending on the jurisdiction in question, may: refuse the application; refuse to grant a marketing authorization until the patent expiration; inform the patent owner to enable it to take any relevant action; or refuse to grant the application depending on the length of remaining term of the patent; among other actions.

The argument to support patent linkage is based on upholding the intellectual property rights, by ensuring that drugs are not approved if they infringe a third-party patent. In particular, it encourages investment in relation to these rights and avoids costly litigation, for all parties, in relation to “avoidable” enforcement proceedings. Originator companies sometimes argue that patent linkage is a logical method to ensure that regulatory approvals do not unduly promote patent infringement. They allege that by granting marketing authorization when a valid patent exists for the drug in question, regulatory authorities willingly collude in the alleged infringement. Many originator companies hold the view that no marketing authorization should be granted until the allegation of patent infringement has been settled. Occasionally, actions are accompanied by a threat to sue the regulatory authority for an injunction or damages if marketing authorization is granted. One of the key jurisdictions adopting patent linkage is the US. As well as adopting this concept itself, the US also seeks to include obligations for countries to adopt this concept as part of trade agreement negotiations.

Advocates against patent linkage often argue that patent linkage is not conducive to a competitive market as it extends the period of market exclusivity enjoyed by originator companies, preventing or delaying entry of generic medicines and biosimilars into the market. They also claim that problems can occur if poor quality patents are granted and then these patents create a barrier for other products entering the market. In addition, there are arguments that granting approval to safe and effective drugs should not be complicated by the ownership of IP rights. Furthermore, drug authorities are often unequipped to decide whether infringement exists and regulatory officials are not in a position to make an informed decision about the application of a patent to a particular generic or biosimilar product, and, therefore, should leave that issue to the courts. Jurisdictions adopting this approach include the EU, Russia and China.
Summary

The majority of the jurisdictions covered by this Guide do not adopt a formal patent linkage regime. These include: the EU Member States, Argentina, Brazil, China, Colombia, Egypt, India, Indonesia, Malaysia, Myanmar, Philippines, Russia, Switzerland, Taiwan, Thailand and Venezuela. That said it is often not as straightforward, as there are other factors that can be taken into consideration when looking at the generic and biosimilar landscape:

- Some countries such as Italy and Belgium have restrictions on the reimbursement by the National Health Service on drugs which infringe third party patents.
- In Indonesia and Thailand, although patent linkage has not been adopted as a legal principle, it is a requirement for applicant’s seeking drug marketing approval to submit patent search results to show drugs are not protected by third party patents.
- In some countries, such as Hungary and Egypt, declarations of non-infringement are sought by applicants at the time of filing.

In addition, there are a number of countries who are considering adopting a patent linkage regime in the future:

- Adopting a patent linkage regime was part of the obligations contained in a trade agreement between Chile and the US, although a patent linkage regime has not yet been adopted by Chile.
- Countries who ratify the CPTPP will also be required to adopt patent linkage provisions and practices.
- China, Thailand and Russia have also discussed the possibility of adopting a patent linkage regime in the future.
- There are some initial steps made within the Eurasian Economic Union towards implementation of the patent linkage concepts in the member states.

The countries that have adopted a formal patent linkage regime include: Australia, Canada, Japan, Mexico, Peru, Singapore, Taiwan, UAE, Ukraine, US and Vietnam.

In relation to those countries who have adopted such a regime, the provisions and the practices differ in relation to their effectiveness. For example, in Australia the patentees do not typically get the notice of the impending launch of a generic or biosimilar product until after it has been approved. Therefore patentees are still required to be vigilant in monitoring product registrations.

For further details on the arrangements in each jurisdiction, see the individual country chapters.
### Summary of Global Patent Linkage Regimes

#### Which jurisdictions adopt a patent linkage regime?

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#### Patent Linkage Regimes

- **Austria**: Patent linkage is an obligation pursuant to a Trade Agreement with the US, but it has not been implemented to date.
- **Belgium**: However, there are laws on the reimbursement of medicines which may have a similar effect.
- **Brazil**: Patent linkage is an obligation pursuant to a Trade Agreement with the US, but it has not been implemented to date.
- **China**: Adoption of patent linkage has been proposed but has not been implemented at the time of writing.
- **Colombia**: Patent linkage is an obligation under the CPTPP, if ratified.
- **Czech Republic**: Certain steps have already been taken towards implementation of the patent linkage concept within the territory of the EAEU.
- **Egypt**: In practice, applicants for drug marketing approval are required to submit patent search results to show drugs are not protected by third party patents.
- **France**: However, legislation states that generic drugs cannot be reimbursed by the National Health Service before expiry of an originator product.
- **Germany**: However, a declaration that a new drug does not infringe a third party right is required at the time of registration.
- **Hungary**: However, a declaration that a new drug does not infringe a third party right is required at the time of registration.
- **India**: Adoption of patent linkage has been proposed but has not been implemented at the time of writing.
- **Indonesia**: In practice, applicants for drug marketing approval are required to submit patent search results to show drugs are not protected by third party patents.
- **Italy**: However, legislation states that generic drugs cannot be reimbursed by the National Health Service before expiry of an originator product.
- **Malaysia**: Patent linkage is an obligation pursuant to a Trade Agreement with the US, but it has not been implemented to date.
- **Mexico**: Patent linkage is an obligation pursuant to a Trade Agreement with the US, but it has not been implemented to date.
- **Poland**: Certain steps have already been taken towards implementation of the patent linkage concept within the territory of the EAEU.
- **Russia**: Certain steps have already been taken towards implementation of the patent linkage concept within the territory of the EAEU.
- **Singapore**: The duty is on the applicant to show that the drug is not protected by any third party patent.
- **Switzerland**: However, a declaration that a new drug does not infringe a third party right is required at the time of registration.
- **Thailand**: However, the applicant does have to provide relevant patent information.
- **UK**: Patent linkage is an obligation pursuant to a Trade Agreement with the US, but it has not been implemented to date.
- **Venezuela**: Patent linkage is an obligation pursuant to a Trade Agreement with the US, but it has not been implemented to date.

This document is aimed at providing multi-jurisdictional reference information relating to patent linkage. You should not rely on its content without taking steps to determine that such content is current and accurate, or without ensuring that you understand the implications arising from the use of the content, whether as is, or with amendment. This information is not, and should not be treated as, legal advice. This document is proprietary of Baker & McKenzie and was last updated in July 2019. The information is a summary only and for more detailed advice on requirements of patent linkage please contact our healthcare specialists.

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Glossary

For the purposes of this guide, we have defined a number of key words and concepts.

**Bolar Exemption**: allows third parties to perform acts in relation to the subject matter protected by a patent, as long as they have the sole object of obtaining a sanitary registration or authorization of a pharmaceutical product.

**CPTPP**: Comprehensive and Progressive Agreement for Trans-Pacific Partnership, a free trade agreement between Australia, Brunei Darussalam, Canada, Chile, Japan, Malaysia, Mexico, New Zealand, Peru, Singapore and Vietnam.

Article 18.53 of the CPTPP Agreement provides:

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.

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.

**Data exclusivity**: the practice where the originator’s drug authorization regulatory data cannot be relied upon by a generic entrant into the market until a certain amount of time has expired (unless with approval from the originator). Such data cannot be relied upon until after eight years of authorization in a Member State or in the EU. For further information on the regulations in the EU, see the EU chapter.

**EU**: the European Union as constituted at the time of publication.

**Market exclusivity**: the practice where generic products must not be placed on the market until a certain time has elapsed from the initial marketing authorization of the originator’s product. This is for no less than 10 years in a Member State or in the EU. For further information on the regulations in the EU, see the EU chapter.

**Member State(s)**: a/the Member State(s) of the EU at the time of publication.
**Originator**: the first manufacturer/brand to bring the pharmaceutical product to the market.

**Patent linkage**: the practice of linking the granting of marketing approval, the pricing and reimbursement status or any regulatory approval for a generic or biosimilar medicinal product to the status of a patent for the originator reference product.

**Regulatory data**: the data required to be submitted to the appropriate regulatory agency by the applicant of a drug authorization to prove the pharmaceutical product is safe and efficacious.

**SPC**: supplementary protection certificates are intellectual property rights that extend the patent right for a pharmaceutical product authorized by the authorized regulatory authority.

**TRIPS Agreement**: the Trade-Related Aspects of Intellectual Property Agreement, which is a multi-lateral agreement administered by the World Trade Organization.

**WTO**: World Trade Organization.
Argentina
Introduction

In Argentina, there is no linkage between the Patent Office and ANMAT (the health authority responsible for the approval of pharmaceutical products for commercialization).

ANMAT has taken the position that the Patent Office or Federal Courts (courts that handle patent matters) should deal with issues related to patents and any IP rights.

Therefore, a pharmaceutical product may be approved for commerce, even if there is a third-party patent in force covering the product in question.

Legal regulation

Confidential information submitted for the approval of a product for commercialization is protected in Argentina by Article 39 of the TRIPS Agreement, which establishes that:

SECTION 7: PROTECTION OF UNDISCLOSED INFORMATION

Article 39

1. In the course of ensuring effective protection against unfair competition as provided in Article 10-bis of the Paris Convention (1967), Members shall protect undisclosed information in accordance with paragraph 2 and data submitted to governments or governmental agencies in accordance with paragraph 3.

2. Natural and legal persons shall have the possibility of preventing information lawfully within their control from being disclosed to, acquired by, or used by others without their consent in a manner contrary to honest commercial practices so long as such information:

   (a) is secret in the sense that it is not, as a body or in the precise configuration and assembly of its components, generally known among or readily accessible to persons within the circles that normally deal with the kind of information in question;
3. Members, when requiring, as a condition of approving the marketing of pharmaceutical or of agricultural chemical products which utilize new chemical entities, the submission of undisclosed test or other data, the origination of which involves a considerable effort, shall protect such data against unfair commercial use. In addition, Members shall protect such data against disclosure, except where necessary to protect the public or unless steps are taken to ensure that the data are protected against unfair commercial use.

Furthermore, Argentina has approved Confidentiality Law No. 24,766, which provides for the protection of confidential information submitted before health authorities for the approval of a pharmaceutical for its commercialization if such information is (i) secret; (ii) if it has a commercial value for being secret; (iii) if reasonable steps have been taken to keep it secret.

According to Article 5 of Confidentiality Law No. 24,766, if products that are already registered or that have already been authorized for commercialization in Argentina and/or any country appearing in Annex I of this law (United States, Japan, Switzerland, Helvetic Confederacy, Israel, Canada, Austria, Germany, France, United Kingdom, Netherlands, Belgium, Denmark, Spain and Italy), ANMAT shall proceed to approve or authorize such similar product for commercialization. In this case, only basic information will have to be filed, such as:

- Name of the product, formula (defined and verifiable), pharmaceutical way(s) in which it will be filed, pharmaceutical classification, code reference, if applicable, of the international classification of drugs of the World Health Organization and retail conditions.
- Control method, lifespan term and manufacture method, in accordance with current manufacture practice, bioequivalence data or bioavailability of the product with respect to similar products.
- Label and tags to be used, which should contain the following: name of the laboratory, address, name of the technical director, name of the product, name of the generic product in the same size and enhancement, formula per pharmaceutical unit or percentage, contents per selling unit, lot and manufacture series number, and the phrase “DRUG AUTHORIZED BY THE MINISTRY OF HEALTH AND SOCIAL ACTION” Certification No. (in capital letters).
- Prospects to be attached to the products, non-variable inscriptions in the labels and tags; pharmacological and therapeutic actions with precise clinical indications, warnings, precautions and adverse effects; habitual posology and minimum and maximum doses, way of administration, product formulation and addictive risks if not used properly.

In case of medicinal or drug specialties imported from countries listed in Annex II of the Confidentiality Law (Australia, Mexico, Brazil, Cuba, Chile, Finland, Hungary, Ireland, China, Luxembourg, Norway and New Zealand), apart from the aforementioned required information, the applicant shall submit a certificate issued by the health authority of the country-of-origin. The product should also be commercialized in the country-of-origin prior to the registration or importation request to be filed before the local health authority.

In Argentina, the drug approval procedure is governed by Executive Decree 150/92 and by ANMAT’s Regulation 3185/99, which follows the line of Article 5 of the Confidential Law. Regulation 3185/99 lists the drugs that require a bioequivalence study for approval.
In view of this, it can be said that if the product has been previously approved in Argentina or in other countries, such as the United States, Japan, Switzerland, Helvetic Confederacy, Israel, Canada, Austria, Germany, France, United Kingdom, Netherlands, Belgium, Denmark, Spain or Italy, it is relatively easy to obtain approval for commercialization of a pharmaceutical product.

**Case law**

This procedure has been objected to by several pharmaceutical companies claiming that Confidentiality Law No. 24,766 and Decree 150/92 are contrary to constitutional provisions and to the TRIPS Agreement Article 39.3, as there is an unlawful use of confidential information.

These claims were rejected by Chamber II of the Federal Court of Appeals in *Novartis v. Monte Verde* sustaining that the approval of “similar products” for commercialization by ANMAT does not entail the violation of guarantees undertaken by Argentina to avoid an “unlawful commercial use” of confidential information and should not be construed as fostering a “dishonest commercial practice” in violation of the TRIPS Agreement.

**Summary and future developments**

There are no foreseeable changes to the current regime in Argentina.

*Status: Law stated as of July 2019*
Australia
Introduction

Australia adopted a form of patent linkage in January 2005 to comply with its obligations under the Australia-US Free Trade Agreement (AUSFTA). The AUSFTA, at Article 17.10.4, requires the authority that provides marketing approval for pharmaceutical products to provide measures so as to:

(a) Prevent an applicant who is seeking regulatory approval for a product based on safety or efficacy information submitted in respect of a previously approved product from marketing a product that is claimed in a patent or from marketing a product for an approved use that is claimed in a patent.

(b) Provide for the patent owner to be notified of a request for marketing approval in relation to such a product or use.

These obligations are reflected in the Therapeutic Goods Act 1989 (Cth) (TG Act), which is the legislation governing the regulation of pharmaceutical products in Australia.

However, in practice, patentees do not typically receive notice of the impending launch of a generic or biosimilar product until after it has been approved and registered on the Australian Register of Therapeutic Goods (ARTG). This means that patentees are required to be vigilant in monitoring product registrations and must act quickly to assert their patent rights if they wish to seek to prevent the entry of a generic/biosimilar product into the Australian market or its inclusion in Australia’s pharmaceutical benefits reimbursement scheme.

Legal regulation

The government authority responsible for the regulation of therapeutic goods (including pharmaceutical products) in Australia is the Therapeutic Goods Administration (TGA). Before a pharmaceutical product can be marketed, offered for sale, sold or otherwise distributed in Australia, it must be registered on the ARTG, which is maintained by the TGA.

To obtain ARTG registration for a pharmaceutical product, the “sponsor” of the product must make an application to the TGA, which, if the first brand of the medicine (originator product), will include data and information requiring the safety and efficacy of the product in the treatment of a particular disease. If the TGA is satisfied as to the safety and efficacy of the product, the TGA will approve the registration of the product and it will then be included in the ARTG.

Applications made to the TGA to register a product in the ARTG are confidential. TGA approval for registration only becomes public when the product is included in the ARTG. The ARTG is publicly available and can be searched by brand name, active ingredient or sponsor.
The TG Act provides for a period of five years of data exclusivity in relation to confidential information about an active component of a pharmaceutical product that is given to the TGA in relation to an application to register a new pharmaceutical product consisting of, or containing, that active component. The five-year period is not linked to any patent term and commences from the date of the first inclusion of the pharmaceutical product on the ARTG. During the five-year period, the TGA is prohibited from relying on the confidential information when evaluating other pharmaceutical products.

A new brand of a pharmaceutical product included in the ARTG (generic product) can obtain TGA approval and ARTG registration if the sponsor of the product can demonstrate bioequivalence to the existing (originator) product. If such bioequivalence can be demonstrated, and the relevant five-year data exclusivity period has expired, the sponsor of the generic product may rely on safety and efficacy data submitted by the originator.

In Australia, pursuant to section 119A of the Patents Act 1990 (Cth), companies may apply to the TGA and obtain regulatory approval for a generic medicine at any time during the patent term of the originator medicine containing the same active ingredient without infringing the relevant patent. This is commonly referred to as “springboarding.”

Products that are registered on the ARTG may be sold in the private market or under the Pharmaceutical Benefits Scheme (PBS). Under the PBS, which is established by the National Health Act 1953 (Cth), the government subsidizes the cost of the product and the patient is only required to make a co-payment to the pharmacist dispensing the product.

For a pharmaceutical product to be subsidized through the PBS, the sponsor of the product must make an application to the Pharmaceutical Benefits Advisory Committee (PBAC) for the product to be listed on the Schedule of Pharmaceutical Benefits.

When the first generic or biosimilar version of a product already included on the PBS is listed on the Schedule, an automatic price reduction of 25% is applied to all versions of the product that have the same manner of administration as the generic or biosimilar, including the originator.

Patent linkage requirements in Australia are set out in sections 26B, 26C and 26D of the TG Act.

**Section 26B**

Where an applicant for approval of a product relies on efficacy and safety data submitted to the TGA by an originator (or other person), section 26B(1) of the TG Act requires that the applicant provide the TGA with either of the following:

(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 relevant product in a manner or in circumstances that would infringe a valid claim of a patent that has been granted in relation to the product.

(b) A certificate to the effect that, where there is an existing valid patent, and the applicant proposes to market the product before the end of the term of the patent, the applicant has given the patentee notice of the application for registration of the product.

It is an offense for an applicant to provide a certificate to the TGA that is false or misleading in a material particular.

In practice, type (b) certificates are rarely used by generic applicants who will typically provide a certificate of type (a) on the basis that a patent is invalid unless a court holds otherwise. Type (a) certificates are
submitted to the TGA as part of the confidential regulatory dossier. The certificates are not required to be provided to the patentee by the generic applicant or the TGA.

This means that where a type (a) certificate is provided, patentees do not receive notice of the impending launch of a generic (or biosimilar) product before the product has been approved by the TGA and appears in the ARTG. Further, there is no automatic notification of the inclusion of the generic product in the ARTG and patentees must generally conduct searches of the ARTG to identify the registration of any generic products.

The ARTG provides a list of approved pharmaceutical products (and other therapeutic goods), together with information such as their active ingredients and indications, but does not contain references to any patents that are relevant to the registered products. Thus, there is no equivalent in Australia of the US Orange Book.

**Section 26C**

This section applies where a patentee or exclusive licensee ("patentee") intends to commence proceedings for infringement of a patent that has been granted in relation to a pharmaceutical product for which a section 26B certificate has been provided to the TGA. In this case, the patentee must provide a certificate to the TGA and to the person who provided the section 26B certificate, to the effect that the proceedings are to be commenced in good faith, have reasonable prospects of success and will be conducted without unreasonable delay.

If a patentee provides a certificate under section 26C that is false or misleading in a material particular or if the patentee breaches an undertaking given in the certificate, the patentee may be ordered to pay the Commonwealth Government a pecuniary penalty of up to AUD 10 million. If that patentee obtains an interlocutory injunction restraining the person who provided the section 26B certificate from infringing the patent, they may also be ordered to pay compensation to the Commonwealth or a state or territory government.

**Section 26D**

This section only applies in circumstances where an applicant for ARTG registration has provided a section 26B(1)(b) certificate and the patentee proposes to apply for an interlocutory injunction to restrain the applicant from marketing a generic product on the grounds that such conduct will constitute patent infringement.

In this case, the patent holder must first notify the Australian Attorney-General, who is deemed a party in the proceedings. Section 26D provides for the award of compensation “pursuant to the usual undertaking as to damages given by the patentee ... to obtain the interlocutory injunction” if the substantive proceedings have been disposed of in a way that is unfavorable to the patentee and the court declares that the patentee had no reasonable grounds to believe it would obtain final relief or the application for an interlocutory injunction was vexatious.

**Case law**

There have been no Australian cases in which remedies have been granted in connection with the provision or non-provision of certificates under sections 26B, 26C or 26D of the TG Act.

Given that the first notification an originator receives of an impending launch of a generic or biosimilar product in Australia is usually the inclusion of the product in the ARTG, after the product has already received regulatory approval, the assertion of patent rights by originators is typically directed at preventing a potentially infringing generic/biosimilar product from entering the Australian market and, where relevant, from being listed on the Schedule of Pharmaceutical Benefits.
To restrain these activities, patentees may apply to the court to obtain an interlocutory injunction which, if granted, may remain in place until the infringement (and any invalidity case) has been determined by the court after a substantive hearing. Theoretically, the generic/biosimilar product can be launched immediately upon ARTG registration and originators must, therefore, act quickly upon becoming aware of the registration if they seek to prevent the product from entering the market. Any unreasonable delay in doing so that causes prejudice to the generic/biosimilar supplier may be sufficient to warrant refusal of the interlocutory injunction application (see for example, Interpharma Pty Ltd v Aventis Pharma SA [2011] FCA 32).

To obtain an interlocutory injunction, the patentee must show that there is a prima facie case, in the sense that there is a sufficient likelihood that the patentee will succeed in their patent claim at the final trial and that the balance of convenience favors the grant of an injunction. In determining the balance of convenience, the court will consider a variety of factual issues, including whether, without an injunction, the patentee will suffer irreparable harm for which damages will not be an adequate remedy.

Reference to the irreversible price reduction triggered by PBS listing of the generic/biosimilar product can often assist originators in demonstrating irreparable harm. However, such harm may also be shown in the absence of PBS listing of the originator product, including based on evidence of the difficulties of calculating damages for loss of market share. On the other hand, if it can be shown that any loss to the patentee will be easily quantifiable, an application for interlocutory injunction will fail in the absence of other factors weighing the balance of convenience in favor of the patentee.

In Australia, an applicant for an urgent interlocutory injunction to prevent allegedly infringing conduct must provide an undertaking as to damages to the court. The “usual undertaking as to damages” given by an applicant for an interlocutory injunction in the Federal Court of Australia is in the following terms:

*to submit to such order (if any) as the Court may consider to be just for the payment of compensation, to be assessed by the Court, or as it may direct, to any person, whether or not a party, adversely affected by the operation of the interlocutory order or undertaking or any continuation (with or without variation) thereof;…*

In essence, the undertaking is intended to protect a respondent or respondents in circumstances where an interlocutory injunction is granted but an applicant is not successful in obtaining a permanent injunction to prevent allegedly infringing conduct. The undertaking and associated risk is the “price” for the grant of an interim injunction.

The undertaking as to damages extends to “any person, whether or not a party” who is adversely affected by the interlocutory injunction. In recent cases, generic manufacturers, who were not parties to the original proceedings, and the Commonwealth Government have sought to claim compensation on such undertakings where the interlocutory injunction was, subsequently, found to have been wrongly granted.

In the October 2018 decision of Sigma Pharmaceuticals (Australia) Pty Ltd v Wyeth [2018] FCA 1556, the Federal Court awarded damages to both generic suppliers and associated manufacturers under an undertaking as to damages for lost opportunities suffered as a result of interlocutory injunctions that were granted to restrain the launch of generic venlafaxine products but which were, subsequently, found to have been wrongly granted on the basis that the patents at issue were invalid. Judgment is currently pending in a further case in which the Commonwealth Government has sought compensation pursuant to an undertaking as to damages given by Sanofi in respect of an interlocutory injunction restraining the launch of generic clopidogrel products, where the relevant patents were held to be invalid at trial (GenRx Pty Ltd v Sanofi-Aventis [2007] FCA 1485; Apotex Pty Ltd v Sanofi-Aventis [2009] FCAFC 134 (generic clopidogrel)).
The Full Court of the Federal Court of Australia has held that the patent linkage provisions in sections 26B, 26C and 26D of the TG Act are not intended to supersede or displace a person’s ability to recover compensation on an undertaking as to damages.

**Summary and future developments**

The patent linkage system currently existing in Australia has received a number of criticisms from both originator and generic suppliers.

Medicines Australia, the organization representing the innovative medicines industry, has commented that the lack of notification that originators receive upon generic products obtaining regulatory approval and the potentially large penalties that can be imposed on patent holders for seeking to defend their patent rights (under section 26C of the TG Act and as a result of the undertaking as to damages) weakens the robustness of the intellectual property system in Australia.

The Generic Medicines Industry Association (GMIA) has argued that generic pharmaceutical suppliers “unfairly bear the very significant burden (cost, time and risk)” of determining which patents may be relevant to a particular pharmaceutical product, including by conducting patent searches and reviews. The GMIA has suggested that sponsors should be required to identify in the Patents Register each relevant patent for its product and that the section 26B certificate process is “strongly and unfairly biased in favor of therapeutic goods patentees” and ought to be amended.

In May 2013, the government published a “Pharmaceutical Patents Review Report,” which recommended the introduction of a “transparency register” to link therapeutic goods included on the ARTG with related patents. The report recommended that:

- The register should include the numbers of all patents owned by, or licensed to, the sponsor of the therapeutic good and relevant to the therapeutic good.
- Patent numbers should be supplied to IP Australia (the Australian agency administering IP rights) when the sponsor receives notification of the ARTG inclusion or when the patent is granted, if grant is subsequent to ARTG listing.
- A sponsor should only be able to commence infringement proceedings in respect of a patent that is on the transparency register.
- Upon inclusion of a generic product on the ARTG that relies on information provided earlier in relation to another product, the TGA should directly notify the owner(s) of the patent(s) listed on the transparency register, in relation to that earlier product, about the inclusion.

However, following the release of the report, there was a change in government and there has been no indication that the current government is considering implementing the recommendations of the report.

**Status:** Law stated as of July 2019
Austria
Introduction

In Austria, the concept of patent linkage is not implemented.

Legal regulation

In Austria, the Austrian patent office reviews patent applications and grants patent protection where considered appropriate. The approval of medicines is carried out by the Federal Office for Safety in Health Care (BASG). During the approval process of medicines, the approving authority reviews the efficacy, safety and quality of the drug. A drug is only approved where the benefits of a medicine outweigh the respective risks. The approving authority does not consider potential patent infringements.

Furthermore, it should be emphasized that the Austrian Patent Act (PA) exempts studies and trials and respective practical requirements resulting from patent protection, to the extent that they are necessary for obtaining the approval, authorization or registration of medicines under pharmaceutical law (§ 22 PatG).

This also complies with Article 10(6) of the EU Directive 2001/83/EC ("Bolar Exemption"). See the EU chapter for a further discussion on EU regulation.

Protection of pre-clinical test results and clinical trials in Austria

Documents submitted by a medicine approval applicant containing information on pre-clinical test results and clinical trials are protected from the use for the benefit of their competitors without the applicant’s consent. This is to ensure that there is no discrimination where the first notifier would have to carry out all tests before being able to place the product on the market and its competitors would benefit from these tests, resulting in the first notifier’s loss of investment and market research information. Document protection, therefore, protects the investment in generating the information needed to obtain an approval. This concept is implemented in Art. 10 of the Medicines for Human Use Directive and § 19 of the Austrian Medicines Act.

The documents for the approval process of a new medicine, which would be the reference drug for the respective generic products, enjoy eight years of document protection, i.e., no approval application for a
corresponding generic drug may be processed by the approving authority in the cost-efficient abbreviated procedure without the consent of the innovator of the reference drug.

The generic application can be filed after this eight-year “blackout period”; the authority is entitled to process it based on the documents of the reference drug, but the product may not be placed on the market before 10 years from the approval date of the reference drug have elapsed (ten-year market protection).

In this context, it is irrelevant whether the application for a generic medicinal product is submitted in connection with a reference medicinal product that is authorized in Austria or in another EU Member State. In the latter case, the original approving authority sends the Member State in which the application was submitted all the documents necessary for the evaluation and confirms to the investigating authority that the reference medicinal product has been authorized.

The abbreviated procedure leads to a simplification of the procedure in the sense that the applicant is exempted from the obligation to submit the results of his/her own pharmacological, toxicological or clinical trials.

**Case law**

In the event of patent infringement, the patent owner is entitled to an injunctive relief and to the removal of infringing products, the publication of the judgment, information on distribution channels and for any damages that, in certain circumstances, include twice the appropriate remuneration for the use of the patent (§ 147 PA, et seq.).

Typically, an action for injunctive relief is combined with an application for a preliminary injunction. The preliminary injunction is a fast-track procedure that aims to prevent further patent infringing acts by the infringer within a few weeks or even days, where considered necessary.

**Summary and future developments**

Due to the existing patent system and respective regulatory framework in the EU, the implementation of the concept of patent linkage in Austria is rather unlikely in the near future.

It is also apparent that the EU aims to facilitate and support access to generic drugs to make drug treatment more cost-effective.

Although the system of patent linkage is not established in Austria, there are enforcement tools available that protect the patent holder from patent infringements. Specifically, preliminary injunctions provide a fast-track procedure to prevent patent infringements within a very short period.

Status: Law stated as of July 2019
Belgium
Introduction

Belgian law does not as such recognize the concept of patent linkage.

Legal regulation

For an overview of the EU regulatory regime, see the EU chapter.

Belgian law does not recognize the concept of patent linkage. However, there are legal rules in Belgium with a similar effect that can be found in the law on the reimbursement of medicines, i.e., the Coordinated Act of 14 July 1994 on the compulsory insurance for medical care and benefits (Gecoördineerde wet van 14 juli 1994 betreffende de verplichte verzekering voor geneeskundige verzorging en uitkeringen / Loi coordonnée du 14 juillet 1994 relative à l’assurance obligatoire soins de santé et indemnités – the “1994 Act”).

Article 34 of the 1994 Act contains a summary of the medical services considered for reimbursement, among which the supply of medicines is mentioned under point 5°:

b) the pharmaceutical specialties whose main active ingredient, as included in the Anatomical Therapeutical Chemical Classification established under the responsibility of the World Health Organizations Collaborating Center for Drug Statistics Methodology, is protected in Belgium by a patent or a certificate supplementing the protection of the patent;

c) the pharmaceutical specialties whose main active ingredient, as included in the Anatomical Therapeutical Chemical Classification established under the responsibility of the World Health Organizations Collaborating Center for Drug Statistics Methodology, is not or is no longer protected in Belgium by a patent or a certificate supplementing the patent. Two groups can be distinguished: 1) branded specialties out of the patent protection period (…)

The 1994 Act establishes the Belgian reference reimbursement system. Introduced on 1 June 2001, the Belgian reference reimbursement system aimed to stimulate the prescription of cheaper medicines. In short, if a (cheaper) generic, reimbursed medicine is available, which contains the same active component (or components), the original medicine enters the reference reimbursement system. This means that the level of reimbursement of the original medicine is diminished by 30% (ex factory level), while its applied price remains the same. Although the level of reimbursement of the original medicine is diminished, the patient’s personal contribution increases, as the difference between the applied price and the new level of reimbursement (the so-called “supplement”) will be charged to the patient. Since 1 April 2010, a maximum ceiling was attributed to this “supplement” (i.e., 25% of the level of reimbursement). However, pharmaceutical companies have the possibility to lower their applied price to reduce or even let the patient’s supplement expire. Article 35ter, § 1 of the 1994 Act provides the following:
§ 1. A new reimbursement basis shall be established for the specialties referred to in Article 34, first paragraph, 5°, c), 1) if a proprietary medicinal product referred to in Article 34, first paragraph, 5°, c), 2) containing the same active ingredient is reimbursable and if the reimbursement basis of the latter is at least 16 pc lower at the time of its adoption than in relation to the reimbursement basis of the specified specialties. To compare the reimbursement basis of the specialties, account is taken of the number of pharmaceutical units per package, but not with the dosage form or with the dosage.

By the end of 2008, Article 35ter of the 1994 Act was supplemented with another patent linkage provision at § 5, the third paragraph of which reads as follows:

If the right to commercialize the specialty referred to in Article 34, first paragraph, 5°, c), 2, which should give rise to the application of paragraph 1, is disputed as a result of a claimed infringement of the patent covering the main active ingredient, and if the proof of this dispute is submitted to the Institute at least 20 days before the entry into force of the new fee base laid down in application of paragraph 1, by means of a copy of the writ of the summons introducing either a summary proceeding or a cease-and-desist action, the determination of the new fee base is postponed either until an enforceable court decision is taken on the aforementioned dispute that allows the commercialization of the specialty in question, or until the moment that another specialty gives rise to the application of paragraph 1.

The explicit references to patents on the main active ingredient of a medicinal product in the aforementioned Articles 34 and 35ter, § 1 of the 1994 Act result, in particular, in the postponement of the application of the reference reimbursement system. During this time, generics are not reimbursed by the Belgian Institute for Health and Disability Insurance (RIZIV/INAMI – the “Institute”), even if the patent concerned has already lapsed or market entry of generics is delayed.

Moreover, Article 35ter, § 5 of the 1994 Act, which entered into force on 8 January 2009, allows an originator company to postpone the application of the reference reimbursement simply by filing a writ of summons with the Institute, introducing a summary proceeding or a cease-and-desist action (an expedited procedure on the merits) for alleged patent infringement, even if a generic alternative is already effectively available on the Belgian market.

Originator companies can use this explicit reference to patents in the 1994 Act to ask the Institute not to issue reimbursement decisions for generics and/or trigger the reference reimbursement system. It provides a legal basis to prevent the reference reimbursement system from being applied so that patients/physicians are less inclined to switch from the “familiar” original to the new generic alternative, even if generic competitors are effectively available on the market. Lastly, even if a patent has expired/is invalidated, an originator company may try to delay the application of the reference reimbursement system based on additional patents (process patents, second medical use, etc.).

Case law

Two Belgian judgments concerning the active ingredient alendronate, commercialized by Merck Sharp & Dome (MSD) under the name Fosamax®, are worth mentioning in this respect.

In a first judgment of 19 October 2007, the Court of first instance in Brussels imposed an explicit prohibition on the Belgian state to apply the reference reimbursement system for alendronate before the lapse or invalidation of MSD’s patent. The Court held that the application of the reference reimbursement system requires that a reimbursement decision regarding a generic medicine has been taken and that the generic medicine is effectively on the market, which was not the case here. The Court further added that the
A reference reimbursement system can only be applied if the main active ingredient of the reference speciality is no longer protected by a patent or supplementary protection certificate (SPC), which was the case for MSD (i.e., SPC nr. 96C0027).

However, a second action brought by MSD against the Belgian state in summary proceedings to stop the reference reimbursement based on MSD’s 70 milligrams dosing patent EP 1 175 904 was dismissed by the President of the Court of first instance in Brussels on 30 June 2008, *inter alia*, on the basis that EP 1 175 904 was declared invalid in Belgium by a judgment of the same court of 8 April 2008 and that generic versions were already on the market in the relevant period.

Summary and future developments

These are the only published court decisions in Belgium on this topic, thus far, which shows that:

(i) Efforts to delay market entry by generics based on patent linkage are applied with varying success.

(ii) The patent linkage system has remained somewhat underexposed in recent years and has not yet reached its full potential.

From a policy perspective, some originator companies have suggested that if a generic company applied for a marketing authorization, at the least, public notice should be given. Ideally, granting of a marketing authorization should be suspended where the owner of the reference product claims infringement of an intellectual property right, until the national courts or the European Patent Office resolves the matter.

The patent linkage system can be taken as an opportunity to strengthen the generics industry through the development of new formulations or products based on expired patents. Some in the industry believe that building a clear regulatory system for cooperation between the patent offices and the regulatory health authorities would result in the consolidation of the generics companies, being committed to development in areas not contemplated by innovator pharmaceutical companies and preserving market exclusivity for innovators.

Status: *Law stated as of July 2019*
Brazil
Introduction

To date, the concept of patent linkage does not exist in Brazil.

The observance of intellectual property rights is the sole responsibility of the patentee, therefore, the regulatory authorities will not stay or reject any regulatory approvals based on such rights. In other words, regulatory authorities, such as the Brazilian Health Regulatory Agency (ANVISA), which would be the Brazilian FDA equivalent, may grant marketing approval for a generic drug even if the compound or formulation is the subject matter of an issued patent in Brazil.

There is no requirement of patent listing and, consequently, no list or official matching between a product and its respective exclusivity rights, such as the US Orange Book.

Below we comment on the possibility of the enforcement of patent rights during the period of validity of an originator’s patent used in such product.

Legal regulation

As mentioned above, regulatory authorities in Brazil have no specific legal duty to stay or delay marketing authorization based on eventual IP Rights. Article 13, of Federal Law No. 10,603/2002, which regulates the “protection of non-disclosed information submitted for marketing approval,” states that:

Article 13. Independently of the granting of registration by the competent authority, the observance of any intellectual property rights protected in the country is the sole responsibility of the beneficiary.

In addition, Brazilian law also provides for what it is known as the “Bolar Exemption.” Indeed, Article 43, VII, of the Brazilian Intellectual Property Law, Law 9,279/1996 (IPL) states that patent rights do not apply to “acts practiced by unauthorized third parties related to the invention protected by a patent, for the sole purpose of producing test results, information, and data in order to obtain the commercialization registration in Brazil or abroad.”
However, originators may rely on other provisions of the IP Law, as well as on the WTO TRIPS Agreement, which was signed and internalized in Brazil by Decree 1,355/1994 to seek legal remedy to enforce their IP Rights.

In particular, the IPL provides that patent owners have the right to prevent third parties from infringing their patent rights by “producing, using, marketing, selling, or importing” the product protected by a patent in Article 42, which states:

*Article 42. The patent grants to the holder the right to prevent a third party, without its consent, from producing, using, offering for sale, selling, or importing for these purposes: I—product subject to patent; II—process or product obtained directly by patented process.*

Therefore, any acts practiced by an unauthorized third party may be opposed by the patentee, even before commercialization, such as the importation, manufacture or an offer for sale.

In addition, Article 39.3 of the WTO TRIPS Agreement, as well as the IP Law (Article 195, XIV), provide protection against unfair competition practices, including the violation of Data Package Exclusivity (DPE):

*SECTION 7: PROTECTION OF UNDISCLOSED INFORMATION*

*Article 39*

3. Members, when requiring, as a condition of approving the marketing of pharmaceutical or of agricultural chemical products which utilize new chemical entities, the submission of undisclosed test or other data, the origination of which involves a considerable effort, shall protect such data against unfair commercial use. In addition, Members shall protect such data against disclosure, except where necessary to protect the public, or unless steps are taken to ensure that the data are protected against unfair commercial use.

*Article 195 - A crime of unfair competition is committed by he/she who:*

*XIV - divulges, exploits or uses, without authorization, the results of tests or other undisclosed data the elaboration of which involved considerable effort and which has been presented to government entities as a condition for approving the commercialization of products.*

Although DPE is still a controversial topic before Brazilian courts, especially due to the lack of a clear exclusivity term, there are judicial decisions applying the rule of Article 39.3 of TRIPS to prevent ANVISA from granting marketing approval to generic and similar drugs, by “relying,” even indirectly, on the regulatory dossier of the reference product.

In addition to preventing the alleged violator from continuing to market and/or manufacture the drug, it is possible for the patent holder to be indemnified for the damages incurred by virtue of the patent infringement. Article 44 provides that:

*Article 44 - A patentee is guaranteed the right to obtain compensation for the unauthorised exploitation of the subject matter of the patent, including exploitation that occurred between the date of publication of the application and that of grant of the patent.*

In the same direction, Article 209 establishes that:

*Article 209 - The aggrieved party is reserved the right to receive losses and damages in compensation for losses caused by acts of violation of industrial property rights and acts of unfair competition that are not provided for in this law but which tend to prejudice another’s reputation*
or business or to cause confusion between commercial or industrial establishments or providers of services, or between products and services placed on the market.

Under Brazilian Law, patent owners may also seek *ex parte* preliminary injunctions against infringing activities. In accordance with Article 209, paragraph 1 of the IPL, “the judge may grant a preliminary injunction, on the case records of the lawsuit, to stop the act or violation, before the defendant is even served of the complaint, upon deposit in cash or guaranty, as deemed necessary, to avoid irreparable damage or damage of difficult indemnification.”

For providing evidence of the infringement, plaintiffs will usually be required to gather i) evidence of the manufacturing, sale, import, etc. of the infringing product by the defendant; ii) technical experts’ reports to compare the patent claims and the infringing products’ features (as courts tend to decide that patent infringement cases are quite technical and, therefore, a patent master’s opinion is required).

The Civil Procedure Code also allows patent owners to file a motion for preliminary injunction before the formal filing of the complaint. However, this is still not very common under Brazilian practice, being such a remedy normally used for cases related to life-threatening situations. In any event, even if a motion for preliminary injunction is filed, the plaintiff would later have to amend such brief for presenting the formal complaint.

Please note that according to the Civil Procedure Code, if the main infringement action is lost, the defeated party must reimburse and repair damages deriving from any preliminary injunction, regardless of fault or willful misconduct. This provision has been recently enacted and, therefore, there is still some discussion on its application by courts.

**Case law**

To date, there are only a few cases where originators tried to enforce IP Rights before a regulatory authority or at a stage where a competitor had just obtained marketing approval, but not yet launched the infringing product in the market.

The most emblematic case is *Lundbeck v. ANVISA, Aché and Biosintética* (complaint No. 0016573-55.2008.4.01.3400), in which the lower court (7th Federal Court of Brasilia), on 9 May 2011, rendered a final decision on the case merits confirming a previous preliminary injunction for preventing ANVISA from using the regulatory dossier submitted by Lundbeck when granting third-party products’ marketing approval. In the final ruling, the lower court applied Article 39.3 of TRIPS and invalidated three marketing approval registrations granted by ANVISA for copies of Lexapro. As the IPL does not regulate the term of such protection, the court applied, by analogy, Federal Law No. 10,603/2002, which provides for the protection of confidential data for agrochemicals and veterinary products:

> Article 3. The protection of information, defined by Articles 1 and 2 and Article 4, shall involve:
>
> I - non-use by the competent authorities of test results, or other data submitted to them, to the benefit of third parties;
>
> II - non-disclosure of test results or other data submitted to the competent authorities, except when necessary to protect the public.
>
> (…)
Article 4. The terms of protection referred to in Article 3 will be:

I - for products that use new chemical or biological entities, of ten years from the grant of registration or until the first release of information in any country, whichever occurs first, guaranteeing at least one year of protection.

The Lundbeck decision was later reversed on appeal and the case is now pending before the Brazilian Superior Court of Justice (STJ).

On the topic of the Bolar Exemption, there is case law from the State Court of São Paulo (the main state court) that adopts the position that the submission of all necessary documents for regulatory approval, during the validity term of a patent, may be allowed, provided that the commercial exploitation takes place after the expiration of the patent’s validity term.

**Summary and future developments**

Despite the lack of legal provisions directly related to the patent linkage concept and the conflicting case law on the scope and limits of the Bolar Exemption, and on the possibility of enforcing DPE rights in Brazil, Brazilian legislation does provide, to an extent, legal remedies enabling an IP Right holder to enforce their rights against a non-authorized third party, even before the stage of commercialization.

Status: **Law stated as of July 2019**
Introduction

Canada adopts a patent linkage regime. A patent linkage regime was originally enacted in 1993 pursuant to the Patent Act. The Patented Medicines (Notice of Compliance) Regulations ("PMNOC Regulations") have undergone various amendments since 1993. The most recent amendment, in September 2017, was significant because it substantially altered the underlying procedure to meet the requirements of the Comprehensive Economic Trade Agreement (the trade agreement entered between Canada and the EU), as described in more detail below.

The Supreme Court of Canada has stated that the purpose of the PMNOC Regulations is to prevent patent infringement by delaying the grant of market approval through the issuance of a Notice of Compliance (NOC) for subsequent entry (including both generic (small molecule) and biosimilar (large molecule)) drug products until it is determined that the manufacture and sale of the subsequent entry drug will not result in the infringement of any listed patent(s).

The above-noted objective of the PMNOC Regulations was achieved pre-2017 by a procedure that required the innovative manufacturer (referred to as the "first person" under the PMNOC Regulations), upon receiving notification from the subsequent entry manufacturer (referred to as the "second person"), to commence an application (paper-based) court proceeding seeking to prohibit the Minister of Health from issuing an NOC for a subsequent entry version of a patented medicine. Such proceedings did not fully determine issues of infringement or the validity of the relevant patents, which often required a second round of litigation once the subsequent entry drug received its NOC and entered the market. With the recent amendment, this pre-2017 procedure has been replaced with a procedure that requires a full action (involving a full trial with discovery and "live" witness evidence in court) resulting in a final determination of patent infringement and validity, thereby eliminating the duality of litigation that often transpired under the old regime.

This chapter will focus on the PMNOC Regulations as they currently exist in light of the 2017 amendment.

Legal regulation

Interplay in the regulatory landscape

The PMNOC Regulations bridge the gap between two different regulatory systems: the patent acquisition and enforcement system provided by the Patent Act and the drug product approval system of the Food and Drugs Act. The PMNOC Regulations prevent the market approval of a subsequent entry drug where it would infringe a patent or patents that relate to the innovative drug product. For the subsequent entry product to receive market approval, the subsequent entry manufacturer must establish that it does not infringe a valid patent that is relevant to the PMNOC Regulations (described below). In this manner, the subsequent entry manufacturer is provided with an opportunity to obtain its market approval in advance of patent expiry, provided that it establishes non-infringement. Moreover, the innovative manufacturer is notified of a
subsequent entry (competitive) product submitted for market approval before that product enters the market and infringes relevant patents.

**Introduction to the terminology**

Before turning to a substantive discussion of the process relevant to the PMNOC Regulations, it is necessary to review the terminology encountered when dealing with this regime.

(a) Patented medicine

Simply put, “patented medicine” is a medicine covered by a patent. A patent that is eligible for listing (described below) pursuant to the PMNOC Regulations must include a claim(s) that covers a new medicinal ingredient, a new formulation or dosage form, or a new use of the medicinal ingredient. Patents that are ineligible for listing include those directed to a process (method) to manufacture a drug product. Other ineligible patents include those directed to metabolites, intermediate compounds, or different chemical forms of the active ingredient (e.g., esters, salts, etc.). Medical device patents are also ineligible under the PMNOC Regulations.

(b) NOC

To advertise for sale and sell a drug product in Canada, the manufacturer of the drug (whether a subsequent entry or innovative manufacturer) must obtain an NOC from the Minister of Health according to the Food and Drug Regulations, which are enacted pursuant to the Food and Drugs Act. An NOC memorializes the Minister’s approval for the manufacture, sale and marketing of a drug in Canada by a pharmaceutical manufacturer. The Minister may issue an NOC in response to regulatory submissions by either an innovative company or a subsequent entry company, depending on the circumstances.

(c) Patent register and patent lists (Sections 3 and 4)

Pursuant to the PMNOC Regulations, the Minister of Health is required to maintain a public register of patents ("Patent Register") that lists the eligible patents against corresponding drug products. The Minister is notified of eligible patents by the patent owner (or licensee or a person with the consent of the patent owner), who has been issued an NOC and has submitted a patent list.

There are specific timing and subject matter eligibility requirements that must be met before a patent can be added to the Patent Register. The patent must be issued (patent applications are not eligible). If the issuance date is prior to filing the drug submission seeking market approval, the patent must be included on a patent list that is filed at the same time. If not, that patent is ineligible for addition on the Patent Register. For a patent issued after the drug submission is filed, it must be submitted on a patent list within 30 days of patent issuance, provided that the Canadian patent filing date precedes the drug submission’s filing date. There are no extensions to these timelines.

In addition to the timing requirements, a patent must meet specific subject matter criteria. To be eligible for inclusion on the Patent Register, the patent must correspond to the drug product and contain a claim for the following: the medicinal ingredient, a formulation that contains the medicinal ingredient, and a dosage form containing the medicinal ingredient, or a use of the medicinal ingredient and that medicinal ingredient, formulation, dosage form or use has been approved through the issuance of an NOC. The patent list must contain an identification of the regulatory submission to which it relates for cross-reference purposes, as well as the medicinal ingredient, brand name, dosage form, strength, route of administration and use, as set out in the submission.

(d) First person and its New Drug Submission (NDS)
An innovative drug manufacturer, known as the “first person,” may not sell or market a drug unless it has filed an NDS or a supplement to an NDS (SNDS) with the Minister and the Minister has issued an NOC in respect of that NDS or SNDS.

A “new drug” that is the subject of an NDS is a drug that has not been sold in Canada for sufficient time or in sufficient quantity to establish the safety and effectiveness of the drug. A drug may be “new” because it consists of a new substance, a new combination of established substances or a new use for an established (old or known) drug. The NDS must contain sufficient information to enable the Minister to assess the new drug’s safety and efficacy.

As mentioned above, a first person may seek to acquire the added protection of the PMNOC Regulations, in respect of eligible patents relating to the drug that is the subject of an NOC by filing a patent list with the Minister pursuant to Section 4 of the PMNOC Regulations.

(e) Second person and its “abbreviated” drug submission

A subsequent entry drug manufacturer (the second person) may file a drug submission on an abbreviated basis that directly or indirectly compares, or refers to, an innovator’s drug product. In this context, subsequent entry drugs are not limited to small molecule (generic) drug products for which a declaration of bioequivalence to another drug, for which an NOC has already been issued, is being sought. The PMNOC Regulations also encompass biosimilar drug products.

Where the subsequent entry manufacturer submits an abbreviated version of an NDS, which compares and relies on portions of the information contained in the first person’s NDS, it must either accept that an NOC will not be issued until the patent(s) listed on the Patent Register expire or deliver a Notice of Allegation (NOA) including a detailed statement, as more fully explained below, thereby engaging the PMNOC Regulations.

**Engaging the PMNOC Regulations**

**NOA and detailed statement (Section 5)**

Where a first person has filed a patent list with the Minister, in respect of an NDS or SNDS, and the Minister has included the patent(s) on the Patent Register, a second person who applies for an NOC for a drug that directly or indirectly compares to the innovative drug for which the patent list was filed must follow one of two options. It must state in its drug submission that it accepts that an NOC will not issue until the expiry of the patent(s) listed on the Patent Register. Alternatively, if it is not prepared to await the expiry of the patent(s), it must otherwise serve an NOA to the first person on or after the date of filing its drug submission, which addresses each of the listed patents by alleging:

1. The innovator does not own the patent, have an exclusive license or the patent owner’s consent to use the patent
2. The patent is ineligible for listing in the Patent Register
3. The patent has expired, is invalid, and/or will not be infringed.

In addition to the above allegations, the NOA must include a description of the medicinal ingredient, dosage form, strength, route of administration and use of the drug in respect of which the submission is filed, including a statement of the legal and factual basis for the allegation. A second person need only address the patents added to the Patent Register prior to the date of filing the second person’s drug submission. In this
sense, the Patent Register is “frozen,” in that patents added to the Patent Register after the date of filing its
drug submission need not be addressed by the second person.

One of the purposes of the NOA is to provide the first person with notice of the grounds on which the
second person considers that no valid claim of a patent listed on the Patent Register would be infringed by
the making, constructing, using or selling of the subsequent entry drug. It is on the basis of the NOA that the
first person decides whether to pursue a proceeding, pursuant to Section 6, and to assess its likelihood of
success or failure.

There is no deadline by which the second person is required to deliver its NOA to the first person. It can take
as much time as necessary to develop the legal and factual bases for its Section 5 allegations.

**Right of action (Section 6)**

Within 45 days of receipt of an NOA, a first person who wishes to challenge the allegation(s) may bring an
action to the Federal Court by filing a statement of claim seeking a declaration that the making,
constructing, using or selling of a drug, in accordance with the second person’s drug submission, would
infringe any patent that is the subject of the NOA. In addition to any patent referenced by a second person
in its NOA, a first person may include within the scope of its action any other patent (or patent claim) not
listed on the Patent Register but otherwise relevant to the making, constructing, using or selling of the
subsequent entry drug that is the subject of the second person’s NOA. In this manner, patent claims covering
a process (method) to make the drug product, or otherwise directed to a related chemical form of the active
ingredient, may become the subject of Section 6 litigation. Collectively, the patents that are the subject of
an NOA and the other patents asserted by the first person, are referred to here as the “asserted patents.”

A first person cannot bring an action involving a listed patent outside the PMNOC Regulations unless it did
not have a reasonable basis for bringing a Section 6 action within the prescribed time.

In response to the first person’s action, the second person files a statement of defense and may bring a
counterclaim for a declaration that the asserted patent(s) is invalid.

The Section 6 action is typically set down for a 10-day trial within 21 months of commencement so a decision
may be rendered prior to the expiry of the 24-month statutory stay (described below). A judge alone hears
and determines trials. No jury trials are available.

If the first person is successful, on any one of the asserted patents, the Minister will be prohibited from
issuing an NOC to the second person prior to the expiry of the asserted patents. The Federal Court may also
order any other remedy that is available under the Patent Act, or law, or in equity in respect of patent
infringement.

There is no option to extend the time within which such proceeding is commenced.

**Statutory stay (Section 7)**

When a first person commences an action under Section 6, the Minister is automatically prohibited from
issuing an NOC to the second person for a period of 24 months from the date of commencement of the
action. This is tantamount to the first person being awarded an interlocutory injunction staying the activities
of the subsequent entry drug manufacturer until the judge hearing the merits of the action makes a
determination, without having to satisfy the usual criteria for obtaining such relief.

The Federal Court may shorten or extend the 24-month statutory stay if it finds that either the first person
or the second person failed to act diligently in carrying out their obligations under the PMNOC Regulations
or did not reasonably cooperate in expediting the action.
A first person may waive the 24-month statutory stay without prejudice to the right to bring the Section 6 action. The result of such a waiver is the avoidance of liability for damages pursuant to Section 8 of the PMNOC Regulations (Section 8 damages, described below).

**Early Disclosures**

Instead of awaiting discovery, both the first person and second person are entitled to early disclosure of specific documents and information. A second person’s NOA must be accompanied by portions of its drug submission that are relevant to determine if any patent referred to in the NOA would be infringed (whether or not an allegation of non-infringement was made). If the second person has made an allegation of invalidity, copies of all documents on which it is relying in support of this allegation must also be provided to the first person.

If a second person makes an allegation of invalidity, it may request in its NOA that the first person confirm the name and contact information for any inventor who may have information that is relevant to the allegation. In addition, the second person may request that the first person deliver copies of any laboratory notebook, research report or other relevant documents to ascertain if a particular property, advantage or use, as asserted in any patent, was established at the patent’s filing date. The first person is required to deliver this documentation and information at the same time that it serves its statement of claim. If the documentation and information requested by the second person cannot be provided with the statement of claim, the first person must provide a letter describing the steps taken to locate such documentation and information and when they will be produced, or the reasons for not providing them.

Reasonable rules for maintaining confidentiality of any disclosed document may be imposed by the disclosing party. These rules are binding and enforceable by the Federal Court.

If either the first person or the second person that believes the disclosure received from the other party is insufficient, they may bring a motion to seek further and better production.

**Remedies and damages**

Pursuant to the PMNOC Regulations, the first person and second person may seek any remedy that is available under the Patent Act, or by the operation of law, or at equity, as the Federal Court may typically grant for patent infringement (e.g., the first person may elect damages for infringement or the second person’s profits) or patent invalidity (e.g., expungement of the patent).

In addition to the typical remedies afforded to the successful party, the second person may avail itself of a remedy that is unique to the PMNOC Regulations in Canada and, in a sense, act as a substitute for the first mover’s (180-day) exclusivity that exists in the US. In the event that the first person (who has not renounced the statutory stay) is unsuccessful with its Section 6 action, or where the action has been withdrawn or discontinued, a second person may commence an action under Section 8 of the PMNOC Regulations for compensation for any loss suffered, starting from the date upon which an NOC would have been issued but for the first person’s action. The first person is liable to the second person for any loss suffered because of its delayed market entry from the period beginning on the date on which an NOC would have been issued, in the absence of proceedings brought pursuant to the PMNOC Regulations. The court has some discretion to vary the start date to establish this period.

In determining damages, the court will consider all relevant circumstances, which may include the following factors, among others: the size of the market for the drug in question; the portion of the market that was retained by the first person; the portion of the market that would have been held by the second person; and
the quantity of damages that would have been suffered by the second person due to its delayed market entry.

The test applied when assessing damages is a hypothetical “but for” world, during a period in the past, to determine the share of the market the second person would have captured if it was able to sell the drug in question. Damages under Section 8 do not encompass the profits of the first person and are limited to losses suffered by the second person, as identified by the court.

The issue of damage quantification was not given full judicial consideration until 2012 with the release of two decisions brought against Sanofi-Aventis Canada Inc. (“Sanofi”) by Teva Canada Ltd. (Teva Ramipril) and Apotex Inc. (Apotex Ramipril). These two decisions clarified a number of issues regarding Section 8.

With respect to the relevant period, the Federal Court clarified that this period cannot start before the date of the Section 7 statutory stay.

Further, the court held that, when conducting the “but for” calculation of damages, the court may consider the presence of potential competitors in the marketplace. However, the court is not required to create a single “but for” world, applicable to all claims involving the same drug and first person. Each case must be decided on its own facts.

**Summary and future developments**

We do not foresee any imminent change in the current regime.

Status: **Law stated as of September 2019**
Introduction

The implementation of patent linkage was one of the commitments assumed by the Chilean Government following the signing of the Free Trade Agreement with the United States in 2004.

To date, Chile has not enacted the patent linkage concept and there is no connection between the Sanitary Authority (Institute of Public Health (ISP)) and the Trademark Office (National Institute of Industrial Property (INAPI)). As a result, Chile appears on the Red List of Special 301 Report on Intellectual Property Rights, which is released each year by the Office of the United States Trade Representative (USTR).

A bill was presented, in 2012, which aimed to modify Act No. 19,039 on Industrial Property Rights and to strengthen the protection of medicament’s active principles, including the patent linkage concept in Chile’s national legislation. However, there have not been any developments on this since 2013.

This initiative proposed to improve judicial protection for patent rights over active principles, on the one hand, and to increase the transparency of the system, on the other hand, by means of the inclusion of a new precautionary measure – the suspension of the granting of the sanitary registration by the ISP before a presumed infringement of the rights protected by patents on active principles. With the suspension of the grant, and not the procedure itself, the objective of the patent system was considered protected and, in particular, the so-called Bolar Exemption contained in the final clause of Article 49 of Act 19,039 on Industrial Property. The Bolar Exemption allows third parties to perform acts in relation to the subject matter protected by a patent, as long as they have the sole object of obtaining a sanitary registration or authorization of a pharmaceutical product.

To provide transparency and safety to the users of the system, the bill also contemplates the creation of a public book, administrated by the ISP, in which all owners of patents on active principles may record their patents. To ensure compliance with this objective, only the precautionary measure created by the project may be used in respect of those patents that have been recorded in the book before the sanitary registration that is seemingly frozen. No further developments have occurred since 2013.

Legal regulation

As mentioned above, Chile’s national legislation does not contemplate the patent linkage concept. Indeed, Article 19 of Supreme Decree No. 3/2010 on National Control of Pharmaceutical Products for Human Use establishes that the administrative act of granting a sanitary registration is independent of the commercial, intellectual property or industrial property aspects, which the terms of Article 49 of Act No. 19,039 so require or obtain. This contemplates the Bolar Exemption in our jurisdiction in the following terms:

*The patent of invention does not confer the right to prevent third parties from importing, exporting, manufacturing or producing the matter protected by a patent with the purpose of obtaining the sanitary registration or authorization of a pharmaceutical product. The above does*
not enable the commercialization of said products without authorization of the holder of the patent.

Also relevant, the ISP states that their role is only to confirm the safety, quality and efficacy of the product from a sanitary and regulatory standpoint, but not to grant a proper marketing authorization (only a sanitary registration).

**Case law**

When a holder of a patent registration considers that their rights have been infringed, general ordinary courts are the ones called upon to decide. In our experience, and based on the existence of the Bolar Exemption, in general, courts are not willing to accede to the patent holder’s requests.

**Summary and future developments**

Chile is a party to the CPTPP, which requires parties to adopt patent linkage provisions, but at the time of writing, Chile has not ratified the agreement.

Status: **Law stated as of July 2019**
China
Introduction

Currently, there is no patent linkage concept in China, although proposals were made in mid-2017. Before mid-2017, there was no concept of patent linkage in China. The Administrative Measures for Drug Registration (for Trial Implementation), which entered into force at the end of 2002, first mentioned the protection of patent rights in relation to drugs. It provided that the applicant of a drug registration should prove the status of the patent and ownership of the drug, and its formulation and manufacturing process. In addition, the applicant was required to submit a declaration that the drug does not infringe third-party patents and an undertaking that it will assume all legal liabilities for patent infringement (Article 12). The Measures further stipulated that in the case of a patent infringement dispute, the parties should resolve the matter through negotiation or resort to administrative or judicial means for dispute resolution (Article 13). A drug patented by a third party was allowed to be filed for registration by a generic drug applicant within two years before the patent’s expiration and the drug would only be approved after the patent expired (Article 14).

In 2005, the Administrative Measures for Drug Registration made slight revisions to the above and added that, if a drug is found to be infringing by an effective decision of the patent administration or a court, the registration of the infringing drug would be canceled upon request of the patent owner. This provision, however, was removed in the latter amendment in 2007.

Despite efforts by the industry in this regard, review of possible infringement was not part of the drug approval process by the China Food and Drug Administration (CFDA) and the generic drug applicant was not held liable for the authenticity of the declaration in practice. The patent owner cannot file an infringement lawsuit until the generic drug has been approved and marketed in China.

In addition, the State Intellectual Property Office (SIPO), in fact, had considered amending the Patent Law to include patent linkage. However, the amendment was removed in the Patent Law amendment in 2007 and, to this date, it is not in the Patent Law.

Legal regulation

On 12 May 2017, the CFDA released a draft notice titled “Relevant Policies for Encouraging Innovations of Drugs and Medical Devices and Protecting Innovators’ Rights and Interests” (‘Order No. 55”), in which the CFDA proposed to establish the patent linkage system in the drug approval practice.

Then, on 8 October 2017, the introduction of the patent linkage system was reiterated in the “Opinion on Deepening Reform of the Review and Approval System to Encourage Innovations in Drugs and Medical Devices” (“Opinion”), and was jointly circulated by the General Office of the CPC Central Committee and the General Office of the State Council. The Opinion mentioned that the purposes of the patent linkage system
are to protect the legitimate rights and interests of patent owners, as well as to reduce the infringement risk of generic drug applicants and encourage the development of the generic drug industry.

Order No. 55 proposed the following mechanism for the patent linkage system:

- A generic drug applicant shall notify the CFDA of relevant patent rights it knows of, or should have known of, at the time of drug filing.
- If a generic drug applicant challenges the relevant patent, it shall declare to the CFDA that its drug does not infringe the patent and notify the patent owner within 20 days after the drug filing.
- The patent owner shall initiate patent infringement litigation within 20 days after receiving the notification if it believes that the generic drug is infringing and inform the CFDA of the litigation.
- The CFDA has discretion to set a waiting period of, no more than, 24 months before drug approval, but will not suspend the technical review of the generic drug application during the waiting period.
- If no judicial decision on infringement or settlement is in place within the waiting period, the CFDA can approve the generic drug after the waiting period is over.
- If the generic drug applicant fails to notify the CFDA of the relevant patent rights and the patent owner initiates patent infringement litigation, the CFDA will, similarly, set a waiting period before drug approval.
- In case of any intellectual property infringement lawsuit after the generic drug is approved and launched, the dispute will be resolved based on the final decision of the court.

**Summary and future developments**

The proposal is quite high-level and only provides a policy direction. More details are expected and will be forthcoming after the regulations are finalized.

While it appears that the purpose of Order No. 55 is to encourage innovation in the pharmaceutical industry, on 3 April 2018, the General Office of the State Council further issued the “Opinion on Reforming and Improving the Supply and Use of Generic Drugs,” a document that is strongly in favor of domestic generic drug applicants where an “early warning” mechanism to prevent generic drug producers from patent infringement is described.

The establishment of the patent linkage system in China calls for the collaboration between multiple authorities and systems. So far, it remains to be seen how the proposed mechanism will work, both practically and efficiently, to protect patent rights of originator manufacturers and to reduce the infringement risk of generic drug producers.

**Status:** Law stated as of July 2019
Colombia
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Introduction

To date, the patent linkage concept, such as that practiced in the United States, does not exist in Colombia.

Patent law and regulations governing health registrations are treated as separate regimes, applied by different authorities with different functions. On the one side, the Colombian Patent Office and the specialized court for IP matters, with competence to decide on infringement cases, are part of the Superintendence of Industry and Commerce (SIC). On the other side, the National Institute for Food and Drug Administration (INVIMA) administers the health registration system for drugs.

When INVIMA evaluates an application for health registration for a generic drug, it is not obliged to review or consider the status of any eventual patent protection for the original drug and, in principle, the health registration by itself cannot be hampered by patent protection granted by the SIC.

When dealing with the interplay between patent law and health regulation, the Colombian Patent Office has clarified the reasons behind the separation of these legal regimes. Health registration is a document issued by the sanitary authority, by means of which a person or entity is authorized to manufacture, pack, distribute and import drugs for human use. In contrast, a patent responds to an authority grant in favor of the inventor involving the temporary right to exclude third parties from manufacturing, using or selling (working) an invention. Under this view, the existence of health registration is not considered an exception to the protection of patent rights nor is the existence of a patent considered an obstacle to obtain health registration for the generic version of a drug.

In absence of legal regulations of the patent linkage, below we comment in detail on the alternatives of obtaining preliminary injunctions in the enforcement of patent rights when involving drugs in Colombia.

Legal regulation

In Colombia, although a patent linkage system would help in terms of the ability to prevent patent infringements in the pharmaceutical area, there are actions that make the Colombian system effective and efficient in dealing with patent infringement.

By statute, Decision 486, Article 52, the following acts are considered patent infringement when performed without the patentee’s consent:

\[(a) \text{ where the subject matter of a patent is a product:}\]

\[(i) \text{ making the product}\]

\[(ii) \text{ offering for sale, selling, or using the product, or importing it for these purposes}\]
(b) where the subject matter of a patent is a process:

(i) using the process

(ii) carrying out any of the acts that are specified under paragraph a) above with respect to a product obtained directly by that process

No distinction is made between direct and indirect patent infringement. Therefore, the following persons could be held liable for patent infringement: (i) the manufacturer; (ii) the distributor; (iii) the person who stores patent infringing products; (iv) the importer; (v) the exporter; and (vi) any other person who participates in the production and commercialization chain.

Besides civil actions to stop the infringement and claim damages, local criminal law sets patent infringement as valid cause to prosecute infringers for making, using, offering to sell, selling, or importing into Colombia any patented invention, during the period of protection of a patent, without authorization. Criminal actions are pursued before a specialized unit for intellectual property affairs. Criminal procedures are expeditious. With the implementation of an accusatorial system in Colombia, legal proceedings are shorter in comparison to the old system and should take no longer than one year.

Now, in the area of civil infringement actions, the General Procedure Code (2012) created a Specialized IP Court (SIPC) as a section of the Superintendence for Industry and Commerce to decide on IP infringement matters. Since then, a patentee may pursue a civil infringement action either before civil circuit courts or before the SIPC.

The creation of the SIPC was a landmark on alternatives to prevent patent infringement. Expert justices in IP form the SIPC and unfair competition matters. In addition, the degree of experience and focus on IP matters has helped the SIPC to set an average time record on deciding on infringement cases – around 18 to 24 months since the filing of the infringement action. This efficiency is reflected, also, in the ability of the SIPC to decide on preliminary injunctions in record time – around 1–2 weeks.

Under Article 245 of Ancom Decision 486, the patentee may request a court to grant a preliminary injunction to cease an infringement or to prevent an imminent infringement. Injunctions may consist of:

- an order to seize infringing activities
- the seizure of all infringing products
- the suspension of the importation or exportation of the infringing products
- the establishment of a bond
- the temporary closure of the business belonging to the defendant if necessary to avoid the continuation or repetition of the alleged infringement

Preliminary injunctions to prevent the commission of an infringement can be ordered without intervention of the infringer, subject to evidence of (i) the existence and ownership status of a patent; (ii) facts or circumstantial evidence to support a reasonable assumption of the imminence of the infringement; and (iii) urgency of the injunctions in the prevention of damages or other unfavorable effects of the infringement.

The obtaining of a health registration of a generic drug has been considered insufficient to demonstrate the imminence of the infringement. Additional facts or circumstantial evidence on positive actions to put the infringing product on the market are usually required. Therefore, evidence or circumstantial evidence on the existence of packaging, raw material, commercial contracts and/or product inventory is necessary to increase the chances of obtaining preliminary injunctions.
A relevant exception/limitation to the enforceability of patent rights in Colombia is the “regulatory exception,” which has similar effects to the US Bolar Exemption, a legal, transplant consequence of the Free Trade Agreement between Colombia and the United States (2012).

By virtue of Article 53 of Ancom Decision 689, third parties may be authorized to work a patented invention before the protection expiry, with the exclusive purpose of obtaining the necessary information to support an application to obtain the necessary approvals (health registration/market authorization) to commercialize the product in Colombia right after the expiration of the patent right. This applies to patented pharmaceutical or agrochemical products.

**Case law**

In 2011, the Superior Court in the District of Bogota decided an infringement action between two pharmaceutical companies, which is noteworthy as the first case against imminent infringements related to pharmaceutical inventions. In this case, *Abbott Laboratories v. Laboratorios Biotoscana S.A.* Ruling of 9 May 2011, the court asserted that, in principle, neither the request nor the grant of market approval for a pharmaceutical product is sufficient cause to declare the imminence of an infringement, and that additional evidence on the urgency of the preliminary injunctions is required to determine the need of a judicial order to prevent an infringement. Under this consideration, the court observed the existence of sufficient evidence demonstrating that the alleged infringer, in addition to obtaining health registration, performed acts aimed to commercialize the drug (designed product labels), and these acts were sufficient proof of an imminent infringement and open attempts against the patentee’s rights.

This decision was controversial. Packaging design is a requirement to obtain health registrations in Colombia and, therefore, the existence of labels could not be seen as separate from health registration requirements. However, this decision became a landmark of the court’s position aimed at giving effect to the protection of patentees against imminent infringements.

This decision was issued before the regulatory exception was incorporated into Colombian law. This is a significant change as it is clear today that patentees must take into account that actions against imminent infringements are effective, but require evidence in addition to the application or grant of a health registration.

**Summary and future developments**

Even though the patent linkage concept does not exist in Colombia, patentees count on effective measures, such as preliminary injunctions to prevent imminent infringements. The entrance of the infringing product into the market is not required to enforce patent rights, but solid evidence on the imminence of the infringement is determinant to succeed.

**Status:** Law stated as of July 2019
Czech Republic
Introduction

The patent linkage concept has not been enacted in the Czech Republic.

Legal regulation

See the EU chapter for a summary of the EU regulation.

Under the applicable legislation, the patent holder may prevent the introduction of a generic product to the market during the period of validity of an originator’s patent protecting a compound used in such product. However, making necessary preparations only for such introduction (e.g., obtaining marketing authorization and registering the maximum sales price of an essential medical preparation) cannot be viewed as use of a patent because such actions are preparatory in nature and, therefore, could not be considered infringing.

Only actual use of the generic product (containing the patented compound) as, for example, production, importation, storage or offering to sale can be prevented by the patent holder.

The potential legal remedies available against an infringer are as follows (Act No. 221/2006 Coll. on Enforcement of Industrial Property Rights and on the Amendment):

(a) Non-pecuniary remedies:

(i) Right for information about the origin, chain of distribution and/or distributors/holders of the infringing goods and/or about the quantities and price of the infringing goods. If the information is not provided voluntarily, the owner of the right may bring a separate action solely with respect to the information request.

(ii) Injunctive relief, i.e., that the infringer ceases and desists from further infringement.

(iii) Remedy infringement by way of, in particular, recall of the infringing goods from channels of sale and/or destruction of the goods.

(iv) Measures to secure evidence.

(v) Publication of the decision.

Remedies under i. and iv. can be also obtained by way of preliminary injunction.

(b) Pecuniary remedies:

(i) In civil proceedings claims – damages, unjustified enrichment and/or adequate compensation.
(c) **Criminal proceedings:**

(i) *Intentional violation of industrial property rights is also an offense under the Criminal Code and criminal legal proceedings. The court may impose a sentence of imprisonment of up to two years or a fine or forfeiture.*

**Case law**

There is no relevant case law.

**Summary and future developments**

Since the patent linkage tool is not applicable in the EU, we have no recommendations in this regard.

**Status:** *Law stated as of July 2019*
Egypt
Introduction

The system of patent linkage is not recognized under Egyptian law, specifically under Intellectual Property Law No. 82 of 2002 (“IPR Law”). However, when registering a pharmaceutical product with the Ministry of Health, the applicant is required to submit a statement (declaration) to the Central Administration for Pharmaceutical Affairs (CAPA) whereby he/she undertakes to abide by the provisions of the Intellectual Property Law and its Executive Regulations and that the pharmaceutical product under registration does not violate any third-party right, without any liability on the Ministry of Health. Please note that CAPA is a governmental body affiliated with the Ministry of Health and is competent to receive all registration applications, and handles all matters relevant to the registration of pharmaceuticals.

The IPR Law does not stipulate any particular acts that constitute patent infringement (the patent gives the right to prevent others from “exploiting the invention by any means”). On the contrary, a list of non-infringing acts is provided under the IPR Law. These acts consist of:

- Acts conducted for scientific research purposes
- Production of; use of the method of production of a specific product, in good faith, by any third party in the Arab Republic of Egypt, prior to the application of a patent, on the same product, by another person. After the grant of the patent, the person operating in good faith shall continue, for the benefit of his/her corporation, the production of the product subject of the patent without expanding such production
- Indirect use of the substance, subject of the patent, for the production of products different than those of the patent owner
- The use of the patent in air, land or maritime transport means affiliated to any of the member countries of the WTO that extends the same treatment to the Arab Republic of Egypt, if such means are temporarily present in Egypt
- Production, manufacturing, use and/or sale of the product subject of the patent, by a third party, during the protection period granted, for the purpose of obtaining market approval, provided that no marketing occurs before the expiration of the protection period
- Any other acts conducted by a third party other than the above listed, provided that such acts do not unreasonably contradict the normal use of the patent, nor unreasonably harm the patent owner business

In addition, the IPR Law provides that the right of the patentee to prevent third parties from importing, using, selling or distributing the goods shall be exhausted by marketing of the goods by the patentee or its licensees in any state.
Finally, according to the fundamentals of Egyptian law, any prejudice suffered by a party is subject to damages if the claimant can prove (a) the occurrence of a litigious act; (b) prejudice/harm suffered; and (c) the causal relation between the litigious act and the prejudice suffered. Having said that, the IPR Law provides an exhaustive list of (i) infringement cases constituting a criminal offense; and (ii) an exhaustive list of what is not an infringing act. If a patent holder were able to prove that a certain conduct constitutes an act of infringement other than the cases provided by law, it shall be regarded as a non-criminal act of infringement.

Legal regulation
Pursuant to the provisions of Law No. 127 of 1955 pertaining to the practice of pharmacies, sales of pharmaceutical products, whether manufactured locally or imported, must be registered with the Ministry of Health. The registration request must be submitted by either (a) pharmacist; (b) licensed doctors; (c) licensed dentists; or (d) local or foreign pharmaceutical companies or their agents.

Furthermore, the registration of pharmaceuticals is governed mainly by Decree No. 425 of 2015 issued by the Ministry of Health ("Decree"), whereas pending registrations undertaken prior to 2015 are governed under the prevailing legislation at the time of registration. It is also important to note that the Decree does not explicitly regulate several matters, leaving wide discretion to the authorities in the interpretation and application of the Decree. We note that the said Decree was amended by the Ministry of Health and Housing Decree No. 600 of 2018 amending and adding some procedures of the renewal of the registration of pharmaceuticals and the cases of cancellation of the said license.

According to the Decree, pharmaceuticals should be registered with the Ministry of Health and issued with a registration number before they can be traded on the local market. The registration should not be admissible unless a pharmacist, doctor, vet, dentist, the owners of local/foreign pharmaceutical factories or their agents provide it. The registration of pharmaceutical products shall be valid for a maximum period of 10 years. Subject to the Decree, the licensee may renew the registration during the last year.

Generally, the registration process is as follows:

- The applicant must have a registered profile on CAPA’s site prior to the submission of the registration request.
- The applicant must then submit an “inquiry form” to CAPA inquiring about the possibility of registering any given pharmaceutical (including if there is space in the “matter box”).
- The formal registration process then involves submitting a registration submission request via email along with the required documents.

It is our understanding that all registration applications are treated with the utmost confidentiality. The competent authorities have further informed us that information related to applications in process are not disclosed to any entity other than the applicant until completion, acceptance or refusal of the application.

Summary and future developments
There are no current plans to change the patent linkage regime in Egypt.

Status: Law stated as of July 2019
European Union
Introduction

The EU does not adopt a patent linkage regime.

The European Commission stated in its 2008 Pharma Sector Inquiry Report:

*Under EU law, linking the granting of marketing authorization for a product to the patent status of an originator company’s reference product is unlawful. The task of marketing authorization bodies is to verify whether a medicinal product is safe, effective and of good quality. Their main function is to ensure that the pharmaceutical products reaching the market are not harmful to public health. Other factors, such as the patent status of the product, should, therefore, not be taken into account when assessing the risk/benefit balance of a medicine.*

The European Commission bases its conclusion on Article 81 of EU Regulation 726/2004 and Article 126 of EU Directive 2001/83, which provide that an authorization to market a medicinal product shall not be refused, suspended or revoked except on the grounds set out in the Regulation and the Directive. It considers that because patent status is not included in the grounds set out in the Regulation and the Directive it cannot be used as an argument to refuse, suspend or revoke a marketing authorization.

The European Generic Medicine Association also considers that patent linkage is contrary to EU regulatory law as it undermines the Bolar Exemption expressed in Article 10.6 of EU Directive 2001/83 on the Community Code, relating to medicinal products for human use (as amended in 2004). Pursuant to said Article 10.6, conducting the necessary studies and trials with a view to applying for a marketing authorization, and the consequential practical requirements, shall not be regarded as contrary to patent rights or to supplementary protection certificates for medicinal products.

Despite the aforementioned EU law provisions, the TRIPS Agreement is said to support the concept of patent linkage by requiring procedures in national laws to prevent infringements and by requiring that, in process patent cases, the burden of proof shifts to the non-patent owner to prove non-infringement.

TRIPS specifically provides that:

*Members shall ensure that enforcement procedures (...) are available under their law so as to permit effective action against any act of infringement of intellectual property rights covered by this Agreement, including expeditious remedies to prevent infringements and remedies which constitute a deterrent to further infringements (...) (TRIPS, Article 41.1)*

(...) if the subject matter of a patent is a process for obtaining a product, the judicial authorities shall have the authority to order the defendant to prove that the process to obtain an identical product is different from the patented process. Therefore, Members shall provide (...) that any identical product when produced without the consent of the patent owner shall, in the absence of proof to the
contrary, be deemed to have been obtained by the patented process: (a) if the product obtained by
the patented process is new (…) (TRIPS, Article 34).

The implication of these provisions in TRIPS is that national authorities must have preventive measures in place
to protect the patent owner before the non-patent owner is granted marketing approval.

The EU-Canada Comprehensive Economic and Trade Agreement (CETA) also includes a patent linkage
mechanism relating to pharmaceutical products in Article 20.28:

If a Party relies on “patent linkage” mechanisms whereby the granting of marketing authorizations
(or notices of compliance or similar concepts) for generic pharmaceutical products is linked to the
existence of patent protection, it shall ensure that all litigants are afforded equivalent and effective
rights of appeal.

Legal regulation

Instead of adopting a patent linkage regime, health regulators, such as the European Medicines Agency (EMA),
and national competent authorities apply the concept of regulatory data protection and market exclusivity

For nationally authorized products Article 10 of Directive 2001/83/EC lays down the basic rules regarding the
periods during which generic product applicants cannot rely on the dossier of the reference product for the
purposes of submitting an application, obtaining marketing authorization (data exclusivity) or placing the
product on the market (market exclusivity).

Data exclusivity means that the applicant is not required to provide the results of pre-clinical tests and of
clinical trials if they can demonstrate that the medicinal product is a generic of a reference medicinal product
that has been authorized for no less than eight years in a Member State or in the Union. Hence, the generic
application cannot be submitted until eight years have elapsed from the initial marketing authorization of the
reference product. The health authority will invalidate any application submitted within such protection
period.

Market exclusivity means that generic products authorized in this way must not be placed on the market until
10 years have elapsed from the initial authorization of the reference product.

The ten-year period of market exclusivity may be extended to 11 years if during the first eight years from the
initial marketing authorization new therapeutic indications are approved representing a significant clinical
benefit in comparison with existing therapies. The overall period of protection cannot exceed 11 years.

To avoid accumulative application of data protection periods for the same product, the EU legislator
introduced the concept of global marketing authorization. This concept groups together the initial
authorization and all variations and extensions thereof, as well as any additional strengths, pharmaceutical
forms, administration routes or presentations authorized through separate procedures and under a different
name, granted to the marketing authorization holder of the initial authorization. All these presentations are
considered part of the same marketing authorization of the same holder for the purposes of applying the rules
on data and market exclusivity.

The ten-year market exclusivity given under Article 10 of Directive 2001/83/EC must be distinguished from the
ten-year market exclusivity given to an orphan drug under Article 8 of Regulation (EC) 141/2000.

The same rules and periods of protection apply in the case of centrally authorized products, pursuant to Article
In relation to patent infringement, it should be noted that Article 10(6) of the EU Directive 2001/83/EC contains what is known as the "Bolar Exemption":

Conducting the necessary studies and trials with a view to the application of paragraphs 1, 2, 3 and 4 and the consequential practical requirements shall not be regarded as contrary to patent rights or to supplementary protection certificates for medicinal products.

This exempts the use of a patented invention for marketing authorization procedures for generic medicines. However, because the terms "studies and trials" were not clearly defined, the directive did not establish full EU harmonization.

Besides regulatory data protection, the EU has introduced a system of supplementary protection certificates (SPCs).

SPCs are an intellectual property right that extend the patent right for a pharmaceutical product authorized by EU regulatory authorities. The rationale of issuing SPCs is to make up for the loss of patent protection due to lengthy testing and the clinical trials these products require prior to obtaining regulatory marketing approval. SPCs are regulated at EU level by Regulation (EC) No. 469/2009 of the European Parliament and of the Council of 6 May 2009, concerning the supplementary protection certificate for medicinal products.

A SPC can extend a patent of an authorized pharmaceutical for up to five years. A six-month additional extension is available in accordance with Regulation (EC) No. 1901/2006, if the SPC relates to a medicinal product for children for which data has been submitted according to a Pediatric Investigation Plan (PIP) approved by the pediatric committee of the European Medicines Agency.

Typically, the authority that has issued the basic patent grant SPCs. Whilst the granting of a marketing authorization is a condition for obtaining a SPC, the competent health authorities are not involved in the process of issuing such SPCs.

On 17 April 2019, the European Parliament adopted legislation introducing a SPC manufacturing waiver. Accordingly, pharma companies established in the EU will be entitled to manufacture a generic or biosimilar version of a medicinal product protected by a SPC, if it is exclusively intended for export to a non-EU market where the patent protection has expired or never existed.

The legislation for a manufacturing waiver includes clear safeguards to ensure transparency and to avoid the possible illicit diversion onto the EU market of generics and biosimilars that are produced for export, including the following:

- **Notification requirement**: companies intending to begin manufacturing SPC-protected medicines for export will be obliged to notify the competent authorities, and the information contained in that notification will be made public.

- **Due diligence requirement**: the manufacturer will be required to inform its supply chain that the products in question are only for export.

- **Labelling obligation**: any export of SPC-protected products outside the EU will be subject to compliance with specific labelling requirements, involving affixing a logo (e.g., "EU Export").

The European Parliament and the Council have not yet adopted the proposal. Therefore, during the relevant legislative process, it is possible that the same will be amended due to innovators’ concerns.
Case Law
There is no relevant case law.

Summary and future developments
There are no relevant developments to report.

Status: Law stated as of July 2019
Patent Linkage - France

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Introduction

To date, a patent linkage concept, such as the one practiced in the United States, does not exist in France. Pursuant to Article L. 5121-10 of the French Public Health Code, the granting of marketing approval is independent from the expiration of the originator’s patent or its supplementary protection certificate (SPC).

Legal regulation

See the EU chapter for an overview of the EU regulation.

Article L. 5121-10 of the French Public Health Code expressly provides that for generic drugs marketing approvals can be granted before the originator’s patent or the SPC expires. This provision is generic-friendly since it allows generic manufacturers to put their products on the French market right after the originator’s patent or the SPC expired. Once the National Agency for the Safety of Drugs and Health Products has granted a marketing approval for a generic drug, it shall only notify the originator.

Moreover, French law No. 2007-248 dated 26 February 2007 also provides, in Article L. 613-5 of the Intellectual Property Code, that “studies and trials required to obtain a marketing approval for a drug,” as well as “acts necessary for their performance and to obtain approval,” are not hindered by patent protection and cannot be considered as counterfeiting acts.

This article deprives the holders of drug patents of the right to object to bio-equivalence tests carried out by generic drug manufacturers with a view to obtaining marketing approval.

The generic-friendly system was further strengthened with the enactment, by the law of 29 December 2011, of a new exception for “acts necessary to obtain the advertising visa referred to in Article L. 5122-9 of the Public Health Code.” The intent was to address any risk of delays in the marketing of generic drugs that might be caused by the new approval required for advertising the drug. Therefore, without waiting for the patents or the SPC to expire, generic drug manufacturers can now conduct bio-equivalence clinical trials, obtain a marketing approval and an advertising visa without the concern of facing counterfeiting claims.

Lastly, the holder of an intellectual property right protecting the appearance and texture of oral pharmaceutical forms of an originator drug may only prohibit oral pharmaceutical forms of a generic drug, replacing such drugs that have the same or similar appearance and texture. Therefore, a generic drug may now replicate or imitate the three-dimensional appearance and texture of an originator drug, even if these characteristics are still protected (by a trademark in particular).

Consequently, the patent linkage concept is not applied in France.
Case law

Reckitt Benckiser v. Arrow Génériques (court of cassation, 11 January 2017)

The fact that a laboratory and its distributor have agreed on a strategic plan to delay or discourage generic entry through the implementation of disparaging practices and loyalty discounts is a competitive distortion.

The purpose of loyalty rebates was to induce, without any economically justified consideration, the constitution of a particularly large stock of the originator drug to saturate pharmacists’ stocks and, thus, dissuade them from substituting generic drugs for originator drugs.

The court of cassation (French Supreme Court) considers that this agreement, and these strategies, have an anti-competitive purpose. This decision is generic-friendly and does not recognize a patent linkage system.

Warner Lamber (Pfizer) v. Generic Laboratories “Pregbaline case” (Paris Court of First Instance, 2 December 2016)

The president of the Paris Court of First Instance was seized in summary proceedings on the plausibility of counterfeiting, in particular, by means of a second therapeutic application patent by Generic Laboratories.

According to Article L. 613-4 § 1 of the French Intellectual Property Code:

It shall also be prohibited, save consent by the owner of the patent, to supply or offer to supply, on French territory, to a person other than a person entitled to work the patented invention, the means of implementing, on that territory, the invention with respect to an essential element thereof where the third party knows, or it is obvious from the circumstances, that such means are suited and intended for putting the invention into effect.

In this case, the generic laboratories did not make any incentive for doctors or pharmacists to prescribe or issue the drug for the application still protected by a patent. On the contrary, the generic laboratories had spontaneously and loyally advised pharmacists that their marketing approval was only granted for applications that were no longer covered by a patent.

On a more global level, French judges have a strict assessment of second therapeutic application, particularly when it is believed to delay the marketing of generic drugs.

Sanofi-Aventis Deutschland v. Lilly France (Paris Court of First Instance, 15 December 2014)

Lilly was testing a biosimilar of insulin, a drug covered by Sanofi’s supplementary protection certificate. Sanofi had ordered an infringement seizure and carried out a preliminary injunction procedure, prior to the marketing approval granting. Sanofi wanted to prevent Lilly from carrying out manufacturing acts with a view of storing for subsequent release or “stockpiling.” On 15 December 2014, the interim relief judge at the Paris Court of First Instance ruled that all the acts for which he had been notified were acts “necessary” for carrying out the studies and tests, and for obtaining marketing approval within the meaning of the law.

Summary and future developments

No changes to the current position regarding patent linkage is, currently, envisaged in France.

Status: Law stated as of July 2019
Germany
Introduction

To date, a patent linkage concept, such as the one practiced in the United States, does not exist in Germany. At the moment, neither the European Union nor Germany appears to support the introduction of any patent linkage concept. The main reason for this is that, according to EU and German law, the market registration authorities must not consider the patent status of the original drug when deciding on the market approval for a generic drug. Patent law and the laws governing the drug registration are separate, treated by different organs with divergent competencies. Therefore, a drug registration for a generic product, in principle, may not be hindered by patent protection for the original drug. However, irrespective of the fact of whether the originator’s product enjoys patent protection, a German or EU generic application may refer to an existing market approval for an original product only eight years after the market approval for the product referred to. In addition, a German or EU market approval for a generic product that refers to the approval of an original product may only be obtained ten years after the market approval for the original product.

Legal regulation

German and EU pharmaceutical law provides some protection for originators against generic manufacturers. Both provide for data and marketing protection for originators’ registrations with respect to referral applications of generic manufacturers for generic products. However, such protection is, at most, about half as long as the regular term of a patent, which is 20 years upon the patent application date.

See the EU chapter for a summary of the EU regulation.

German Drug Act (GDA)

Sec. 24b para. 1 sent. 1 GDA states that a referral application for a generic product may only be filed eight years after market approval was granted to the originator’s product. In addition, the generic product may only receive market approval by way of such a referral application 10 years after market approval was granted for the originator’s product.


The same applies under EU law. Recital 11 of Regulation No. 726/2004 on the EU drug approval states:

For medicinal products for human use, the period for protection of data relating to pre-clinical tests and clinical trials should be the same as that provided for in Directive 2001/83/EC. (…)

Baker McKenzie
Art. 14 para. 11 of the Regulation No. 726/2004 accordingly states:

*Without prejudice to the law on the protection of industrial and commercial property, medicinal products for human use which have been authorized in accordance with the provisions of this Regulation shall benefit from an eight-year period of data protection and a ten-year period of marketing protection, in which connection the latter period shall be extended to a maximum of 11 years if, during the first eight years of those ten years, the marketing authorization holder obtains an authorization for one or more new therapeutic indications which, during the scientific evaluation prior to their authorization, are held to bring a significant clinical benefit in comparison with existing therapies.*

For further detail on the EU regulations and regime, see the EU chapter.

In the absence of a legal regulation of the patent linkage concept, originators may only rely on the provisions of the German Patent Act (GPA). In Sec. 139 GPA et seq., a patentee is granted several remedies that may be enforced against infringers, including injunction (Sec. 139 para. 1 GPA), information (Sec. 140b GPA) and damage (Sec. 139 para. 2 GPA) claims.

In particular, the GPA provides for an injunction claim with regard to any actions that either infringe the patent (danger of repetition) or, at least, cause the risk of a first-time patent infringement (Sec. 139 para. 1 GPA), whereby this also applies for SPCs by reference in Sec. 16a para. 2 GPA.

Art. 139 para. 1 GPA states:

*Any person who uses a patented invention contrary to sections 9 to 13 may, in the event of the risk of recurrent infringement, be sued by the aggrieved party for cessation and desistance. This right may also be asserted in the event of the risk of a first-time infringement.*

The relevant provision for the manufacture and marketing of generic products is Sec. 9 GPA. An injunction claim according to Sec. 139 para. 1 GPA is, in particular, given against a person or entity that, contrary to Sec. 9 sent. 2 no. 1–3 GPA without the patentee’s consent:

(i) produces, offers, puts on the market or uses a product that is the subject matter of a patent, or either imports or possesses such a product for the aforementioned purposes;

(ii) uses a process that is the subject matter of the patent or, if the third party knows or if it is obvious from the circumstances that the use of the process is prohibited in the absence of the consent of the proprietor of the patent, offers the process for use within the territory of the Federal Republic of Germany;

(iii) offers, places on the market or uses a product that is produced directly by a process which is the subject matter of the patent, or either imports or possesses such a product for the aforementioned purposes.

Although the requirements of an injunction claim may already be given, if the risk of a first-time infringement is caused, mere preparations to carry out one of the above-mentioned actions are, in principle, not considered as sufficient. Rather, such risk needs to be concrete, i.e., it requires serious and tangible indications that the infringer will commit actions according to Sec. 9 GPA in the near future. Hence, neither the mere request to be granted marketing authorization for a generic drug nor obtaining market approval are generally considered sufficient to cause such risk of a first-time infringement. This has already been clarified in German case law.
Therefore, we only briefly describe below the relevant case law and present the reasons why neither applying nor obtaining market approval for a generic drug is, generally, considered to be insufficient to cause the risk of a first-time infringement, and focus more on decisions in which an originator was entitled to an injunction claim against a generic manufacturer before the generic product had in fact been put on the market.

Case law

Already in 1996, the Higher Regional Court of Munich decided that neither the request for nor the grant of market approval for a generic product caused the risk of a first-time infringement of the originator’s patent or SPC respectively. As of the time of writing, this view has not changed in succeeding case law.

However, originators do not have to wait until a generic drug has entered the German market before taking legal remedies against it. If the generic product is advertised for sale (i.e., an offer according to Sec. 9 sent. 2 no. 1 GPA) or if it is listed in the “Lauer-Taxe” (a common German reference book for all pharmaceutical professionals, e.g., pharmaceutical manufacturers, pharmacies and pharmaceutical wholesalers), which lists drugs that obtained market approval and are about to enter the market, the originator is already entitled to claim cease and desist (because the listing causes, at least, the risk of first-time infringement). Therefore, the originator may enforce such a claim, e.g., by means of a preliminary injunction.

In detail:

Higher Regional Court of Munich, Mitt. 1996, 312 – Patentverletzung durch ärztliche Verschreibung

The Higher Regional Court of Munich granted the originator a preliminary injunction against a generic product that had already been on the market at that time. The preliminary injunction could, however, only be granted since the originator’s request did not lack urgency, because no risk of a first-time infringement had been caused when the defendant applied and obtained market approval. If either applying or obtaining market approval caused such risk, the request would have lacked urgency because the plaintiff could have filed their request a lot sooner. The court found that the plaintiff’s notice of the authorization process did not cause harm because the “if and how” of a drug, subject to authorization proceedings, entering the market always remained unclear.

Higher Regional Court of Düsseldorf, GRUR-RR 2013, 241 – HIV-Medikament

The Higher Regional Court of Düsseldorf, finally, (after the first instance already denied an injunction claim) dismissed the originator’s request for a preliminary injunction against a generic product that had already obtained market approval. Firstly, the court held that no lower criteria for the risk of a first-time infringement apply in pharmaceutical cases. Secondly, the court denied such risk, even though the approval was requested and obtained a long time before the lapse of the patent and the patent was going to lapse soon. The court’s arguments may be summarized as follows:

- It was generally accepted that neither applying for nor obtaining market approval indicate a certain time for market entry (whereby, reference is made to the above decision of the Higher Regional Court of Munich).
- In particular, if the approval does not lapse before the patent lapses, such risk was not given since it may have been intended to use the approval for market entry afterwards.
In addition, registration proceedings were time-consuming and may take up to two years, so generic manufacturers should initiate them before the patent lapses.

This was also supported by the ratio of Sec. 11 no. 2b GPA, according to which generic manufacturers shall be able to prepare for market approval before the lapse of a patent (so-called Bolar Exemption).

The market for pharmaceuticals was transparent, which was why a market entry of a generic product could easily be identified.

The court concluded that a risk of a first-time infringement required more than applying and obtaining market approval for a generic product. However, no such indications were given in the case presented to the court.

Federal Supreme Court, GRUR 2007, 221 – Simvastatin

The Federal Supreme Court confirmed the ruling of the first and second instance that ordered the defendant, a generic manufacturer and distributor, to cease and desist from offering their generic drug, to render accounts and to pay the plaintiff, an originator, damages. The court found that the defendant had offered their generic product before the SPC of the originator had lapsed. The product was not physically on the German market. However, the court held that the defendant offered the product by advertising it (in a magazine for doctors) and by listing their generic product in the “Lauer Taxe” (a common German reference book for all pharmaceutical professionals including manufacturers, pharmacies and wholesalers). Such activities were considered sufficient for a patent (SPC) infringing offer in Germany according to Sec. 9 sent. 2 no. 1 GPA. The defendant argued that the advertising related to the time after the SPC would have lapsed, which, until then, was a controversial question in German patent law. However, the court decided in favor of the view of the majority and confirmed that Sec. 9 sent. 2 no. 1 GPA generally prohibits the offer of infringing products for the time a patent or SPC is valid. Therefore, even if advertising means related to the time after the corresponding protection would have lapsed, such means still constituted an infringing offer, which the patentee could contest as long as he/she enjoys protection.

Higher Regional Court of Düsseldorf, BeckRS 2011, 25649

The Higher Regional Court of Düsseldorf upheld a preliminary injunction granted to an originator against a generic manufacturer and distributor because the defendant had listed its product in the “Lauer Taxe.” Since the corresponding listing was published during the lifetime of the originator’s SPC, the court confirmed that such listing constituted an infringing offer according to Sec. 9 sent. 2 no. 1 GPA. In addition, the court confirmed that it was irrelevant that the defendant intended to distribute its generic product only after the SPC would have lapsed.

Higher Regional Court of Munich, GRUR-RS 2016, 09402 – Pemetrexed

The Higher Regional Court of Munich upheld a preliminary injunction granted to an originator against a generic manufacturer and distributor based on the originator’s SPC. The court found that there was a risk of first-time infringement after the mother company of the defendant announced in a pre-court correspondence with the plaintiff that they intended to list their generic product in the “Lauer Taxe,” beginning from 15 December 2015 after the lapse of the SPC (i.e., 10 December 2015).

Even though it appears that the case law is clear about the fact that obtaining market approval does not constitute a patent infringing offer of a generic product, the Higher Regional Court of Düsseldorf emphasized, as well, that this was particularly true in a case where the obtained approval stayed valid over the lapse of the patent/SPC. Since we have not found a decision in which an approval lapsed prior to a
patent/SPC, in such a case, it could be argued that market approval was only obtained to put the generic product on the market. With such argumentation, originators could try to enforce their rights even earlier than to date.

Apart from that, case law is also well developed with respect to what already constitutes an infringing offer of generic products. The Higher Regional Court of Düsseldorf was correct when it stated that the pharmaceutical market is transparent. Originators are, therefore, in a good position to identify generic products that are about to enter the German market. Further, in favor of originators, German procedural law provides for preliminary means – in particular, preliminary injunctions. Usually, it takes roughly two to three months to obtain such a preliminary injunction in patent law. Such an injunction is an enforceable title that is enforced by serving it to the defendant (normally after the provision of a security).

**Conditions for a generic product applying for market approval**

**Summary and future developments**

Notwithstanding the lack of legal provisions and the rather restrictive case law, originators may still enforce their rights before a generic product has been put on the German market. Case law is well developed in this respect and advertising means, even if the product may only be available after the lapse of a patent or SPC, are already considered as infringing offer because the specialized German patent infringement courts (in particular in Düsseldorf, Mannheim and Munich) tend to interpret the term “offer” in Sec. 9 sent. 2 no. 1 GPA in a rather broad and patentee-friendly sense.

As of today, the German government does not appear to support the introduction of a patent linkage concept, particularly as practiced in the United States. The same view appears to apply at EU level. In 2014, for example, the European Federation of Pharmaceutical Industries and Associations (EFPIA) made a proposal for an EU-wide patent linkage concept; both the German government and the EU Commission did not approve this. Besides the separation of patent and authorization law and bodies, one reason for this could be that such an EU-wide patent linkage concept requires at least obtaining EU-wide patent protection for pharmaceuticals, i.e., a patent with unitary effect. However, the current EPC system only bundles the application process before the European Patent Office (“EPO”), while a granted European patent is only a bundle of national patent rights, but no patent with unitary effect.

Therefore, it remains to be seen whether the implementation of the Unitary Patent (“UP”) and Unified Patent Court (“UPC”) system will change the situation and the opinion of the Commission. At the moment, the ratification of the UP/UPC only relies on Germany, where a constitutional complaint with an urgency motion was filed in 2017. Even though the Federal Constitutional Court intends to decide this year, it currently remains unclear whether and if/how it will dismiss the complaint.

**Status:** Law stated as of July 2019
Hungary
Introduction

There is no patent linkage regime in Hungary.

Legal Regulation

For an overview of EU regulation see the EU chapter.

The National Institute of Pharmacy and Nutrition ("OGYÉI") is the regulatory authority in Hungary. The Guideline of OGYÉI declares its competence regarding intellectual property rights considerations and market authorization. It states that due to the fact that OGYÉI has no legal competence, intellectual property rights considerations do not fall under the subject of the market authorization procedure, so OGYÉI does not take into account this factor as it does not even have the authority to do so.

The decision on reimbursement falls within the competence of the National Health Insurance Fund of Hungary ("NEAK"). According to NEAK practice, it is possible to access certain data of a price reimbursement application, which includes the planned date of market launch.

The metropolitan court has exclusive jurisdiction in Hungary to hear patent infringement cases.

Section 19 of the Act XXXIII of 1995 on the protection of inventions by patents ("Patent Act") defines the scope of patent protection.

On the basis of the exclusive right of exploitation, the patentee shall be entitled to prevent any person not having his/her consent:

(a) from making, using, putting on the market or offering for sale a product which is the subject matter of the invention, or stocking or importing the product for such purposes

(b) from using a process which is the subject matter of the invention or, where such other person knows, or it is obvious from the circumstances, that the process cannot be used without the consent of the patentee, from offering the process for use

(c) from making, using, putting on the market, offering for sale or stocking or importing for such purposes a product obtained directly by a process which is the subject matter of the invention

The Patent Act provides for the Bolar Exemption by stating that the exclusive right of exploitation shall not extend to acts done for experimental purposes relating to the subject matter of the invention, including experiments and tests necessary for the marketing authorization of the product constituting the subject
matter of the invention or the product obtained through the process constituting the subject matter of the invention.

**Patent infringement**

Pursuant to the Patent Act, any person who unlawfully exploits a patented invention commits patent infringement. The patentee may, among others, request an injunction that the infringer cease his/her infringement or any acts directly threatening with it. This may also be requested by way of preliminary injunction.

**Case law**

**Marketing authorization**

According to the Hungarian Supreme Court, section 19 of the Patent Act is not exemplificative; it definitively specifies those commercial exploitations that qualify as infringement in the lack of the right holder’s authorization. Thus, the list of acts provided for in section 19 is regarded as an exhaustive list of restricted acts. Therefore, the Supreme Court has concluded that the registration of the product by the competent authority, which is the precondition for marketing a product and obtaining MA, cannot be considered as an infringing act. The Patent Act does not define preparatory actions as infringement.

**Request for reimbursement**

The decision on reimbursement falls within the competence of NEAK. Pursuant to Decree 32/2004. (IV. 26.) EszCsM, NEAK requires generic companies to make a statement about the lack of infringement of third parties’ patents as part of the regulatory submission as follows:

> “4. The undersigned applicant hereby declares that I am planning to start the sales of the product proposed for reimbursement in Hungary on [year, month, day], and I do not breach the provisions of the Act XXXIII. of 1995 on the protection of inventions by patents.”

No special sanction is provided for in the regulation for the eventual breach of this obligation. If the applicant’s statement is untrue and the patent owner requests and is granted a PI (cease and desist) the applicant will not be able to comply with the obligation to put and keep the pharmaceutical product on the market, and thereby the right to the reimbursement terminates.

NEAK shall publish on its official website the complete list of subsidized medicinal products by the 20th of each calendar month for information purposes. This notice contains the following data: the registration number of the medicinal products, including its name, packaging, producer price, gross retail price, the rate and the amount of subsidy, the retail price with the amount of subsidy deducted (retail price as charged) and the starting day of reimbursement under the social security system. The list indicates whether the product is available or not (status “0” or “1”).

**Filing request for reimbursement as imminent threat of infringement**

As the filing of a request with an administrative body, in this case NEAK, generally does not come under the acts falling within the exclusivity right under Section 19 of the Patent Act, the metropolitan court, as the first instance court, concluded in 2012 that the request for the reimbursement cannot be considered infringement per se. To prove the imminent threat of infringement it is necessary to further show activities for imminent market launch. It is important to note that the patent holder did not file an appeal against the decision.
rejecting the request for preliminary injunction. Therefore, the higher courts have not reviewed the findings of the first instance court.

The metropolitan court of appeals found, in another case, that the court may examine, only in connection with acts falling under Section 19 of the Patent Act, whether the action can be considered as an imminent threat of infringement.

The court pointed out that it is in the public interest that competitors should have the possibility to prepare themselves for launching the product immediately after the termination of the patent protection. The preparation for the launch may require actions several months before the actual start of the sales. Therefore, no market participants can be enjoined from preparatory actions unless such acts amount to an infringing act or to an act that qualifies as an imminent threat of infringement in terms of the exhaustive list of acts of unlawful exploitation. Such imminent threat may be demonstrated by the planned date for market launch.

As reimbursement proceedings are covered by the Act on Administrative Proceedings, the patent holder may file an inspection request. NEAK considers the date of the market launch as a business secret. However, it provides access to this information if the patent holder can demonstrate that the inspection is necessary for the enforcement of rights. To balance the interests of both parties, NEAK notifies the applicant of price reimbursement about the inspection request. According to NEAK’s practice, access to the date of the market launch is granted even if the price reimbursement applicant has filed an objection.

By having access to commercial information of an allegedly infringing product before it is granted price reimbursement, the patent holder is able to make better strategic decisions on the timing of enforcement and has the option to adjust its own marketing and commercial approach accordingly. One downside of an inspection is that the alleged infringer will become aware that they might be facing an enforcement action in the near future.

Despite the above-cited decisions, that the request for MA and the reimbursement before the patent expiry cannot be qualified as an act of infringement, the court may, at any time, come to the conclusion that the actions of the alleged infringer constitute an imminent threat of infringement based on an evaluation of all the circumstances (e.g., preparatory acts to put the infringing product into circulation). In particular, the court may evaluate when the alleged infringer has requested the reimbursement (or the MA). Section 3(1)f of Act No. XCVIII of 2006, on the safe and economic supply of pharmaceutical products and on the rules of distribution of pharmaceutical products, provides that NEAK exclude the product from the reimbursement scheme if the product has not been available for more than six months (or in the case of reference products, for more than one month). Therefore, in light of this rule, the application for the reimbursement may substantiate the launch of the product within a six-month-period, otherwise the reimbursement will not be applicable (the same logic can be applied to MA applications with due regard to the deadlines provided for the decision-making in such procedures).

**Summary and future developments**

A preliminary injunction based on patent infringement may only be ordered if the patent holder demonstrates that the patent is being infringed or that such infringement is likely to happen. It is established court practice that patent infringement may be committed only by the acts expressly listed as infringing acts in Section 19 of the Hungarian Patent Act.

Although there are decisions available detailing the activities that may reach the threshold for imminent threat of infringement, it is still hard to predict the court’s approach as each case will depend on the circumstances. The crucial task is to substantiate that market launch is “really” imminent. Court decisions vary as to which preparatory activities may be considered as infringement. When interpreting the meaning
of “imminent,” the court tends to use a temporal approach, i.e., the sooner the activity is expected to happen the more imminent the threat is, as it was reported in Hungary.

It is clear that, from a practical point of view, patent holders necessarily see the application or granting of price reimbursement for generic products as an activity triggering an imminent threat of infringement and prediction of upcoming market launch. However, to demonstrate that a price reimbursement request, or even its grant, is not only a theoretical threat but, also, an actual imminent threat taking into account all circumstances of the case, it is crucial to obtain the right evidence, especially on the planned date of market launch.

Status: Law stated as of July 2019
Baker McKenzie does not have an office in India. However, any healthcare queries related to India and patent linkage can be directed to Sonia and Julia who will be happy to assist.

Introduction

At present, India’s laws do not provide for patent linkage, directly or indirectly, either statutorily or through administrative measures. Under the current law, the Indian pharmaceutical regulatory authority can grant marketing approval for a generic drug four years after the approval of the originator drug. In evaluating a drug for marketing approval, the regulatory authority is not required to verify or consider the remaining term of any existing patent in India. This enables a potential infringer to obtain marketing authorization for a generic drug before the patent expires, forcing a patent holder to seek a remedy in India’s court system to enforce its patent in the country.

Historically, India has resisted the establishment of a patent linkage regime, which it believes would hamper its thriving generic drugs industry and would be detrimental to its public health policy. India continues to be on the Office of the United States Trade Representative’s Special 301 Priority Watch List for its lack of an effective IP system in many areas, including the lack of an early notification system alerting interested parties of marketing approvals for follow-on pharmaceuticals in a manner that would allow for the early resolution of potential patent disputes. Trade groups representing global investors in India’s innovative sectors have also highlighted the patent linkage gap and the opportunity provided by implementing an early notification system to advance the resolution of this issue in various forums. In 2017, the Ministry of Health and Family Welfare eliminated the requirement that applicants submit information about a new drug’s patent status as part of the application form (Form 44) to get permission for importing to or manufacturing a new drug in India. This eliminates any burden on the applicant seeking marketing approval to declare the patent status of the drug to the regulator, thereby reducing transparency and accountability.

Through trade negotiations with its key trading partners, such as the US and the European Union, India is under increasing pressure to reform its IP rules and streamline its regulatory drug approval process, among other reforms. Recently, the Indian drug regulator, Central Drugs Standard Control Organization has undertaken efforts to streamline regulatory submissions and digitalize its activities as part of the Government of India’s flagship initiatives, of the “Ease of Doing Business in India” and “Digital India” to boost foreign investment and remove regulatory bottlenecks. As part of such efforts, the Indian drug regulator launched a centralized online portal, named SUGAM, to facilitate online regulatory submissions for drug applications via a “single processing window.” In 2018, the Ministry of Health and Family Welfare published new draft rules that would likely enable the Indian drug regulator to leverage the online SUGAM portal to track drug marketing approvals in real time, which is a positive development for market participants and stakeholders. Not only would such a database be essential to promote better sharing of information between regulators in all states, and the center, and expedite approvals, but it could also serve as a central repository of information that patent holders could use to identify potential infringers at first instance.
Furthermore, the transparency, efficiency and administrative ease provided by the online portal may pave the way toward an early notification system designed to alert patent holders of marketing approvals sought by generic drug companies.

In general, Indian legislature has been supportive of the generic drugs industry and has adopted various mechanisms for the promotion of generic drugs through amendments to drug laws and policies. For instance, to ensure the quality of generic drugs, the Ministry of Health and Family Welfare issued a notification, in April 2017, requiring bio-equivalence studies to be conducted for drugs in certain categories of the biopharmaceutical classification system. In March 2017, there was also a proposal to amend the labeling regulation that would require printing the generic name in at least two font sizes larger than the brand name.

Below we comment on the enforceability of patent rights to prohibit the introduction to the market of a generic drug during the period of validity of an originator’s patent used in such drug. As reflected by the case law described below, the lack of legal protections directly related to the patent linkage concept in India is a key obstacle to an originator’s ability to enforce its patent rights against a generic drug manufacturer applying for a market authorization in India.

**Legal regulation**

In India, the import, manufacturing, sale and distribution of drugs is regulated under Drugs and Cosmetics Act, 1940 ("Drugs Act") and the Drugs and Cosmetic Rules, 1945 ("Rules"). The Central Drugs Standard Control Organization (CDSCO) is India’s central regulatory body for pharmaceuticals and medical devices, and is part of the Ministry of Health and Family Welfare. The Drug Controller General of India (DCGI), who directs CDSCO, handles the drug and device regulatory process, and is responsible for registering all imported drugs and new drugs, and for overseeing clinical trials. Before a pharmaceutical drug is introduced in India, marketing approval is required from the DCGI under the Drugs Act. In making its evaluation, the DCGI reviews the safety and efficacy of the drug. As previously stated, the Indian legislature has not expressly recognized the patent linkage concept and the DCGI is not obligated to consider the patent status of the original drug when evaluating a generic drug for marketing approval.

If the relevant drug is a new drug, the inventor of the drug would usually apply for patent protection under the Patents Act, 1970. Historically, one of the controversial provisions of the Patents Act, 1970 was Section 5, which provided only a limited term process patent protection for inventions related to food, medicine, drugs and substances produced by chemical process. The deletion of this controversial section was one of the most notable aspects of India’s 2005 Patents (Amendment) Act. Overall, the 2005 Patents (Amendment) Act brought the country’s patent system into compliance with the WTO’s Agreement on Trade Related Aspects of Intellectual Property Rights ("TRIPS Agreement"). This was a major legislative milestone in India. Section 107A of the 2005 Patents (Amendment) Act, which is particularly relevant to the patent linkage concept, reflects the TRIPS Agreement Article 30 experimentation exemption, providing that “[a]ny act of making, constructing, using, selling or importing a patented invention solely for uses reasonably related to the development and submission of information required under any law for the time being in force ... shall not be considered as a infringement of patent rights.” Sanctioning early experimentation with patented goods is another example of how Indian legislature has supported the generic drugs industry through amendments in India’s drug laws.
**Case Law**

*Bristol-Myers Squibb Co v. Hetero Drugs Ltd (Delhi High Court ex parte order, dated 19 December 2008)*

The Delhi High Court confronted the patent linkage question in two cases. In 2008, in the case of *Bristol-Myers Squibb Co v. Hetero Drugs Ltd*, Bristol-Myers, a US drug company, filed a petition against Hetero, an Indian generic company, to restrain Hetero from proceeding with its application for marketing approval of the generic version of the cancer medicine Dasatinib. Bristol-Myers Squibb held an Indian patent over this drug. The court order against Hetero appears to establish a patent linkage, despite the fact that no such mechanism exists within the Drugs Act. More specifically, the order restrained Hetero from “manufacturing, selling, distributing, advertising, exporting, offering for sale or in any manner dealing directly or indirectly in any product infringing the plaintiffs’ patent subject matter of the suit bearing No. 203937” and noted that “[i]t is expected that the Drug Controller General of India while performing statutory functions will not allow any party to infringe any laws and if the drug for which approval has been sought by the defendants is in breach of the patent of the plaintiffs, the approval ought not be granted to the defendants.” The order raised the question of whether it was a judicial manner of linking the patent and drug regulatory approval process. While the order stated that the DCGI was expected to “not allow any party to infringe any laws,” DCGI was not made a party to the suit and such function would, arguably, be outside DCGI’s approved mandate to assess drug safety and efficacy and, subsequently, to grant drug approval.

*Bayer Corporation and Ors v. Cipla, Union of India (UOI) and Ors (LPA 443/2009, Delhi High Court)*

In 2009, Bayer Corporation filed a writ petition before the Delhi High Court against the Union of India, the DCGI and Cipla, an Indian generic drugs company, seeking an order that the DCGI should consider the patent status of its drug, sorafenib tosylate (Nexavar), and refuse marketing approval for any generic versions of this drug. Bayer held an Indian patent for the cancer drug Nexavar and Cipla sought regulatory approval for the generic version of the drug from the DCGI. Although the facts in this case were similar to those in the Bristol-Myers case, the court held that a patent linkage system could not be read into the existing Indian law.

Bayer contended that Section 2 of the Drugs Act, read with Section 48 of the Patents Act, supports the concept of patent linkage. Section 2 of the Drugs Act states that the provisions of the act shall be in addition to, and not in derogation of, any other law in force. Bayer emphasized that any other law included in Section 48(a) of the Patents Act, 1970 gives the patent holder of a product the exclusive right to prevent third parties, who do not have his/her consent, from the act of making, using, offering for sale, selling or importing for those purposes that product in India. Accordingly, Bayer argued that the DCGI should ensure that its approval of a generic marketing application does not violate the provision of any other statute, and that generic approval would allow a company to infringe on the patent and negate the rights expressly granted under the Patents Act, 1970.

Bayer also stated that DCGI was on notice with respect to the patent status of the relevant drug given the requirement in Form 44 of the Rules that mandates the applicant to declare the patent status of the relevant drug (which requirement was subsequently eliminated in 2017) and the publication of the grant of the patent.

Bayer further, pointed to Section 156 of the Patents Act, 1970, which provides that “a patent shall have to all intents the like effect as against Government as it has against any person.” Bayer argued that if the DCGI granted marketing approval to Cipla, the DCGI would not only be acting contrary to Section 2 of the Drugs
Act but would also be “abetting” the tort of patent infringement. Bayer also claimed that Cipla’s generic version of the drug was “spurious” pursuant to Section 17B of the Drugs Act in that it was an imitation of, or a substitute for, another drug, or resembled another drug in a manner likely to deceive.

Cipla rebutted Bayer’s arguments, stating that the regulatory and patent regimes were designed to fulfill distinct functions and that reading into these statutes the patent linkage concept would be overstepping the interpretive bounds of the court. Furthermore, Cipla counter argued that the existence of patent infringement should be established in court, not just stated by the patent holder, and that the assessment of patent infringement is outside the DCGI’s area of expertise. Enabling the DCGI to consider the patent status before providing marketing approval would empower the DCGI to enforce both valid and invalid patents. Cipla asserted that under the experimentation exemption of Section 107A of the 2005 Patents (Amendment) Act, a drug manufacturer could experiment with patented drugs to generate data to be submitted to the drug control authority, and that the provision was meant to ensure and facilitate the immediate entry of generic drugs on patent expiration. Cipla also argued that it was incorrect to apply the terms “spurious” to generic drugs, as the drugs were not meant to “deceive” – a key element that triggers the provision.

The court in a single judge decision rejected Bayer’s arguments and held that no patent linkage regime could be de facto read into the existing provisions of the two statutes. It further held that a patent linkage system would put a burden on the regulatory authority and would undermine the experimentation exemption under Section 107A of the Patents (Amendment) Act. The DCGI lacked the expertise to adjudicate questions of patent infringement and doing so would be outside the scope of the Drugs Act. Furthermore, establishing a patent linkage system was outside the bounds of the court. The court also noted that the omission to create a specific patent linkage system showed the negative intention of the legislature. Lastly, the court also rejected Bayer’s argument that Cipla’s drug was spurious because casting all generic drugs as spurious is contrary to the intent of the Drugs act.

On appeal, the Delhi High Court affirmed the decision of the single judge holding that “[i]t is not for the court to determine if the government should bring in a system of patent linkage” and that there is no positive obligation on any department of the central government to protect a patent from infringement. The Supreme Court affirmed the Delhi High Court’s Division Bench Order, stating that given the disparate objectives of the Drugs Act and the Patents Act, and both being separate codes enacted for different purposes, there was no merit in the contention that there was a “patent linkage.”

### Summary and future developments

Given the status of patent linkage in India, and the lack of transparency relative to marketing approvals for generic drugs, originators face challenges in enforcing their patent rights against generic drugs entering into the marketplace. Many innovator companies resort to using the Right to Information (RTI) Act to ferret out the marketing approval submission details from the DCGI and initiate appropriate legal action before the generic drug comes to market. Given the trends discussed earlier, it appears unlikely that India will adopt a patent linkage regime in the near future. However, if India were to implement an early “notification” system for new drug applications on a publicly accessible database that would be a significant step toward providing the much-needed transparency to stakeholders, and striking a balance between facilitating entry of cheaper generic drugs into the marketplace and incentivizing pharmaceutical innovation. We anticipate the patent linkage issue will continue to be a key topic of contention among local and international stakeholders across trade and industry groups relative to the Indian pharmaceutical market.

Status: Law stated as of July 2019
Indonesia
Introduction

To date, the patent linkage concept has not been enacted in Indonesia. At this stage, the government is yet to discuss the inclusion of the concept in future regulations on patent or drugs marketing activity.

Legal regulation

Under current practice, any drugs distributed in Indonesia must be registered with the Food and Drug Supervisory Agency (Badan Pengawas Obat dan Makanan (BPOM)), to whom authority is delegated by the Ministry of Health, and must obtain a distribution license (Izin Edar).

Under the BPOM Regulation No. HK.03.1.23.10.11.08481 of 2011, on Criteria and the Procedure of Drug Registration as lastly amended by BPOM Regulation No. 24 of 2017 (“BPOM Regulation 3/2011”), registration of drugs with patent protected active compound can only be done by either:

- the patent rights holder; or
- the party appointed by the owner of the patent right.

The patent right must be evidenced by a certificate of patent.

Furthermore, BPOM Regulation 3/2011 allows applicants of first generic drugs registration with active compound that is still protected by patent to submit their request of distribution license within five years before the patent protection ends. However, BPOM would only issue the distribution license once the patent protection ends.

In practice, the BPOM will require an applicant for drugs marketing approval to submit patent search results from the Directorate of Patents to confirm that the drugs (including their key compound) are no longer protected under any parties’ patents in Indonesia.

In the absence of legal regulation of the patent linkage concept, we may refer to general provisions of the Patent Law that allows patent right holders to enforce their patent rights in Indonesia.
In light of the above, actions may be taken to both the BPOM and the party carrying out infringing activities, as discussed below.

**Courses of action against patent infringement**

**Cease and desist (C&D) action**

Even though the Patent Law does not require a patent right holder to send a C&D letter to an alleged infringer before a court action can be taken against him, as a preliminary action, it is recommended that the patent right holder send C&D letters to the infringers, requesting them to cease any infringement activities.

In practice, this would be the most feasible course of action in terms of time and cost efficiency, as the patent right holder would not deal with enforcement officials or go through lengthy criminal or civil proceedings.

However, C&D action might not be effective to stop widespread and systematic distribution of infringing products.

**Criminal action**

If the infringers fail to comply with the C&D action, the patent right holders might initiate criminal action against the infringers, aiming to raid the premises to seize the infringing products or services and to shut down the business operation of the infringers. Exceptions to the criminal provisions of the patent law apply to both:

(a) the importation of patented pharmaceutical products that have been sold in other countries by the patent holder and imported to Indonesia according to the prevailing importing regulations; and

(b) manufacturing patented pharmaceutical products in Indonesia within five years before the expiration of the patent for the purposes of processing post-expiration permits (Bolar Exemption)

The Patent Law stipulates the maximum imprisonment penalty as four years and a fine up to a maximum of IDR 1 billion. For simple patent infringement, the maximum imprisonment penalty is two years and the fine is IDR 500 million.

Patent right holders can swiftly file a criminal complaint, as long as there is a valid patent registration. The process of police (raid) action, however, does not involve a definite period, as timing depends on the discretion of the police team. It is also subject to the discretion of the public prosecutor to prosecute and deliver the case to the criminal court. In practice, the entire criminal proceeding, from the first hearing at the criminal court until receipt of a final and binding decision, may take up to five years.

**Civil action**

In addition to the criminal action, the patent right holders may also initiate civil action to seek:

(a) compensation for damages resulted from the infringement activities

(b) termination of all infringement activities

There are no strict guidelines on the limitation of damages that may be awarded in a patent lawsuit. As long as the patent right holder can prove that (i) there is a patent infringement act; (ii) there are damages suffered by the patent right holder; and (iii) there is a causal link between the patent infringement act and the damages suffered, the patent right holder may seek compensation for damages in any amount.
However, it would still be at the court’s discretion to decide the fairest amount of compensation. As a matter of practice, proving damages may be challenging.

However, please bear in mind that if the main purpose were to stop infringing activities and obtain the deterrent effects, the civil action would not be as effective as criminal action, since the nature of civil action would be to seek economic compensation.

Theoretically, a patent litigation proceeding, from filing the lawsuit until receiving a final and binding decision, would take a little more than one year, with details as follows:

- The panel of judges must issue a decision on the case within, no longer than, 180 days after the lawsuit is filed with the registrar’s office at the commercial court.
- Should there be an objection from one of the parties concerning the commercial court’s decision, then such party is entitled to file a cassation request to the Supreme Court within 14 days after the issuance of the commercial court’s decision.
- The Supreme Court must issue the cassation decision within, no longer than, 180 days after the cassation request is registered on the Supreme Court’s registry.

In practice, it is expected that the Supreme Court’s decision would be received within 18–24 months after the Supreme Court gets the case file from the commercial court.

Enforcement actions through the Directorate General of Intellectual Property (DGIP) Enforcement Division

In addition to the conventional criminal action carried out by the police (a police raid), enforcement officials can now carry out criminal action from the DGIP.

Compared to a police raid, we believe that the criminal action by the DGIP enforcement officials would be more favorable for the following reasons:

(a) In practice, the chance of initiating a criminal action would greatly depend on the patent office’s opinion confirming the patent infringement acts.

In relation to this, if the patent right holder chooses to initiate a police raid, it might be more difficult to coordinate, as a request should first be asked from the Patent Office to issue an opinion and then submitted as evidence to the police.

On the other hand, if the DGIP officials carry out the criminal action, the patent right holder might only need to liaise with the DGIP and the Patent Office’s officials. Thus, the preparation would be more time-efficient since coordination with any other government officials, i.e., the police, is no longer needed.

(b) When coordinating with the police raid the patent right holder might face obstacles in setting up the appropriate raid timing, as police officials might have conflicting schedules. Please also bear in mind that the police deal with various cases and not only with intellectual property-related cases.

If the DGIP officials were to carry out the criminal action, the patent right holder might not face such obstacles, as DGIP officials specifically deal with intellectual property-related cases. Thus, it would be easier to set up the timing of the raid.
Case law

In practice, we have yet to see any landmark cases on this matter.

Summary and future developments

There are no planned changes to the current regime concerning patent linkage.

Status: Law stated as of July 2019
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Introduction

Until 2012, the Italian Code of Industrial Property (CIP) included a specific provision (paragraph 1-bis of Article 68) that allows generic drugs manufacturers to start the registration process for the relevant products only during the last year of validity of the patent or supplementary protection, as stated below:

(...) companies intending to manufacture medicinal products outside patent protection may start the registration procedure for the product containing the active ingredient one year prior to the date of expiration of the supplementary protection or, in the absence thereof, of the patent protection of the active ingredient, having regard to any possible extension.

This provision was repealed by Law No. 27/2012, following the initiation by the European Commission, on 14 March 2011, of an infringement procedure against Italy in relation to paragraph 1-bis of Article 68 CIP for violation of the EU legislation on medicinal products. According to the European Commission, the Italian provision was in breach of Article 10 of Directive 2001/83/EC in the Community Code relating to medicinal products for human use. In fact, although Article 10 of Directive 2001/83/EC provides that an authorized generic drug cannot be placed on the market until 10 years have elapsed from the initial authorization of the referenced product, it does not impose any time restriction for the beginning of the approval process for generic drugs.

Following the repeal of the above provision, the patent linkage concept does not find any application in Italy. The current Italian legislation (both patent and pharmaceutical laws) no longer includes any provisions preventing the manufacturer of a generic drug from starting the approval process and obtaining a marketing authorization for the relevant generic drug in the case where the originator’s product/active ingredient is still under patent/supplementary protection. Therefore, a drug registration for a generic product may not be, in principle, hindered by patent protection for the original drug.
Legal regulation

For an overview of the EU regulatory regime, see the EU chapter.

Legislation on medical products does not include any provisions preventing the regulatory authority (the Italian Medicines Agency) from starting the approval process and granting a marketing authorization for a generic drug in case the relevant originator is still under patent/supplementary protection.

The Italian situation is in line with the European Commission’s objection to the inclusion, within the legislation on medicinal products, of a link between the market approval process of generic drugs and the patent status of the originator products because, according to EU legislation, marketing authorization bodies cannot take the patent status of the originator medicine into account when deciding on marketing authorizations of generic drugs. In other words, according to the EU legislation on medicinal products, regulatory authorities shall have no evaluation role with respect to intellectual property rights connected with the market approval of generic drugs and are only responsible for assessing safety aspects relating to them. Consequently, provisions that make the possibility of conducting clinical trials/studies aimed at achieving the market approval, or the grant of the marketing authorization for generic drugs, subject to the prior expiration of the patent/supplementary protection of the originator would be unlawful.

Notwithstanding the above principle, in September 2012, the Italian legislator enacted a piece of legislation (paragraph 1-bis of Article 11 Law Decree No. 158/2012, converted into Law No. 189/2012) that established that generic drugs could not be reimbursed by the National Health Service before the expiration of the patent/supplementary protection of the originator.

Manufacturers of generic drugs have strongly criticized this provision, claiming that this is a form, even if sui generis, of patent linkage, which conflicts with the position adopted by the European Commission and unduly defers the availability of generic drugs for the National Health Service, causing severe economic damages to citizens as well. Assogenerici (the Italian Association of the Generic Drugs and Biosimilars Industry) filed, in 2015, a position paper with the Italian Senate requesting the repeal of paragraph 1-bis of Article 11 Law Decree No. 158/2012, although said provision is still in force.

In conclusion, the Italian legislation on medicinal products does not prohibit the granting of the marketing authorization for a generic drug, and, therefore, placing it on the market (which would, however, represent an infringement under the CIP), where the relevant originator is still under patent/supplementary protection. The legislation prevents, where patent/supplementary protection is in place, the National Health Service from reimbursing the generic drug.

Furthermore, additional protection for originators against generic manufacturers can be found in the provisions of Italian and EU pharmaceutical law, which provide for data and marketing protection for originator’s registrations with respect to referral applications of generic manufacturers for generic products. However, such protection is, at most, about half as long as the regular term of a patent, which is 20 years upon the patent application date.

In the absence of legal regulations on patent linkage, originators may only rely on the provisions of the CIP. Article 66 CIP sets forth the rights granted to a patent owner. A patent owner has, in principle, the following exclusive rights:

(i) producing, using, placing on the market, selling the product that is the subject matter of a patent, or importing such a product for the aforementioned purposes
(ii) using a process which is the subject matter of the patent or offering, placing on the market, selling a product which is produced directly by a process which is the subject matter of the patent, or importing such a product for the aforementioned purposes

The patent owner may also prevent third parties from exercising these rights without their authorization. The patent owner is granted several remedies that may be enforced against infringers, including injunction, seizure and destruction of the infringing products, request of information and damages claims. In particular, according to Article 131 CIP, the right holder may file an injunction claim against any action that represents an imminent (not necessarily actual) infringement of its right.

The exclusive rights of a patent owner are, however, subject to a number of limitations set forth by Article 68 CIP, which specifically excludes the infringing nature of, among others, the following conducts:

(a) acts performed in private or for non-commercial purposes or experimental activities (lett. a) bis or art. 68 CIP)
(b) studies and experiments (e.g., pre-clinical studies and clinical trials) aimed at obtaining, also abroad, drug marketing authorization and the subsequent practical activities, including the preparation and use of the active principles strictly necessary for the aforementioned purposes

Article 68 Lett. b) expressly allows any experimental activity related to the preparation (and filing) of a marketing authorization by a subject other than the patent owner, for the purpose of commercializing the relevant drug once the patent/supplementary protection has expired (so-called Bolar Exemption). In conclusion, as long as the generic drug manufacturer does not offer the generic product for sale and/or puts it on the market, they are allowed to conduct any type of activity in preparation for the future commercialization of the generic product.

Case law

Italian case law dealing with cases where originators tried to enforce their rights at the stage of obtaining marketing authorizations by generic companies (mostly issued before the repealing of Article 68.1-bis CIP) is quite well developed.

Since the famous Roche Products Inc. v. Bolar Pharmaceutical Co. decision, Italian courts (with few exceptions) have agreed that pre-clinical tests and clinical trials aimed at obtaining the marketing authorization for generic drugs are permitted under the so-called Bolar Exemption, regardless of the prohibition set forth by (the now repealed) Article 68 paragraph 1-bis CIP. The Court of Milan, in particular, has rendered a number of decisions stating that, despite the one-year limit set forth by Article 68.1-bis CIP for starting the registration process, the request for marketing authorizations for a generic drug falls within the scope of the Bolar Exemption, so not qualifying as patent infringement. According to the Court of Milan, both the filing and granting of marketing authorizations simply constitute steps of an administrative process, and can neither be regarded as preparatory acts of a commercial activity nor can they be in any way hindered by the existence of patent protection for a product that coincides with the subject matter of such administrative proceedings.

Below, we have summarized some of the most recent and relevant decisions of the IP specialized courts of Milan and Turin.
The Court of Milan, following the interpretation of Article 68 CIP adopted in other decisions by the same court, stated that the mere filing of a request for marketing authorization for a generic drug lacking any actual proof of the commercial exploitation of the same is not sufficient per se to ground a patent infringement claim. In fact, the filing of a request for, and even the subsequent obtainment of, the marketing authorization does not necessarily indicate a certain time for market entry. According to the court, the principle set forth by Article 68.1 CIP (the Bolar Exemption) overcomes the (one-year) limit imposed by Article 68.1-bis CIP. In this respect, the court clarified that only the actual undertaking of specific preparatory activities for the manufacturing and commercialization of a generic product — such as the purchasing or production of the active ingredient, the storage of the product, the set-up of an actual distribution network on the territory or the launch of a promotional campaign — may amount to patent infringement.

Similar decisions: Court of Milan, 5 May 2009, in Giur. ann. dir. ind., 2009, 880; Court of Milan 15 April 2009, in Giur. ann. dir. ind. 2009, 864.

The Court of Milan upheld the originator’s request for a preliminary injunction against a generic product that had already obtained market approval. The decision was issued after the repealing of Article 68.1-bis CIP. In addition to the registration process for the generic product, the Court of Milan found that the activities carried out by the defendant — namely the publication on the Official Gazette of the price of the generic drugs, the communication to the database service provider, ADF Service, of the intention to start selling the generic drugs for the purpose of including the product in the Pharma database and the inclusion of the drug in the transparency list held by the Italian Medicine Agency — clearly represented infringing preparatory activities capable of causing prejudice to the originator, both in terms of distracting customers’ attentions and economic damages due to the reduction of the reimbursement allowed by the National Health Service. Please note that the Court of Milan eventually dismissed the action on the merits started by the patent holder upon finding that the SPC had expired.

The Court of Milan adopted a different legal stand on the relevance of marketing authorizations for generic drugs while Article 68.1-bis CIP was still in force. In particular, the court found that the filing of a marketing authorization request for a generic drug before the last year of validity of the patent protection over the originator’s product should be considered as a preparatory activity aimed at the subsequent commercialization of the generic product and, as such, it amounts to patent infringement. According to the court, the Bolar Exemption only extends to pre-clinical tests and clinical trials, and to the practical — but not bureaucratic/administrative — activities, which indeed qualify as merely instrumental to the following marketing authorization; whereas the marketing authorization is a far more advanced activity, clearly directed at the commercialization of the product.

Notwithstanding the lack of legal provisions and the rather restrictive case law, originators may still enforce their rights before a generic product has been put on the Italian market. The case law is quite consistent in this respect and preparatory activities, such as set-up of a distribution network, advertising campaign,
publication of the generic drug price, even if the product may only be available after the lapse of a patent or SPC, are already considered as infringing offers by the Italian courts.

As of today, the Italian Government does not appear to support the introduction of a patent linkage concept, in particular, as practiced in the United States.

Status: Law stated as of July 2019
Japan
Introduction

It is generally understood that Japan has a patent linkage system in place because patents of original medicines are taken into consideration by the Ministry of Health, Labor and Welfare (MHLW) in the approval process for generic medicines, which is required under the Act on Securing Quality, Efficacy and Safety of Products Including Pharmaceuticals and Medical Devices ("Pharmaceutical Affairs Act"). If an application for approval for a generic medicine were filed where an original medicine is protected by validly existing patents, approval for the generic medicine would not be granted unless its conflict with the original medicine’s patents is first cleared.

According to the MHLW, the purpose of the patent linkage system is to ensure a stable and consistent supply of medicines. More specifically, by checking conflicts between generic medicines and patents covering original medicines in the process of granting the required approval, the MHLW attempts to avoid patent disputes, which may have an adverse impact on the supply of generic medicines.

Patent linkage drew attention in relation to the Trans-Pacific Partnership Agreement ("TPP Agreement") and the subsequent CPTPP. See the glossary in Article 18.53, which stipulates an obligation regarding patent linkage. Due to this provision, signatory countries of the CPTPP (including Japan) need to implement a patent linkage system, as described, if they have not yet done so.

The Japanese Government takes the position that Japan has already introduced a patent linkage system that is still maintained. Therefore, the Japanese Government believes that the CPTPP has not necessitated an amendment to the relevant law or a change of the current legal system relating to patent linkage.

Legal regulation

The laws of Japan do not expressly stipulate rules for a patent linkage system. However, in an official notice released by the MHLW, it clarified that when it examines an application for approval for generic medicines, it checks whether the generic medicine conflicts with patents of original medicines. Moreover, approvals for the generic medicine shall:

- not be granted if manufacturing of the generic medicine is prohibited due to substance patents (patents of active ingredients of the original medicine) and/or use patents (namely patents of active ingredients and its new usage/application)
- be granted if patents are granted only to a part of efficacy, dosage or administration of the original medicine, and those patents do not prevent manufacturing of the generic medicine
In the second case, efficacy, dosage or administration of the generic medicine falls outside the scope of the approval, i.e., the generic medicine will be approved only with respect to its efficacy, dosage or administration that are not covered by the patents of the original medicine.

Please note that patents of original medicines restrict neither filing an application for approval for generic medicines nor manufacturing generic medicines to gather information required to file an application for approval. The Patent Act provides that manufacturing for the purpose of examination and research does not constitute patent infringement. Furthermore, a Supreme Court decision clarified that conducting the examination and research necessary to file an application for approval for generic medicines does not constitute infringement of the original medicines’ patents, even if the application is filed before expiration of the patents for the purpose of selling the generic medicine upon expiration of the patents.

Therefore, under the patent linkage system in Japan, approval for generic medicines would not be granted unless conflicts with original medicines’ patents are first cleared. However, it does not restrict generic medicine manufacturers from preparing for the sale of generic medicines right after the expiration of the patents of the original medicines.

In addition, please note that the approval for generic medicines is not a perfect clearance of the relevant patents – in other words, there is still a possibility that the patentee(s) will take patent infringement litigation against the manufacturer or sellers of the generic products based on, usually, patents other than the patents reviewed in the approval process. It is even possible to take patent infringement litigation based on the patents that have been reviewed in the approval process at the MHLW, as it does not prevent the filing of litigation with courts (although it is usually not a good option). For more details about such litigation, please see the following section.

Case law

Although the MHLW does not grant approval for generic medicines unless it first confirms clearance of conflicts with the original medicines’ patents, as described in the previous section, there are some cases where manufacturing and/or sales of approved generic medicines are recognized as infringing on the patents covering the original medicines.

For example, in Chugai Pharmaceutical v. DKSH Japan et al., the plaintiff, a patentee of the original medicine, claimed that the defendants infringed the plaintiff’s patent on the manufacturing method of the original medicine. On 25 March 2016, the IP High Court determined that the manufacturing method of the generic products did not fall within the literal scope of the claim of the plaintiff’s patent, but was equivalent to the claimed method of the patent, and, thus, sales of the generic medicine constituted infringement against the plaintiff’s patent. The defendant appealed to the Supreme Court, but the appeal was rejected.

As shown in this example where patents on manufacturing methods and doctrine of equivalents were at issue, there are certain types of conflicts between generic medicine and patents of original medicines, which the MHLW may not necessarily be able to recognize in its approval processes. Therefore, the patent linkage system in Japan does not always prevent the manufacture or sale of generic medicines that infringe patents of original medicines.

Summary and future developments

As shown in the previous sections, under the Japanese patent linkage system, the sale of generic medicines will not be approved by the MHLW to the extent that the generic medicine’s conflict with original medicines’ patents is recognized by the MHLW.
Therefore, to delay the generic medicines’ entry into the market as long as possible, it would be effective for the original medicine manufacturers to obtain relevant patents step-by-step, such as, starting from filing a patent application for a new substance to be used in their medicine, followed by an application for a method of manufacturing of the substance, and then for the new medicine consisting of the new substance and other additives.

Patentees of original medicines should also be aware that the patent linkage system does not always prevent generic medicines from being approved for sale in the market without the consent of the patentees. The MHLW’s approval should not be considered as perfect clearance of possible patent conflicts between generic medicines and patents of original medicines. If any suspicious generic medicine is found, patentees need to better analyze the generic medicine to check if it infringes their patents.

Please note that it is lawful to manufacture generic medicines for examination and research purposes, including manufacturing to obtain relevant data necessary to apply for the MHLW’s approval before expiration of patents for original medicines to sell the generic medicine right after expiration of the original medicine’s patents. Therefore, patent claims by patentees of original medicines need to be made against sales or manufacturing of generic medicines for other purposes (e.g., for the purpose of sale).

Status: Law stated as of July 2019
Kazakhstan
Introduction

Before March 2015, Kazakhstan supported the patent linkage concept without exception. The medicine marketing authorization rules restricted a marketing authorization of generics until patents of original medicines expired. In March 2015, the marketing authorization procedure was changed. The new changes allowed a marketing authorization of generics regardless of the fact that the relevant patents were still valid. However, the new rules restricted the sale of such generics until the patents expired.

Regardless of the above restrictions, the regulator only adopted the practical measures aimed at supporting the generic sale restrictions in 2018. Until then, marketing authorization certificates issued by the regulator for generic products did not contain any sale restrictions. Therefore, generic companies were able to introduce their products on the market. The delay of the supporting measures resulted in several patent disputes, created a new court practice in Kazakhstan and developed additional practical protection measures.

Considering recent initiatives in the enforcement of originators’ patent rights and internal state policy focusing on the acquisition of low-price medicines and medical devices which tend to speed up generics’ access to the Kazakhstani market, there are no significant developments from the Ministry of Healthcare towards patent linkage. Following significant discussion between the business community and the regulator, which followed after patent disputes between 2016–2017 around patent infringement and state procurement, the regulator promised to consider the opportunity to return to the patent linkage concept by amending the medicines and medical devices marketing authorization regulations. However, as of today, these discussion are still pending. The new measures that were introduced by the regulator slightly increased the protection of the original medicines (for example, the applicant was required to submit a detailed confirmation that the medicine proposed for authorization did not violate IP rights). However, generally, the generic products registration procedure, introduced in March 2015, is unchanged.

Below we comment on the possibility of the successful enforcement of patent rights by prohibiting the introduction into the market of a generic product while the originator’s patent for such product or its part is still valid. Despite the lack of legal provisions directly related to the patent linkage concept and coherent case law, Kazakhstani legislation provides legal remedies that enable an originator to enforce their patent.
rights against a generic product manufacturer trying to sell generics, which infringe the patents, as original medicines.

**Legal regulation**

In the absence of a straightforward legal regulation of the patent linkage concept, originators may refer to general provisions of Kazakhstan’s Civil Code ("Civil Code") and the Law of the Republic of Kazakhstan Patent Law ("Patent Law"), which contain legal remedies allowing right holders to enforce their patent rights.

In particular, the Civil Code provides a patent owner with the option to file a claim to cease any activities that infringe or create the threat of infringement of intellectual property rights (IPRs). Such a claim may be filed against a person or entity that is:

(i) carrying out infringing activities (e.g., offering for sale through public tenders or producing, storing or distributing a generic medicine)

(ii) making necessary preparations to carry out such activities and, thus, creating a threat of infringement

In addition, under the Civil Code, a patent owner may request confiscation of infringing products, mandatory publication about the infringement and compensation of damages. The law also allows a patent holder to seek the suspension of a certificate of medicine registration in case of a breach of the patent, until the court issues the decision on merits.

Documental evidence is a very important issue in Kazakhstan because legislation does not allow for a discovery procedure, which is available in other jurisdictions, such as the US and the UK. Typically, under local civil procedure regulations, the court does not participate in the process of collecting evidence and bases its decision on evidence provided by the parties.

At the same time, Kazakhstan’s pharmaceutical laws contain a rule that can be regarded as weakening patent protection in the country. In particular, the Rules for State Registration, Reregistration and Amendment of Registration Dossiers of Medicines and Medical Products and Equipment provide for the following rule:

> State registration of a generic drug shall be conducted with issuing a registration certificate without granting the right to sell the drugs prior to the expiry of a patent for the original drug. The applicant shall inform in writing of non-infringement of third party rights protected by the patent in connection with the registration of the pharmaceutical product.

In essence, this rule allows the marketing authorization of a generic in spite of the fact that it infringes the patent rights of the originator. While, from the legal perspective, the generic manufacturer is not entitled to sell the relevant products, the registration is connected with high risks of the patent infringement. For example, the standard form of the registration certificate with the prohibition of sales was approved only in 2018. Accordingly, during 2015–2018, there was no sale restriction in relation to the registration certificates. This gave rise to a number of disputes connected with sales and participation in tenders of generic manufacturers.

Below we briefly describe recent cases that are relevant to this question.
Case law

To date, there are only a few cases where originators tried to enforce their rights at the stage of the drug registration. These cases are described below.

Marketing authorization of generic pharmaceuticals

There are a few cases where the court stipulated that registration of a generic drug is not infringement of the patent rights of the originator.

For example, in the case Global Holding LLP v. Almaty Department of the Committee for Monitoring of Medical and Pharmaceutical Activities of the Ministry of Health (Case No. 3g-211-12 dated 27 August 2012), the Supreme Court stated that “... an application for registration of a medicine does not constitute the introduction of the medicine into the market, and therefore, does not entail infringement of rights of the patent holder.”

In a similar case, the manufacturer of the original medicine applied to the court with the claim to invalidate registration of a generic product obtained by a generic manufacturer Getz Pharma (Pvt) Limited. The Almaty Court of Appeals (Case No. 2a-4988-2015 of 29 July 2015) in its decision stated:

(... an application for marketing authorization of a medicinal product does not constitute a violation of civil law, as the legislation regulating such registration does not prohibit the submission of such an application by any person; likewise submission of an application for marketing authorization of a medicine does not constitute the introduction of the medicine into the market, and therefore, does not entail infringement of rights of the patent holder.

The above cases represent a general trend that marketing authorization of a medicine does not in itself infringe patent rights, with some exceptions (please see our comments below).

Participation of generic manufacturers in tender procedures

Another issue that gave rise to controversial court decisions is the absence in the tender regulations of the requirement to ensure compliance with intellectual property legislation.

For example, in a court case initiated by the originator against a seller of generic drugs, the Almaty Specialized Interdistrict Economic Court stated:

The seller participated in a tender and offered for sale of a generic medicine ... Sale and other introduction into the market in the territory of the Republic of Kazakhstan, while the Eurasian Patent ... was in force, without consent of the patent holder, and thereby infringed the rights of the patent holder and provisions of legislation, as the defendant may not perform any actions aimed at putting the medicinal product into the market without consent of the patent holder, i.e., the claimant.

Unlike the above decision, the court took an opposing view in another case. In particular, in a case initiated by an originator against a same seller (Case No. 2-19100/15 of 9 March 2016), Almaty Specialized Interdistrict Economic Court stated:

(... marketing authorization of medicine (the owner of the registration certificate and the manufacturer of the medicinal product is Aurobindo Pharma Limited, an Indian pharmaceutical company) has not been terminated. Furthermore, the registration certificate does not contain any reservations. The seller supplies Abacavir and lamivudine based on results of a tender won by LLP; results of the tender have not been cancelled either.
Therefore, the court supported the generic manufacturer’s position in view of the fact that, among other things, the registration certificate did not contain any sales restrictions. This decision was also supported by the court of appeal.

Summarizing the above, the analysis of the court practice allows the following conclusions to be made:

• The court practice in Kazakhstan does not support the patent linkage concept.
• The local court practice is still controversial and needs further improvement to strengthen protection of patent holders’ rights.
• While the practice of IPRs protection is gradually evolving, there are still some issues that need to be improved by both legislative amendments and the development and implementation of the law.

**Alternative protection measures**

As an alternative to the patent linkage concept protection measures, the court practice proposed to use the so-called “data exclusivity” concept as a tool for protecting the rights of manufacturers of original pharmaceuticals having patents or having no patents.

In March 2019, the Supreme Court of Kazakhstan resolved a case initiated by a leading American biotechnology company, a manufacturer of medicine for a cancer, against an Indian manufacturer of a generic version of the same drug.

The originator sought cancellation of the Ministry of Healthcare’s order approving registration of the generic product on the basis of the data exclusivity concept. This concept was first introduced in Kazakhstan in 2015 in connection with Kazakhstan’s accession to the WTO and is aimed at preventing generic drug manufacturers from relying on the original medicine’s clinical trial data within a six-year period from the date of registration of the original medicine.

The original medicine was registered in Kazakhstan in 2016. In 2017, the Indian generic company obtained registration for a generic product and marketed it in Kazakhstan.

The originator unsuccessfully challenged the generic product’s registration in the court of first instance and the appeal court. Its claims were rejected, mostly, on the basis that the originator did not hold a patent for its products and failed to provide evidence of disclosure of its clinical trial data.

However, the Supreme Court overturned decisions of the lower courts, arguing that the lower courts did not consider the data exclusivity concept in a proper way and returned the case to the court of appeal. Thereafter, the court of appeal considered the case again and upheld the claim in full.

This case is a good precedent for demonstrating that originators may seek the protection of their rights referring to the data exclusivity concept and in absence of the patent linkage concept.

**Summary and future developments**

In view of the above, we believe that the following measures should be taken in order to strengthen IPRs protection in Kazakhstan:

• The establishment of a specialized intellectual property court for resolving IPRs-related disputes.
• Issuance of a Supreme Court directive on IPRs-related disputes that would lead to uniformity in the court practice.
Amendment of the state procurement legislation to require bidders to submit license agreements or other documents confirming their right to deliver goods or other products protected by IPRs.

All existing generic marketing authorizations issued before March 2015 (date of change of the rules of registration medicines and medical devices) should be amended to include a prohibition to sell generics until relevant patents expire.

Status: **Law stated as of July 2019**
Introduction

In March 2018, Malaysia signed off on the Comprehensive and Progressive Agreement for Trans-Pacific Partnership (CPTPP). Chapter 18 of the CPTPP imposes an obligation on the Drug Control Authority (DCA) in Malaysia to implement a patent linkage system. However, the CPTPP has yet to be ratified and, as such, there is currently no patent linkage system in Malaysia.

Notwithstanding the absence of a patent linkage system, originators, owners of pharmaceutical patents in Malaysia, rely on alternative methods to protect their patent rights, including:

(a) monitoring the notifications published by the National Pharmaceutical Regulatory Agency (NPRA) with regard to new drug products that have been approved
(b) cross-checking the newly approved drug products with any patents owned by the originators
(c) commencing legal proceedings for patent infringement against the manufacturers and/or producers of the generic drugs if the generic drugs are found to have infringed any of the patents owned by the originators

This chapter shall discuss the potential challenges that may be faced by originators in protecting their patent rights in Malaysia and the recent initiatives concerning the implementation of a patent linkage system in Malaysia.

Legal Regulation

As there is no patent linkage system in Malaysia, the registration of generic drugs is, generally, allowed, notwithstanding the subsistence of valid patents covering the drug product or approved use. Therefore, it is fairly common for generic companies to register their products even during the validity period of the patent. Originators can certainly take action if there is further commercial activity other than registration.

A method that can be adopted by originators in Malaysia to overcome the lack of a patent linkage system would be to proactively monitor the notices with regard to newly approved drugs that are periodically published by the National Pharmaceutical Regulatory Agency ("NPRA Notice") and identify any generic drugs that may potentially infringe any of the originators’ patents.

The NPRA Notice includes the following information:

(a) the registration number of the drug
(b) the name of the drug
(c) the name of the company that registered the drug
Further to the above, it is worth noting that additional information pertaining to the drug can be ascertained from the product codes located at the end of the drug’s registration number. An example is reproduced below for ease of reference:

<table>
<thead>
<tr>
<th>Registration Number</th>
<th>Additional Information</th>
<th>Full List of Product Codes</th>
</tr>
</thead>
<tbody>
<tr>
<td>MAL20172855ACREZ</td>
<td>A - Schedule Poisons</td>
<td>A: Scheduled Poisons</td>
</tr>
<tr>
<td></td>
<td>C - Contract Manufactured</td>
<td>X: Non-scheduled Poisons</td>
</tr>
<tr>
<td></td>
<td>R - Repacked</td>
<td>(over-the-counter products)</td>
</tr>
<tr>
<td></td>
<td>E - Export Only</td>
<td>T: Traditional Medicines</td>
</tr>
<tr>
<td></td>
<td>Z - Zero Rated GST</td>
<td>C: Contract Manufactured</td>
</tr>
<tr>
<td></td>
<td></td>
<td>E: Export Only</td>
</tr>
<tr>
<td></td>
<td></td>
<td>R: Repacked</td>
</tr>
<tr>
<td></td>
<td></td>
<td>S: Second source</td>
</tr>
<tr>
<td></td>
<td></td>
<td>N: Health Supplement</td>
</tr>
<tr>
<td></td>
<td></td>
<td>H: Veterinary</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Z: Zero Rated GST</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Y: Orphan Products</td>
</tr>
</tbody>
</table>

The above information will be helpful to originators because they provide preliminary information pertaining to the nature of the generic and the potential business activities that the generic company is planning to carry out with regard to the generic. The information will also provide an indication on the potential next steps that have to be taken by originators to determine whether a generic drug infringes their patent. For example, there is a high likelihood that originators may have to incur additional costs to engage the services of a private investigator to obtain a sample of generic drugs that have been designated as "Export Only," as these drugs will not be readily available on the market.

Another potential obstacle that originators in Malaysia may face is the generic company only registering the generic drug but not carrying out any business activities in relation to the generic drug. Pursuant to Section 37(1A) of the Patents Act 1983, a patent holder’s rights shall not extend to acts done by third parties for the purposes of obtaining marketing approval from the relevant authority, which regulates the manufacture, use or sale of drugs. Under such circumstances, originators would have no choice but to actively monitor the market to ensure that the generic company does not carry out any other commercial activities with regard to the generic drugs prior to the expiry of the originators’ patents.

However, if the generic company carries out activities other than the registration of the infringing generic drug, for example, by contracting with a manufacturer to manufacture, produce and stock the generic drug and advertise the generic drug, originators may bring an action for "imminent infringement" against the generic company, pursuant to Section 59(2) of the Patents Act 1983, if they have evidence that said activities
will be carried out during the subsistence of their patents. Nevertheless, to date, there are no reported pharmaceutical cases under Section 59(2) of the Patents Act 1983.

Case law

In Malaysia, there is no criminal liability for the infringement of patents and the patent owner may file a civil action for infringement of patents pertaining to pharmaceutical products in the High Court of Malaysia (Intellectual Property Division) (“IP High Court”). Such civil proceedings usually take 10–18 months from the filing of the claim to the delivery of the court’s decision. The remedies available to originators, if successful in a patent infringement action, include:

(a) a permanent injunction to restrain or prevent the infringer from further infringing the rights of the originators
(b) delivery of the infringing products
(c) being compensated by way of damages for losses suffered as a result of the infringer’s infringing acts, or seeking an account of the infringer’s profits derived from the sales of such products

Originators in Malaysia must bring a claim for patent infringement within six years of discovering a generic’s infringement. The IP High Court, typically, hears all patent infringement suits.

Evidence in a patent infringement case can be obtained via the following discovery methods:

(a) an Anton Piller Order
(b) a Pre-Action Discovery Order
(c) a Discovery Order after filing of action

Anton Piller Order

Evidence in a patent infringement case can be obtained via an Anton Piller Order. An Anton Piller Order (named after the English case in which this type of order was first granted) may be obtained from the court to prevent the infringer from destroying or disposing of the infringing goods, or any evidence of his/her infringing activities, by allowing for the search and seizure of such goods and evidence. However, due to the draconian effect of such an order, it will only be granted where the patent owner shows a strong prima facie case against the infringer, such that the damage to the patent owner would be very great if the order were not granted. The court must also be convinced that there is an imminent risk of the infringer disposing of or destroying all evidence of his/her infringing activities and, in this regard, it is insufficient to show that an infringer has been dishonest. It is important to note that an infringer cannot be forced to comply with an Anton Piller Order or to permit the patent owner and his/her solicitors to search the premises. Nevertheless, said infringer may be found in contempt of court if he/she does not comply with the order. In this regard, the penalties for contempt of court are imprisonment and/or a fine.

Pre-Action Discovery Order

Other than an Anton Piller Order, parties are now able to seek a Pre-Action Discovery Order. This means that a patent owner can seek a court order for a potential defendant to disclose information and documents requested by the patent owner. To succeed in this application, the patent owner would need to provide some evidence of the likelihood of infringement before such an order can be granted. This has now been proven to be a useful pre-action tool to enable a patent owner to seek more evidence before deciding whether to pursue an infringement action.
Discovery Order after filing of action

Once an action has been filed, parties are required at the pre-trial case management stage to exchange documents. Nevertheless, where there has been an inadequate disclosure by a party, pursuant to the informal process of pre-trial exchange of documents, an application for a further or more specific discovery order may be made to the court. It is also worth noting that an application for discovery may be made during the course of the trial when the cross-examination of witnesses reveals previously undisclosed material and/or documents.


The plaintiff generic company obtained regulatory approval from the National Pharmaceutical Control Bureau (NPCB) for Covance tablets in Malaysia and sought a declaration that its Covance products do not infringe the claims of the originator’s Malaysian patent, which concerned the active pharmaceutical ingredient used in the plaintiff’s Covance products – losartan potassium. The originator counterclaimed for patent infringement.

The judge held that the plaintiff’s Covance tablet infringed the originator’s patent and granted an order for the delivery, disclosure and/or destruction upon oath of all the plaintiff’s infringing products, and an enquiry as to the damages suffered by the originator or, alternatively, at the originator’s discretion, an account of profits made by the plaintiff derived from their acts of infringement.

Notably, the High Court also took the position that the registration of a drug by the NPCB is a regulatory process and that there is no nexus between the registration of the plaintiff’s Covance tablets by the NPCB and the infringement of the defendant’s patent. This means that the registration of a drug per se is not an infringing act.

Challenges faced by originators in Malaysia

Future developments

Articles 18.53(1) and 18.53(2) of the CPTPP impose an obligation on the DCA in Malaysia to have a system to provide notification to patent holders that another entity is seeking marketing approval of a pharmaceutical product that is still under patent protection and to allow the patent holder to seek, prior to the marketing of said pharmaceutical product, any judicial and/or administrative measures to resolve potential disputes concerning the validity of the patent holder’s patents, or to restrain the pharmaceutical product from being marketed.

The above patent linkage system is different from the conventional concept adopted in countries such as the United States, where the Food and Drug Administration (FDA) must ensure that there is no infringement of a subsisting patent before approving the marketing of a generic drug. There will be no such requirement in Malaysia and, as discussed above, the obligations of the DCA will only be limited to notification. Thus, should the CPTPP be ratified, the patent linkage system to be implemented in Malaysia will place the onus on originators to enforce their rights. Conversely, governmental authorities would not be required to play an arbitrary role and decide whether the generic drug would infringe a subsisting patent.

Nevertheless, the patent linkage system that may be implemented in Malaysia will require the DCA to stay the issuing of a marketing approval for generic drugs until the patent holder either consents or acquiesces to the registration of the generic drugs.
On 8 March 2019, Malaysia signed the CPTPP. However, said signing does not signify that the agreement has come into force, but is merely an indication that Malaysia accepts the outcome of the negotiations of the CPTPP and will start its domestic process to enable ratification of the agreement to bring it into force. There is no official indication as to when the ratification of the CPTPP will take place at the time of writing.

Status: **Law stated as of July 2019**
Introduction

In 2003, the patent linkage system was created in Mexico to provide legal certainty to patent holders avoiding the granting of marketing authorizations of medicines that may infringe their intellectual property rights.

The patent linkage system establishes a mechanism for the cooperation and coordination between the Mexican Institute of Industrial Property (IMPI), as the authority in charge of granting patents, and the Federal Commission for Protection against Sanitary Risks (COFEPRIS), as the authority in charge of granting marketing authorizations for the commercialization of medicines. Before the incorporation of the patent linkage, there was no official channel of communication between these authorities, which led to the granting of marketing authorizations in violation of Mexican patents.

Based on the patent linkage, the IMPI publishes periodically (every six months) a gazette that has a list of patents of pharmaceutical products (“Medicines Gazette”). This gazette lists key information on patents, including the generic denomination of the substance or active ingredient, relevant patent claims and the type of patent, among other information.

Notwithstanding the above, the Medicines Gazette is not exhaustive. At the beginning of the patent linkage system, the IMPI only published patents of active ingredients. However, from 2012, derived from a court precedent, formulation patents (pharmaceutical compositions) were also included. Patents of use and dosage, currently, can also be included in the Medicines Gazette, but only by a court order obtained by each interested party after litigation. Patents of processes of production of medicines are expressly excluded from the patent linkage and the Medicines Gazette.

Legal regulation

Patent linkage was incorporated at secondary regulation level, in both the intellectual property regime and the health regulation. Two articles were added to the Secondary Regulation of the Industrial Property Law and the Secondary Regulation of Health Products:

- Secondary Regulation of the Industrial Property Law (Article 47-bis)

  In the case of patents granted to allopathic medicines, IMPI will publish in the Gazette, and will make available to the public, a list of products that should be subject to protection in accordance with the substance or active ingredient, which will specify the validity of the respective patent.

  This list will contain the correspondence between the generic name and pharmaceutical identity of the substance or active ingredient and its nomenclature or identification form in the patent, which must correspond to the internationally recognized name.
The list referred to in this article will not contain patents that protect production processes or of drug formulation.

- **Secondary Regulation of Health Products (Article 67-bis)**

The applicant of the registration of an allopathic medicine must attach to the application the documentation that proves that the applicant is the patent holder of the active substance or active ingredient, or that he holds the corresponding license, both recorded at IMPI.

Alternatively, and in accordance with the list of products established in article 47 bis of the Secondary Regulations of the Industrial Property Law, the applicant may state, under oath, that it complies with the applicable provisions regarding patents with respect to the substance or active ingredient subject matter of the application. In this case, COFEPRIS will immediately request the technical cooperation of IMPI so that, within the scope of its authority, it determines at the latest within ten working days after receipt of the request, if it infringes existing patent rights. In the event that IMPI concludes that there are valid patents on the substance or active ingredient of which the applicant is not the owner or licensee, it will inform COFEPRIS so that it requests the applicant to demonstrate that he is the owner of the patent or that has the respective license, within the term determined by COFEPRIS, which may not be less than five business days after the notification has taken effect. In the event that the applicant does not remedy the omission, COFEPRIS will reject the application and inform the applicant the reasons for this determination so that, if applicable, they can be resolved before the competent authority. The lack of response from IMPI within the period indicated will be understood in a favorable sense to the applicant.

Based on the above, the COFEPRIS will review the Medicines Gazette published by the IMPI. Although COFEPRIS guarantees, from a regulatory point of view, that a medicine is effective, safe and of good quality, it must consider the rights of third parties. In this way, if the information published in the Medicines Gazette is sufficient to determine that third-party patents are not invaded, it may approve the marketing authorization application. Alternatively, the COFEPRIS may initiate a consultation procedure with IMPI, who will conduct a search, make a comparative analysis between the medicine subject to the marketing authorization application and the patents found, and issue a technical opinion with conclusions. In this way, the COFEPRIS will be able to determine if the marketing authorization application can be approved.

When the patent linkage system was implemented in 2003, the IMPI only published patents of active ingredients, making a literal interpretation of Article 67-bis of the Secondary Regulation of Health Products. However, holders of patents for medicines argued that the spirit of the system was to (i) include patents over products; and (ii) exclude patents over the process. This led to the successful automatic inclusion of patents of composition and the inclusion through litigation of patents of use and dosage.

The above was achieved by taking into account that the General Health Law (Article 224) defines allopathic medicines as "any substance or mixture of substances of natural or synthetic origin that has a therapeutic, preventive or rehabilitative effect, that is presented in pharmaceutical form and it is identified as such due to its pharmacological activity." Furthermore, Article 47-bis of the Secondary Regulation of the Industrial Property Law only excludes from the Medicines Gazette those patents that claim processes. Consequently, pharmaceutical compositions could be included.

Law.*\) the Supreme Court of Justice (SCJ) ruled that formulation patents must be included in the Medicines Gazette because they are medicines that include an active ingredient. Currently, pharmaceutical compositions are automatically included in the Medicines Gazette.

Patents of use and dosages are not automatically included in the Medicines Gazette. Holders of these patents have to request and litigate their inclusion in the Medicines Gazette on a case-by-case basis.

**Conditions for applying to the patent linkage concept**

Most of the patent linkage system is supposed to work automatically. The IMPI and the COFEPRIS communicate to each other without the direct intervention of parties. The relevant elements to consider in the patent linkage are the following:

- **Inclusion in the Medicines Gazette.** After the SCJ precedent, the inclusion of patents in the Medicines Gazette is automatic for patents of active ingredients and pharmaceutical compositions. In some cases (e.g., patents of use and dosage), the inclusion must be requested and litigated by the patent holders, in contrast to other legislations, where it is made by the authority automatically.

- **Intergovernmental Consultation.** In contrast to other jurisdictions, the consultation is carried out directly between authorities, without the intervention of the holders of the patents or applicants for marketing authorizations. The consultation is for the exclusive use of both institutions, the COFEPRIS and the IMPI. If the applicant for the marketing authorization or the owner of a patent wishes to obtain information about the consultation, it is possible to obtain it through a different procedure relating to access to public information. Neither IMPI nor COFEPRIS inform the holders of the patents if there is a marketing application in process that may affect their rights.

- **Burden of proof for the applicant of the marketing authorization.** In the cases in which the IMPI does not issue a conclusive opinion on a possible invasion of patent rights, for instance, due to the absence of data, the applicant for a marketing authorization has the burden of proving to the COFEPRIS that there is no risk of invasion. This can be done through various strategies that are determined on a case-by-case basis.

**Effective use of the patent linkage tool**

As mentioned above, the patent linkage should be automatic. However, in practice, both the patent holder and the applicant for a marketing authorization should take a proactive approach with the authorities, so that the patent linkage works correctly. Taking into account the above, the following should be considered:

- **From the point of view of the patent holder (innovator):**
  - Review the validity of its patents.
  - Record before the IMPI any existing license of patents rights.
  - Verify that all relevant patents are duly included in the Medicines Gazette. As a rule, patents of active ingredients and compositions should be published automatically. If patents are not included, as may be the case of patents of use or dosage, their inclusion must be requested and litigated.
  - Once the patents are included in the Medicines Gazette, it is recommended that the COFEPRIS be notified of its inclusion.
Monitor at the COFEPRIS the applications for marketing authorizations that could infringe patents. If any relevant application is found, it is recommended that the COFEPRIS be informed of the possible infringement.

Monitor the marketing authorizations granted by the COFEPRIS. If there are authorizations that could infringe intellectual property rights, a defense strategy shall be implemented, including an action to claim a nullity of the marketing authorization and, if applicable, the initiation of patent infringement procedures before the IMPI.

• From the point of view of the applicant for a marketing authorization (generic):

  o Monitor the Medicines Gazette and the Patents Gazette. It is recommended to review both the Medicines Gazette and the Patents Gazette of the IMPI to rule out that there are patents that protect the process of production of a drug. Although, patents of process of production are currently excluded from patent linkage, they represent an area of patent infringement.

  o Conduct an internal analysis (clearance search) to determine risks of violation of intellectual property rights of third parties.

  o If risks are identified, submit, along with the application for marketing authorization, a letter informing that third parties’ rights are not being infringed. Obtaining opinions from experts of an interdisciplinary nature (both regulatory and intellectual property lawyers as well as professionals with scientific background) is recommended.

  o In case of identifying patents owned by companies of the same corporate group or business partners, the company should confirm whether there is a license of rights. If not, the company should obtain and record it, following which the company should submit the recorded license to the COFEPRIS. An abbreviated license can be prepared for recording before the IMPI for this purpose, taking into account that this information will be disclosed.

Exceptions to the patent linkage concept

There is an exception to the patent linkage system, which refers to the general rules of patent infringement. An applicant for a marketing authorization of a generic product, the substance of which is protected by patents, can still file their application before the regulator, within the last three years prior to the expiration of the relevant patent, provided that the applicant is already involved in the experimental use and production of the product. This is the so-called Bolar Exemption.

Notably, this exception does not operate automatically. To defend successfully against patent enforcement actions, this applicant will be required to show that they have obtained a regulatory approval of the respective clinical trial. These applications for marketing authorization will be accepted for evaluation, but could only be granted at the end of the validity of the patent.

Summary and future developments

Mexico recently signed and ratified the CPTPP, which entered into force on 30 December 2018.

The operation of the patent linkage system in Mexico could be impacted. The impact would refer to the current local controversy over which types of pharmaceutical patents are covered under the rules of the patent linkage system. As mentioned above, the IMPI only automatically recognizes two types of patents: active ingredients and pharmaceutical composition. Other types of non-process patents still have to be litigated to be included in the system, such as patents over method of use and dosage.
With the new provisions of the CPTPP, innovators could argue that this international treaty, which is hierarchically higher than the secondary regulations described above, is clarifying that any type of patent claiming a product shall be included and should trigger the system. This would include current patenting practices, such as claims over the active substance, the pharmaceutical composition the method of use and the dosage, but would also cover future claiming practices, provided that these relate to the product.

Mexico recently ratified the Unites States, Mexico and Canada Agreement (“USMCA”) which will replace the North American Free Trade Agreement (“NAFTA”) once USA and Canada ratify it. The provision on the patent linkage replicates the text of the CPTPP, thus the USMCA would reinforce a similar impact on the Patent Linkage system in Mexico.

USMCA states that each country shall establish proceedings to compensate patent owners for unreasonable delays of Patent Offices to grant a patent, as well as to compensate delays of Health Authorities to grant marketing authorizations for pharmaceutical products. Remarkably, the CTPP contained similar provisions, but were suspended.

Status: Law stated as of July 2019
Introduction

Myanmar has recently enacted a Patent Law which paves the way for the protection of patents in Myanmar. However, the new law (along with the laws on trademarks, copyrights and designs) is yet to take effect, and this requires an implementing notification to be issued by the Myanmar President. It is still unclear when this will take place, but recent information suggest that the law may take effect sometime in Q2 of 2020, although at this point the accuracy of this timeline is still very difficult to predict with any degree of certainty.

Meanwhile, Myanmar has no law on patents. There was a Burma Patents and Designs Act that was enacted in 1945, but it was never brought into force, making the registration procedure of patents and designs in Myanmar ambiguous at best. As a result, there is currently no law or regulation specifically covering the registration of patents in Myanmar.

That said, the impending Patent Law does not cover the topic of patent linkage  *per se*, and for this reason it is not clear how prevailing law and practice relating to food and drugs would interrelate with the new patent law in a patent linkage context. In our opinion, this gap in the legal framework would likely prevent the implementation of any patent linkage regime in the country.

Further, it bears noting that as a member of the WTO and ASEAN, Myanmar is mandated to harmonize its laws with the relevant treaties administered by both, including the TRIPS Agreement and the ASEAN Framework Agreement on Intellectual Property. Note that for TRIPS, all least developed countries (LDC), which includes Myanmar, are required to comply by enacting TRIPS-compliant local laws by 1 July 2021. Myanmar is also not a member of the Paris Convention for the Protection of Industrial Property nor the Patent Cooperation Treaty. These deficiencies in the legal framework makes it increasingly challenging to recognize any international patent rights in the country.

Legal regulation

Myanmar has a National Drug Law governing the registration of pharmaceutical products, which is a prerequisite to manufacture, import, export, store, distribute or sell pharmaceutical products in the country. The function of registering drugs is handled by the Department of Food and Drug Administration (FDA) under the Ministry of Health and Sports. This framework of regulation is further enhanced by regulations implementing the National Drug Law, and recently by the issuance of guidelines on Drug Registration Application released in February of this year. Further, Myanmar has adopted the ASEAN Common Technical Dossier (ACTD) for the registration of pharmaceuticals for human use.
Summary and future developments

Despite this regulatory framework, the lack of a functioning local patent law coupled with the non-accession to critical international patent treaties make it difficult, if not impossible, to implement any patent linkage framework in Myanmar at present. This may change in the next few years as laws and regulations on patents continue to develop.

Status: **Law stated as of September 2019**
Peru
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Introduction

To date, in practice, there is a soft patent linkage regime in Peru, which requires publication of new drug applications.

Legal regulation

By virtue of the United States-Peru Free Trade Agreement ("US-Peru FTA"), which entered into force in 2009, Peru agreed to provide:

• A transparent system to provide notice to a patent holder that another person is seeking to market an approved pharmaceutical product during the term of a patent.

• Sufficient time and opportunity for a patent holder to seek available remedies prior to the marketing of an allegedly infringing product.

Furthermore, when it permits a person to rely on another person’s safety or efficacy information of an approved pharmaceutical product, it may implement the above obligations by:

• Implementing measures in its marketing approval process that prevent such other person from marketing a product during the term of the patent.

• Enabling the patent holder to be informed about the identity of any person requesting marketing approval during the term of the patent.

Following these commitments undertaken in the US-Peru FTA, a transparency measure was included in Legislative Decree No. 1072 on the Protection of Undisclosed Test and Other Data of Pharmaceutical Products, which requires the publication of the marketing approval applications, as well as the identification of the applicant and product, on the website of the Ministry of Health.

In 2018, Peru signed the Comprehensive and Progressive Agreement for Trans-Pacific Partnership ("CPTPP"), which incorporated into and made part of this agreement the provisions of the Trans-Pacific Partnership Agreement ("TPP"), but suspended the application of certain provisions. The CPTPP retains the TPP provisions relating to the marketing of certain pharmaceutical products, which are those that refer to patent linkage. In line with what was previously agreed in the US-Peru FTA and the TPP, Peru agreed that when it permits a person to rely on another person’s safety or efficacy information of an approved pharmaceutical product, it shall provide: (i) a system to notify or allow for a patent holder to be notified, prior the marketing of the product, that such other person is seeking to market that product during the term of a patent; and (ii) adequate time and opportunity for a patent holder to seek available remedies prior the marketing of an allegedly infringing product. As an alternative to such obligations, Peru could instead adopt an extrajudicial system that prevents the approval of the marketing of a product during the term of a patent, based on
patent information filed by the interested parties or based on direct coordination between the health and patent authorities. To date, the CPTPP has not been ratified yet nor brought into domestic law.

**Case law**

To date there is no case law applying those provisions.

**Summary and future developments**

It is recommendable that the website of the Ministry of Health be monitored continuously to be alerted about marketing approval applications that could be infringing a patent holder’s rights.

**Status:** Law stated as of July 2019
Philippines
Introduction

There is currently no patent linkage system in the Philippines. Under Republic Act 8293, or the Intellectual Property Code of the Philippines, it is the Intellectual Property Office of the Philippines (IPO) that is authorized to grant patent protection over inventions, including those in the pharmaceutical field. Under Republic Act 9711, or the Food and Drug Administration Act, it is the Food and Drug Administration (FDA) that regulates the approval and entry of pharmaceutical drugs into the Philippine market. According to FDA Administrative Order No. 2005-0001, a pharmaceutical product may be granted registration by the FDA without regard to the registrant’s patent or trade secrets rights, or its absence from such product. The FDA, however, shall comply with an order issued by a court of law or the IPO enjoining the grant of product registration on the ground that the registrant has no patent or trade secrets rights to the product subject of the registration. A final court or IPO decision stating that the product registrant has no intellectual property rights over the same shall result in the automatic cancellation of the FDA product registration.

The practical implication is that a competitor can acquire a Certificate of Product Registration (CPR), which functions as a marketing and sale authorization, from the FDA provided that it complies with all the requirements of the FDA. An innovator or patent holder cannot prevent a competitor from acquiring a CPR from the FDA by simply informing the FDA that the said competitor is a patent infringer or trade secret violator. The innovator or patent holder must first file a civil, criminal or administrative case of infringement against the competitor and request an injunction against the issuance of the CPR. Filing a case will entail additional costs to be spent by the innovator or patent holder.

Legal regulation

While a CPR is not, per se, patent infringement, it can reasonably be assumed by the innovator or patent holder that the competitor intends to sell the patent-infringing product on the market. As such, considering the lack of patent linkage in the Philippines, the remedies available for innovators or patent holders are largely based on intellectual property rights granted by the Intellectual Property Code of the Philippines. Generally, the following acts constitute patent infringement if done without the authority of the patent holder:

- Making, using, offering for sale, selling, or importing of a patented product or a product obtained directly or indirectly from a patented process
- Use of a patented process

Civil action

Patent holders may seek the following remedies against infringers of their patent rights through the filing of a civil action:

- An injunction against the infringer
- Damages or reasonable royalties
- Attorney’s fees and other expenses of litigation

Also, anyone who actively induces the infringement of a patent or provides the infringer with a component of a patented product or of a product produced because of a patented process, knowing it to be especially adopted for infringing the patented invention and not suitable for substantial non-infringing use, shall be liable as a contributory infringer and shall be jointly and severally liable with the infringer.

A civil action for infringement of patent rights does not apply to instances covered by the limitations of patent rights, use of the invention by the government, compulsory licensing and issuances of a special compulsory license.

Criminal action

Criminal action is available only for repeated patent infringement. If the infringer or anyone in connivance with him/her repeats the infringement after finality of the court judgment against the infringer, the offenders shall, without prejudice to the institution of a civil action for damages, be criminally liable.

Administrative action

Administrative remedies against patent infringement may be sought before the IPO, under the provisions of the IP Code, and the Bureau of Trade Regulation and Consumer Protection of the DTI given its mandate under Executive Order No. 913.

Requirement of notice and prescriptive period to recover damages

Damages cannot be recovered for acts of patent infringement committed before the infringer had known, or had reasonable grounds to know, of the patent.

It is presumed that the infringer had known of the patent if on the patented product, its packaging or its advertising materials, the words “Philippine Patent” are placed with the number of the patent.

No damages can be recovered for acts of patent infringement committed more than four years before the institution of the action for infringement.

Case law

There is no relevant case law.

Summary and future developments

There is no relevant developments to report.

Status: Law stated as of July 2019
Poland
Introduction

The patent linkage concept has not been implemented in Polish law. In particular, Polish patent law does not allow a drug patent owner either to oppose against filing an application for generic drug marketing authorization or oppose against granting such a marketing authorization to a generic drug company. However, Poland has adopted legal concepts emerging from European Union law, such as data and market exclusivity, aimed at strengthening the originator’s position on the market.

Legal regulations

For an overview on EU regulation, see the EU chapter.

Polish pharmaceutical regulations included in the Act of 6 September 2001 – Pharmaceutical Law (PL), similar to European regulations, provides two mechanisms of the originator’s protection, which are independent of patent protection.

The first one, called “data exclusivity,” prohibits a generic drug manufacturer from using and relying on scientific (pre-clinical and clinical) data provided by the originator to the regulatory agency, unless a period of eight years from the date of the first authorization has passed. The above rule does not prohibit a generic company from preparing the pre-clinical and clinical data required for marketing authorization itself. However, in practice, costs related to it are usually extremely high. Therefore, in practice, the patent owner remains exclusively entitled to obtain marketing authorization of the patent-protected medicinal product.

The second, called “market exclusivity,” prohibits the generic drug manufacturer from introducing a generic drug onto the market until 10 (or in some cases, 11) years have passed from the date the initial marketing authorization for the reference (innovative) medicinal product was granted. This provision grants the patent owner full exclusivity in terms of marketing an innovative medicinal product.
Patent law perspective – Bolar Exemption and patent owner’s exclusivity

Polish patent law (Act of 30 June 2000 – Industrial Property Law (IPL)) adopted in full scope the so-called Bolar Exemption. Pursuant to Article 69, section 1, point 4 IPL, a patent is not infringed by using an invention to the extent required to perform activities that, pursuant to the law, are required to obtain registration or a permit, constituting a condition for marketing certain products in view of their purpose, particularly medicinal products.

Although a catalog of activities permitted under the Bolar Exemption is not determined by law, it is commonly agreed that applying for marketing authorization for a generic medicinal product or even obtaining such an authorization falls within this scope. The reason for this standpoint is that the originator’s exclusivity rights are determined by the IPL in Article 66, section 1 IPL. According to this provision, the patent holder’s exclusivity involves either:

(a) making, using, offering, putting on the market or importing for these purposes a product that is the subject-matter of the invention; or

(b) using the process that is the subject-matter of the invention, and also using, offering, putting on the market or importing for these purposes products obtained directly by such process.

Taking the above into consideration, applying for or obtaining a marketing authorization for a generic medicinal product potentially infringing the innovator’s rights is not covered by the patent owner’s exclusivity under Polish patent law. Therefore, there is no reason to consider these actions as violations of patent rights. On the other hand, Article 69, section 5 IPL leaves no doubt that obtaining of a marketing authorization under the Bolar Exemption does not exclude civil liability for introducing products to trade without the required consent of the rights’ holder.

In addition, case law cleared doubts that arose in relation to the manufacturing and selling of small amounts of patented active substances used for obtaining a marketing authorization for a generic medicinal product. In the judgment of 23 October 2013 (case No. IV CSK 92/13), the Supreme Court decided that the Bolar Exemption set forth in Article 69, section 1, point 4 IPL does not cover situations where the patented active substance is delivered to a generic company, which benefits from the Bolar Exemption, by a third party. In such event, selling of the patented active substance by a third party would constitute patent infringement.

From a regulatory perspective, the competent regulatory authority in Poland is not entitled to examine, after receiving a marketing authorization application, whether the medicinal product covered by the application may potentially infringe the originator’s patent rights. A company applying for marketing authorization is not even required to include in the application form any information relating to patent protection of an innovative medicinal product.

Case law

There is no relevant case law.
Summary and future developments

Poland, similar to other EU countries, does not recognize the patent linkage concept in its legal system on the grounds that it would be contrary to European regulatory law and would undermine the Bolar Exemption. Applying for marketing authorization for a generic medicinal product or even obtaining such an authorization would not be recognized as a violation of the originator’s rights. Different to the US or other countries that have adopted the patent linkage concept, the competent authorities responsible for issuing marketing authorizations in Poland are not entitled to examine whether granting such authorization would infringe a third party’s patent rights and the applicant is not required to include any patent-related information in the marketing authorization application.

Instead, Poland and other EU countries adopted the concepts of data and market exclusivity, which are both aimed at supporting innovations and safeguarding the innovator’s interests by providing a form of market exclusivity outside that provided by patent rights.

Taking into account that Poland is a pro-generic country, it is rather unlikely that further linking of patent protection with regulatory proceedings related to generic products will be introduced into the Polish legal system in the not-too-distant future.

Status: Law stated as of July 2019
Russia
Introduction of the patent linkage concept and its importance for protection of IP rights

As of August 2019, the patent linkage concept is still not legally available in Russia. Considering recent initiatives in the enforcement of originators’ patent rights, there are some positive trends towards patent linkage. Academic discussions and certain Russian state authorities, such as the Russian Ministry of Economic Development and the Federal Service for Intellectual Property (“Rospatent”), in general also support the idea of implementing patent linkage by amending Russian legislation on the procedure for registration of (granting marketing authorization for) medicines and maintenance of the corresponding state register of authorized medicines by referring to valid patent(s) protecting inventions for a substance, compound, etc. used in the relevant medicinal product. Further to the draft laws prepared by the Ministry of Healthcare, the Association of International Pharmaceutical Manufacturers (AIPM) and Baker McKenzie being the AIPM’s and originators’ legal advisor are working on guidelines which will hopefully become the basis for future amendments.

Below we comment on the possibility of successful enforcement of patent rights by prohibiting the introduction onto the market of a generic product while the originator’s patent for such product or its part is still valid. Despite the lack of legal provisions directly related to the patent linkage concept and coherent case law, Russian legislation does, to a certain extent, provide legal remedies enabling an originator to enforce its patent rights against a generic product manufacturer applying for a marketing authorization.

Legal regulation

In the absence of straightforward legal regulation of the patent linkage concept, originators may refer to general provisions of the Russian Civil Code (“Civil Code”), which contains legal remedies allowing right holders to enforce their patent rights.

In particular, the Civil Code provides a patent owner with the option to file a claim to cease any activities that infringe or create a threat of infringement of intellectual property rights (“IPRs”). Such a claim may be filed against a person or entity that is:

(a) Carrying out infringing activities (e.g., offering for sale through public tenders, producing, storing or distributing a generic medicine).

(b) Making necessary preparations to carry out such activities, thus creating a threat of infringement (e.g., obtaining marketing authorization and registering the maximum sales price of an essential medicine).

From a legal perspective, an originator may potentially claim that obtaining a marketing authorization for a generic product and registration of its price (for medicines on the Essential Medicines List) constitute a threat of infringement of the originator’s patent rights, provided that the relevant patent is used in the generic product. According to the most recent case law, Russian courts tend to grant originators’ claims and may oblige a generic company to file an application to cancel a marketing authorization for a generic product and registration of its price with the Ministry of Healthcare.

Documental evidence is a very important issue as Russian legislation does not provide for a discovery procedure as is available in jurisdictions with case law, such as the US and UK. For example, there are several court rulings where intentions have been recognized by courts as insufficient grounds for patent infringement due to the weak documental evidence collected and provided.
Below we briefly describe recent case law in which an originator argued that obtaining a marketing authorization should be regarded as a threat of infringement, and thus should be prohibited until the patent has expired.

**Case law**

To date, there are only a few cases where originators tried to enforce their rights at the stage of generic companies obtaining marketing authorizations. Relevant case law is still ambiguous and is not extensive but we see and are assisting with its development in patent disputes.

One of the first cases where the originator made an effort to prevent the distribution of generic medicines at the stage of obtaining of a marketing authorization was considered by the High Arbitrazh Court 10 years ago in 2009.

Considering the law which was in force back in 2009, the court stated that carrying out actions aimed at obtaining the marketing authorization cannot be viewed as use of a patent as such actions are preparatory in nature and therefore could not be considered infringing.

Further to the above judgement, in some cases, courts still tend to reject claims based on infringement or threat of infringement arising in connection with obtaining a marketing authorization.

However, in several very recent cases courts recognized that obtaining a marketing authorization could be considered a threat of infringement in some circumstances based on sufficient evidence of use intentions prior to the expiry of a patent.

In a 2017 case, the plaintiff claimed that the defendant infringed its patent by obtaining approval to carry out clinical trials on the bioequivalence of original and generic medicines and registration of the pharmaceutical substance.

Following the position of the High Arbitrazh Court adopted in 2009, the court of first instance rejected the claim. Although it initially appealed this judgment, the plaintiff then withdrew the claim, which legally means that the courts did not adopt a definite position which could be taken into account in further cases.

In another recent case, the plaintiff claimed that the defendant infringed its patent which covers an original medicine. In support of its position, the plaintiff referred to the fact that a generic medicine registered by the defendant with the Russian Ministry of Healthcare ("Ministry of Healthcare") is covered by the originator’s patent. The plaintiff requested the court to:

- Stop the defendant’s activities that create a threat of infringement of the plaintiff’s patent rights, by compelling the defendant to apply to the Ministry of Healthcare to suspend the registration of the generic product until the expiry of the patent.
- Compel the defendant not to introduce the generic medicine onto the Russian market until the expiry of the patent.

The court of first instance, supported by the appeal court, granted the second claim, but rejected the first one. This court judgment is a step forward in favor of patent owners enforcing their patent rights against patent infringers at the stage of obtaining a marketing authorization.

From an enforcement perspective, the position of the court cannot be considered 100% effective since the registration of the generic medicine is still valid. This means that, in practice, it would be difficult to prevent the introduction of a generic medicine to the Russian market.
Thus, despite the fact that the decision was adopted in favor of the originator, it is not a sufficient guarantee against infringement since the generic registration remains valid.

Despite its shortcomings, this case shows a positive trend towards the patent linkage concept, and a further goal of originators is to explore the option of changing the existing case law with a view of creating a mechanism that would allow them to challenge generic medicines at a very early stage, i.e., at the stage of obtaining a marketing authorization and price registration (for medicines on the Essential Medicines List) and preventing sales of generic medicine in public procurement tenders and the like during the validity of a patent.

However, the positive trend described above should not be overestimated and requires further monitoring and legal analysis. In one of the patent dispute cases considered in mid-2018, a court of first instance rejected an originator’s patent infringement claim brought against a major generic company. In rejecting the claim, the court stated that the generic company was using its own patent, which had not been invalidated by the originator. An appeal court upheld this decision and confirmed that there were no grounds for conducting a patent expert examination. The decisions of the lower courts were cancelled by the intellectual property court, so the case is still ongoing. In addition, the generic company filed a counterclaim to obtain a compulsory license, stating that the patent owned by the generic company is dependent.

In another recently considered case, a court followed the same position and rejected an originator’s claim, stating that a generic company was using its own patent.

However, in 2019, two major originators managed to convince Russian courts that obtaining marketing authorization and price registration shall be considered as a threat of infringement. The court obliged generic companies to file a request with the Ministry of Healthcare to cancel marketing authorization and/or price registration of a generic medicine. These decisions show that the case law in the field of protecting originator’s rights may be reconsidered in the near future.

Considering the above, there is no doubt that obtaining a marketing authorization for a generic medicine is still not viewed as an infringement per se. At the same time, this does not mean that obtaining a marketing authorization, which is one of the main initial steps aimed at the introduction of a medicine to the market, could not be considered a threat of infringement and hence could be prohibited through the court.

Sometimes generic companies are trying to obtain patents for so-called “dependent” inventions, to be further used in claims for compulsory licenses in courts. This approach was applied by a generic company in 2018 when courts of the first and appeal instances ruled to grant a compulsory non-exclusive license for a Russian patent. As a defense, the patentee successfully challenged the subject generic’s patent at the Chamber for Patent Disputes. As a result, the parties entered into a settlement which was approved by the court at the end of 2018. According to the settlement, the generic company does not have any claims to obtain a compulsory license for the patent owned by the originator. Despite its outcome, this case shows that compulsory licenses should be considered a real risk to originators’ medicines business.

**Conditions for applying the patent linkage concept and exceptions to it**

**Pharmaceutical regulation applicable in Russia**

There are no clear-cut and exhaustive criteria as to which actions may constitute a threat of infringement. From a practical perspective, to date, proving the threat of infringement is the only option that originators may realistically rely upon when challenging a generic marketing authorization and price registration for the purposes of effectively preventing generic medicines from being distributed. Obtaining marketing authorization and price registration should fall within the concept of “threat of infringement,” provided that originators are able to come up with persuasive evidence that obtaining a marketing authorization and
registering the price should be considered a preparatory stage for selling the generic medicine and hence, per se, creates a threat of infringement.

The current Law on the Circulation of Medicines ("Law") could be used to substantiate the threat of infringement claim. The Law provides that a marketing authorization for new medicines is issued for five years and must be confirmed after the expiry of this term. Further, the current law provides that the marketing authorization is cancelled if a medicine is not present on the Russian market for a period of three or more years, which means that the marketing authorization is directly aimed at introducing medicines onto the Russian market and that it will be cancelled if the medicines are not actually put on the market within the prescribed time. This should entail reconsideration of the "threat of infringement" concept in the field of enforcement of pharma patents, as obtaining a marketing authorization for a generic medicine should be interpreted as preparatory measures creating such threat, provided that a patent expires three or more years after the date of obtaining such marketing authorization.

In addition, according to the Law, the registration certificate of a medicine should be cancelled if a court adopts a decision stating that the turnover of such medicine infringes the intellectual property rights of a third party, i.e., a patent owner. Consequently, if a generic medicine has already been introduced to the Russian market, originators may try to obtain a court decision confirming infringement of their patent rights by the distribution of such medicine. Having obtained the relevant court decision, an originator may refer to the Ministry of Healthcare to cancel the registration certificate of the infringing medicine.

As Russia is a member of the Eurasian Economic Union (EAEU) and should comply with EAEU regional legislation, in addition to the national registration procedure, a marketing authorization in Russia may be obtained on the basis of the rules for registration and examination of medicines for medical use adopted by Decision of the Eurasian Economic Commission No. 78 ("EAEU Rules"), which entered into force in May 2017.

The EAEU Rules stipulate that an application for a marketing authorization must include information on patents covering the medicine concerned. Moreover, along with the application, an applicant must file a statement that the medicine does not infringe the intellectual property rights of third parties. If a generic medicine filed for registration infringes an originator’s patent, such statement is false. Theoretically, this may be considered the "provision of inaccurate information," which is one of the grounds for refusing registration or re-registration according to the EAEU Rules.

There are no doubts that there is some inconsistency between the Federal Law “On the Circulation of Medicines” (national system) and the EAEU Rules (regional system) in terms of the medicine registration procedure.

Currently, it is possible to choose either the regional or national system of registration, but starting from 2021 the national procedure will no longer be available and all national marketing authorizations must be re-registered according to the EAEU Rules.

Considering the above, the EAEU Rules and the Law need to be harmonized as one of the purposes of the EAEU Treaty is to form a single market of medicines within all EAEU members. To bring Russian laws on medicine circulation into line with the supranational regulation of the EAEU, it is necessary to make amendments to the Federal Law “On the Circulation of Medicines.” The relevant amendments have already been proposed by the Ministry of Healthcare, which prepared a draft law amending current legislation. Under the draft, an application for a marketing authorization would have to include both (i) information on the patents and trademarks protecting a medicine and (ii) a non-infringement statement. In addition, if an applicant is authorized to use a patent covering a medicine, it would have to provide a copy of the relevant license agreement. The amendments proposed by the Ministry of Healthcare are aimed at creation of a
register reflecting information on patents and the medicines covered by such patents. The information from such register could be used by originators as an additional argument in patent infringement cases.

But most importantly, the draft law described above is a huge step forward, as it implements a number of elements of the patent linkage concept in Russia. In addition to the creation of a patent-medicine registry, the amendments to the Federal Law “On the Circulation of Medicines” also change the current procedure for registration of medicines so that generic companies would obtain a marketing authorization with a delayed effective date based on the information contained in the patent-medicine registry.

Currently, the draft is under public discussion and has not yet been considered by the State Duma of the Russian Federation, but this is a huge step towards implementing patent linkage in Russia and harmonization with EAEU legislation.

Thus, we hope that, in the near future, the patent linkage concept will be implemented in Russia both by national legislation and supranational EAEU Rules.

**Competition law**

As an additional measure to enforce patent rights, originators may try using competition law. A generic company may be held liable for unfair competition (specifically, for unfair use of an originator’s patent when applying for a public tender) if:

(a) A generic medicine infringes an originator’s patent, which is confirmed by a court and/or expert’s report.

(b) A generic company participates in public tenders.

In addition to the administrative sanctions to be imposed on a generic company for unfair competition, the anti-monopoly authorities may add a generic company to the list of unfair suppliers (the so-called “black list”), thus restricting such company’s ability to participate in tenders.

**Summary and future developments**

Notwithstanding the lack of efficient legal provisions and consistent case law on patent linkage, there is a positive trend towards implementation of this tool in Russia.

Based on the case law described above and recent trends, there are arguments based on civil law and pharmaceutical regulation that may increase the possibility of successful enforcement of patent rights by originators. To strengthen the position, a patent owner may rely on the following:

(a) The active substance of the generic medicine filed for marketing authorization is covered by the patent

(b) The initiation of the procedure for obtaining marketing authorization for the generic medicine when there are more than three years before the expiry of the patent creates a threat of infringement since:

(i) The procedure for obtaining confirmation of the marketing authorization implies that the medication will be in commercial circulation in Russia and if the medication has not been in the circulation for three years or more the marketing authorization should be cancelled.

(ii) Taking into account that the marketing authorization needs to be confirmed in five years and should be subject to cancellation if there had been a three-year absence from the circulation in Russia, the actions of generic companies of obtaining the authorization when
there are more than five years before the expiry of the patent can be viewed as an indication of its preparation for market entry in the near future.

(c) Besides filing for a marketing authorization, a generic company undertook additional registration procedures which may be necessary to introduce a generic medicine to the Russian market (for example, registered the maximum sale price of a medicine on the Essential Medicines List), which could also show that there is a threat of infringement of an originator’s patent rights.

As a general comment, Russia has taken some initial steps towards the patent linkage concept, which is currently being discussed by academics, business associations and state authorities. AIPM and Baker McKenzie favor the implementation of the patent linkage tool in Russian legislation and hope that this will enable originators to effectively prevent infringements of their patent rights in the near future to help avoiding expensive and time-consuming litigation for both originators and generic companies.

Status: **Law stated as of September 2019**
Singapore
Introduction

The US-Singapore Free Trade Agreement ("US-Singapore FTA") introduced patent linkage as one of the requirements for applying for marketing approval. Patent linkage helps the drug patent owner in policing potential infringement even before generic drugs are launched. The patent linkage provisions provide for a framework to warn the patent owner of a competitor’s application to market the same patented drug.

Legal regulation

Pursuant to Singapore’s obligations under the US-Singapore FTA, the patent linkage scheme has been introduced to assist drug patent owners in policing potential infringement of their patents prior to the launch of generic drugs.

In Singapore, the Health Sciences Authority (HSA) administers regulatory control of therapeutic products. As the authority under the Health Products Act (HPA), the HPA empowers the HSA to register health products, and to grant, renew, vary, suspend and revoke licenses. Under the HPA, all therapeutic products must be registered before they can be supplied in Singapore.

In this regard, the applicant for registration of a therapeutic product needs to declare whether a patent is in force in respect of any therapeutic product to which the application relates. Where the therapeutic product in question is covered by a patent, the application may fall under any of the following categories:

(a) Category A1: where the applicant is the proprietor of the patent, or where the applicant has procured the consent or acquiescence from the proprietor of the patent.

(b) Category A2: where the applicant seeks the grant of registration upon the expiry of the patent (this application should not be made earlier than 18 months before the expiry of the patent).

(c) Category B: where the applicant believes that the patent is invalid or that the drug will not be infringing on the patent in force.

For Category B applications, the HSA will require a notification to be sent to the patent holder ("Notice") to give them the opportunity to take action against the applicant.

If the HSA is satisfied that the Notice has been served on the proprietor of the patent, the HSA may register the therapeutic product if the proprietor does not, within 45 days of the service of the Notice either:

(a) Apply to -

   (i) A court for an order restraining the act for which the registration of the therapeutic product is sought ("Order").
A court or the Registrar of Patents or a Deputy Registrar of Patents holding office under the Patents Act, for a declaration that the patent is valid or will be infringed by the doing of the act for which the registration of the therapeutic product is sought ("Declaration").

(b) Give written notice to the HSA stating that the application for the Order or Declaration has been made, accompanied by evidence of the application.

The HSA may register the therapeutic product without further notice to the proprietor of the patent if no Order or Declaration has been made at the end of 30 months after the date of the application for the Order or Declaration.

A person who makes a false declaration shall be liable on conviction to a fine ≤ SGD 20,000 and/or imprisonment for a term ≤ 12 months.

Case law

Novartis AG and Another v. Ranbaxy (Malaysia) Sdn. Bhd. [2013] 2 SLR 117

The plaintiff was the proprietor of a Singapore patent and the defendant sought to import a pharmaceutical product which related to the plaintiff’s patent. Under the Singapore Medicines Act (which governed pharmaceutical products at the time), the defendant had a duty to inform the plaintiff of their applications for import licenses.

On receiving the information, the plaintiff commenced an action to declare that the import licenses, if granted, and the products imported and marketed in Singapore, would infringe their patent. The defendant counterclaimed that the patent was invalid as it had been anticipated by the prior art. Subsequently, the plaintiff took out an application to amend its patent claims to further distinguish the claims in the patent from the prior art cited by the defendant. The High Court held that the plaintiff’s intended amendments would not result in the specification disclosing any additional matter.

The High Court also held that a patentee must act without undue delay in applying to amend the patent claims upon discovering the relevant prior art. In this regard, the High Court recognized that mere delay is not, in itself, necessarily sufficient to justify the refusal of amendment, and there must have been or be likely to be some detriment to the respondents or to the general public caused by such delay before it can be an effective bar to relief.

AstraZeneca AB v. Sanofi-Aventis Singapore Pte Ltd. [2013] SGHCR 7

Sanofi-Aventis had applied for a product license with the HSA. As part of the application process, Sanofi-Aventis was required to inform AstraZeneca, as the patent holder, that it had applied for a product license and that, to the best of its knowledge, the patent had not been infringed or was invalid.

AstraZeneca alleged that Sanofi-Aventis infringed its patent and therefore a 30-month stay in the application process was set in place. AstraZeneca also demanded that Sanofi-Aventis provide details of its product so that AstraZeneca could determine whether or not its patent was indeed infringed by Sanofi-Aventis. Sanofi-Aventis proceeded to provide details on the High Court’s request. In return, Sanofi-Aventis requested that AstraZeneca provide further and better particulars of how its product infringed the patent.

While the High Court disagreed with some of Sanofi-Aventis’ requests, it partially allowed Sanofi-Aventis’ request for the particulars of infringement. The High Court recognized that the 30-month stay period on the application process, while intended to encourage settlement of patent infringement claims before the allegedly infringing product entered the market, could be misused to delay the manufacture, importation
and sale of pharmaceutical products by competitors of the patent holder and could therefore have the effect of hindering public access to competitors’ products.

Hence, the High Court concluded that where a claim had serious consequences to the public and to a competitor’s legitimate business, as a matter of good practice, the patent holder should be required to give proper particulars of its claim to save a considerable amount of time, energy and expense.

**Summary and future developments**

The patent linkage scheme provides a useful mechanism which alerts patent holders of threats of infringement, and which enables patent holders to obtain a 30-month stay of approval of any product license upon applying for the necessary Order or Declaration.

Nevertheless, patent holders which commence legal action face the risk of counterclaims challenging the validity of the patent in question. In this regard, the onus remains on patent holders to take the earliest opportunity to amend their patent claims without undue delay upon discovering relevant prior art, as the court may otherwise deny the patent owner leave to amend the patent. As a matter of prudence, patent owners should also ensure that their proposed amendments do not extend the scope of protection of the patent.

Patent holders should be further mindful that failure to provide the necessary particulars of their claim may derail their action for infringement. In this regard, the court has cautioned that the 30-month stay period should not be misused to delay the business activities of competitors of the patent holder and impede the public’s access to competitors’ products.

The mandatory Notice therefore marks the first step in a series of many, given that patent holders will still have to prove their infringement claims.

**Status:** Law stated as of July 2019
Switzerland
Introduction

To date, the patent linkage concept does not exist in Switzerland and is not intended to be introduced in the near future either. Until 2008, Swiss courts have inconsistently handled the application for market authorization prior to the expiry of the patent for the original pharmaceutical with regard to a violation of the patent owners’ rights. However, since 2008, it is stated in Article 9, para. 1, lit. c of the Federal Act on Patents for Inventions ("PatA") that applying for a market authorization for a generic pharmaceutical (and all acts that are necessary to fulfill the requirements of the application), prior to the expiry of the patent for the original pharmaceutical, does not infringe the respective patent rights.

Legal regulation

The inventor of a pharmaceutical product can rely on the PatA to protect his/her exclusive rights. Pursuant to Article 14 PatA, the patented invention is protected for 20 years. During this period, the right holder may prohibit others from commercially using the invention. Commercial use means, pursuant to Article 8 PatA, manufacturing, storage, offering, placing on the market, importing, exporting and carrying in transit, as well as possession for any of these purposes. Furthermore, the right holder can apply for a supplementary protection certificate, which grants the same rights and remedies as the patent and thereby enables the right holder to extend the patent-protected period. The duration of the supplementary protection certificate corresponds to the time between the filing of the patent application and the granting of market authorization, but is limited to five years maximum.

In the absence of legal provisions related to the patent linkage concept, there is no linkage between the patent and the application for market authorization. Neither applying for nor obtaining market authorization for a generic pharmaceutical is considered an infringement of the patent owners’ rights. Hence, the application for market authorization can be filed and edited prior to the expiry of the patent.

What needs to be taken into account is the Federal Act on Medicinal Products and Medical Devices ("TPA") which provides further protection for the inventor of the original pharmaceutical by stipulating data exclusivity. This data exclusivity protects the findings made during the pharmaceutical, toxicological and clinical tests. The protection period of the data is specified in Article 12 para. 2 TPA and Article 17 of the Ordinance on Medicinal Products ("VAM") and amounts to 10 years for new pharmaceuticals. If a new indication, a new route of application, a new pharmaceutical form or a new dosage has been approved for the original preparation, the data protection period for this pharmaceutical is limited to 3–5 years, Article 17, para. 2 VAM. The high relevance of the data exclusivity arises from Article 12, para. 1 TPA and the fact that the application for market authorization for a generic pharmaceutical can, pursuant to this article, be based on the pharmaceutical, toxicological and clinical tests of the original pharmaceutical. However, only under the provision that either the applicant for the original preparation provides written permission or the data exclusivity for the original pharmaceutical has expired. During this maximum 10 years protection period, Swissmedic, the relevant authority, does not even edit the application. Hence, until the expiry of data...
exclusivity, the applicant of a generic pharmaceutical needs to wait for the application to be processed before he/she is able to receive his/her market authorization.

If both of the findings above are considered in context, there is, in the absence of a patent linkage concept, still a situation imaginable in which similar effects as those under the concept of patent linkage are observable, as, on the one hand, we have a protected period of 25 years due to the patent as well as the supplementary protection certificate. However, the application for market authorization for a generic pharmaceutical can be filed during this time. On the other hand, there are several years of research before the original product is authorized on the market, followed by a 10-year data exclusivity period during which the application for the generic pharmaceutical will not be edited by Swissmedic. This means that if the research prior to the market authorization takes 15 years or longer, the market authorization for the generic product cannot be applied for or the application will, at least, not be edited, even though the patent has already expired. Only after the data exclusivity has expired as well will the application be verified. This results in a protection period which could exceed the patent-protected time.

**Case law**

Although Switzerland is not a common law jurisdiction, past decisions of the courts will, of course, be taken into account in future decisions and thereby have a great impact. Therefore, there are three decisions looked at in more detail listed below.

The first two decisions deal with the definition of the term "original preparation." The definition of the term "original preparation" is of high importance with respect to the data protection period, the duration of which depends on whether a pharmaceutical is an original preparation or just a new indication, a new method of administration, a new pharmaceutical form or a new dosage. The term "original preparation" is not defined in the TPA.

In its decision dated 7 November 2007 (C-2263/2006), the Swiss Federal Administrative Court dealt with the question of whether a combination of two chemical substances could be considered an original preparation in itself, or whether it is only a further development of the initial original preparations. The court held that combinations of two substances cannot be considered as original preparations and, therefore, do not trigger a 10-year data protection period. However, they may profit from a 3–5 year protection under the TPA.

Less than two years later, on 6 May 2009, the Swiss Federal Administrative Court (C-7020/2007) held that the pharmaceutical must contain a new chemical substance to fall under the definition of an original preparation. It follows that for each active or chemical substance there is only one original preparation which can benefit from the 10-year data protection period. Therefore, an original preparation is only a preparation with an active substance approved for the first time in the regulatory framework of Switzerland.

The third decision is of the Swiss Federal Supreme Court of 9 January 2015 (BGE 141 II 91) and deals with the combination of substances. In this decision, the court found that marketing authorization for a generic product cannot be granted if such product can only be used in combination with a pharmaceutical for which the 10-year data protection period is still running. This is especially interesting because the generic product does not even have to be similar to the original preparation, but the inventor of the generic still gets deterred from the application process during the data protection period of the original preparation.
Summary and future developments

In sum, there is no patent linkage concept in Switzerland. The original pharmaceutical is patent-protected for 25 years maximum, and the generated data from pharmaceutical, toxicological and clinical tests is protected for 10 years. Only if the time between granting of the patent and the market authorization for the original pharmaceutical amounts to 15 years or more, the inventor of the original pharmaceutical profits from protection which outlasts the patent protection, therefore delaying the market authorization of the generic product.

Status: Law stated as of July 2019
Taiwan
Introduction

To join the Trans-Pacific Partnership (TPP) Agreement and the Trade and Investment Framework Agreement (TIFA), the Taiwan Food and Drug Administration (TFDA) proposed an amendment to the Pharmaceutical Affairs Act (PAA) in compliance with the TPP Agreement. The amendment was passed on 29 December 2017 and has been implemented from 20 August 2019.

Legal regulation

In the PAA Amendment, Chapter 4-1 “Drug Patent-Approval Linkage” is newly added to establish the patent linkage system. These newly added articles contemplate patent listings, patent declarations certified by an applicant filing an Abbreviated New Drug Application (ANDA), notification of the ANDA filing by the ANDA applicant to the New Drug Application (NDA) holder, stay of issuing market approval for the generics by the TFDA, and the marketing exclusivity provision conferred to the first ANDA applicant who successfully defends a patent infringement suit.

1. Patent Listing

An NDA holder must list patents and claims that cover the drug within 45 days of issuance of the NDA market approval. The listed drug patent is limited to the patent that claims (1) substance, (2) composition or formulation, or (3) method of use. Listed patent information includes the patent number, patent expiry date, patentee, exclusive licensee, etc. In particular, the NDA applicant should specify claims relating to the drug while the listed patent claims a method of use.

(i) Argument against the patent listing

A third party who alleges that the listed patent information is incorrect or irrelevant to the drug can notify the TFDA with a written explanation and evidence attached. The TFDA will notify the NDA holder of the third party’s notification and relevant documents within 20 days of receipt of the notification. The NDA holder shall respond with a written explanation and optionally request to amend or cancel the listed patent information.
(ii) Patent declaration for ANDA

The ANDA applicant shall select the following item(s) as a declaration for the patent(s) listed by the NDA holder: (i) No patent information has been listed for the new drug; (ii) the patent corresponding to the new drug has extinguished; (iii) the TFDA will issue the generic market approval after the extinguishment of the patent(s) corresponding to the new drug; or (iv) the patent corresponding to the new drug should be revoked or will not be infringed by the generic drug for which market approval is sought.

(iii) After completing the examination, the TFDA issues the market approval if paragraphs (i) and (ii) are declared, and the TFDA will issue the market approval at the time of expiration of the patent if paragraph (iii) is declared.

(iv) Challenge based on Paragraph IV, Litigation and Stay

When paragraph (iv) is declared, the ANDA applicant shall notify the NDA holder and the TFDA with a written notification within 20 days of receipt of official acknowledgement notice that all ANDA required documents have been submitted. Upon receipt of the notification, the NDA holder, patentee or patent exclusive licensee can file a patent infringement suit within 45 days and notify the TFDA.

The TFDA shall stay the issuance of the market approval within 15 months after receipt of the ANDA applicant’s notification to the NDA holder. However, the stay is lifted and the market approval can be issued when: (1) the NDA holder, patentee or patent exclusive licensee does not file a patent infringement suit within 45 days; (2) the NDA holder, patentee or patent exclusive licensee does not file a patent infringement suit based on the patent listing of the drug; (3) the court decides that the patent is revoked or the ANDA applicant does not infringe the patent; (4) the Intellectual Property Office makes an invalidation decision regarding the patent; (5) the two parties settle; (6) the patent expires.

2. Marketing exclusivity

The first ANDA holder who successfully challenges based on paragraph (vi) is granted a 12-month period of marketing exclusivity.

3. Settlement or agreement between NDA and ANDA holders

The TFDA should be notified of any settlement or any agreement on the arrangement of the patent linkage-related drug, including manufacture, sale and duration of market exclusivity between the NDA applicant/holder and the ANDA applicant/holder. The TFDA shall notify the Taiwan Fair Trade Commission (TFTC) if necessary.

4. Penalty

Parties who fail to notify the TFDA of the settlement/agreement shall be subject to certain administrative penalties. The NDA holder who reports the patent listing by fraud or false information shall bear criminal responsibility.
Data exclusivity

For a drug containing a new active ingredient, the NDA holder has five-year data exclusivity. A generic pharmaceutical can be submitted for application, relying on the NDA holder’s data after three years upon the issuance of NDA market approval, but the market approval for the generic pharmaceutical’s application can only be issued after expiration of the five-year data exclusivity period.

Similarly, for a drug with a new indication, the NDA holder has three-year data exclusivity. A generic pharmaceutical can be submitted for application, relying on the data after two years, but can only obtain market approval after expiration of the three-year data exclusivity period. It should be noted that if the NDA holder’s clinical trial for the drug with the new indication is conducted domestically, an additional two-year data exclusivity term is granted to the NDA holder.

Case law

There is no relevant case law.

Summary and future developments

The enforcement rules for the patent linkage system (“Rule”) was published by the TFDA at the beginning of 2019. The Rule provides details on how the patent linkage shall be implemented; here we especially address two issues:

(I) As described, the listed drug patent is limited to the patent that claims (1) substance, (2) composition or formulation, or (3) method of use. In the Rule, the substance is defined as an active ingredient and the patents claiming different polymorphs of the active ingredient are eligible for listing. Further, the polymorph includes different crystalline, amorphous, hydrated and solvated forms of the active ingredient.

(II) New therapeutic compounds, new method of administration and biosimilar products are eligible for the patent linkage system.

The Patent Linkage has taken effect from 20 August 2019 in Taiwan. For the NDA holder whose drug permit was issued before the Patent Linkage system was implemented, the patent information must be submitted within three months from the effective date of the PAA Amendment, namely by 20 November 2019. If the NDA holder fails to submit the patent information within the above statutory period, the provisions about Patent Linkage will not apply.

Status: Law stated as of September 2019
Thailand
Introduction

The concept of patent linkage has not yet been enacted in Thailand. Something similar is set forth in the Notification re: ASEAN Harmonization Product on Pharmaceutical Registration of the Thai Food and Drug Administration (FDA), which was implemented in 2009 to regulate the registration of new drugs in Thailand. This notification requires applicants seeking registration of new drugs to provide, among other things, a declaration of patent information (if applicable) when submitting an application. According to the FDA, the term “new drugs” has a broad meaning for the purposes of this notification, encompassing new chemical entities, new indications, new combinations, new delivery systems, new routes of administration, new dosage forms and new strengths.

Recent initiatives of relevant government agencies indicate positive trends towards patent linkage in Thailand. First and most significantly, the existing Drug Act is currently being amended to require that all applications for registration of new drugs include patent information (if applicable). A public hearing on the draft Drug Bill was completed on 31 March 2018, the results of which are undergoing administrative review before they are submitted to the Council of State for further consideration. Additionally, the Department of Intellectual Property (DIP) seems to be amending the current Patent Act so as to comport with the eventual implementation of patent linkage concepts in Thailand. Finally, there are indications that the FDA and the DIP plan to coordinate to establish a link between their respective databases at some point in the future.

In any discussion of patent linkage in Thailand it is worth noting that, in 1993, new drugs that had been patented overseas between 1986 and 1991 and subsequently sold in Thailand were subject to a Safety Monitoring Program (SMP) for a minimum of two years. Drugs registered under the SMP received market exclusivity during the monitoring period, meaning that no generic drugs could be launched nor any bio-equivalence conducted. The SMP was unceremoniously cancelled in 1999 and SMP market exclusivity is no longer available. No replacement program was ever made available.

Legal regulation

In the absence of effective regulation governing patent linkage, the patent owner of an original drug may, as appropriate, rely on one or more of the grounds below to take action against a patent infringer.
Patent infringement

The Patent Act allows a patent owner to take criminal and/or civil action against an infringer who makes, uses, sells, offers for sale, or imports patented products into Thailand without the permission of the patent owner. The maximum penalty for patent infringement is a term of imprisonment not exceeding two years and/or a fine up to THB 400,000 (approx. USD 12,121).

Tort and bad faith

The Civil and Commercial Code (CCC) prohibits anyone from exercising his/her rights in bad faith so as to cause damage to any person. The manufacture, use, sale, offering for sale, or import of patented products falls under general tort provisions of the CCC. Such action may reflect an intention of bad faith by the infringer to gain commercial benefit and damage the patent owner’s reputation.

Trade secret

Thailand does not yet have a specific law covering data exclusivity protection. However, similar protection is afforded through trade secret law, which allows an applicant who submits a drug registration to submit a corresponding request that the FDA keep its registration information (e.g., clinical data) secret. If the confidentiality request is approved, the FDA will be obligated to keep the relevant information confidential for five years from the approval date.

This provision is of limited use, as it does not prevent the FDA itself from referring to and relying upon an originator’s registration data when considering subsequent generic applications.

In a civil action, the patent owner may request that (a) the court award compensation for damages and/or (b) issue a permanent injunction to stop the infringing activities.

Case law

To date, there are not many Thai Supreme Court cases concerning patent matters. In May 2018, a Supreme Court decision was issued regarding the revocation of Novartis AG’s patent for a tablet drug containing the active ingredient “Valsartan” based on obviousness. Valsartan is used to treat high blood pressure and congestive heart failure and to stabilize patients after heart attacks. Given that this decision is recent, the full text has yet to be published online at the time of this writing.

Summary and future developments

Despite the current lack of efficient legal provisions on patent linkage in Thailand, there are positive trends towards implementation of such legislation. Patent linkage, as a concept, is supported by the FDA and the DIP as a means to more efficiently register new drugs and to minimize the possibility of patent infringement of such drugs.

The draft amendments to relevant legislation and updates to relevant procedures are still in early stages and thus subject to significant change. However, progress seems to be forthcoming and it is hoped that the eventual implementation of patent linkage in Thailand will improve patent ownership in Thailand.

Status: Law stated as of July 2019
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Introduction

In a Ukrainian law context, the patent linkage concept means linking a generic drug marketing authorization (MA) with the originator drug’s patent status and it involves refusing a generic MA until the relevant originator’s patent expires. Cancellation of an MA of a generic pharmaceutical product proves to be a more effective remedy against patent infringements than just claims for termination of patent infringements every time they are revealed on the market. If an MA cancellation remedy is unavailable, patent owners will have to file patent infringement actions each time they discover an infringement.

In Ukraine, obtaining an MA for a generic drug prior to the expiration of the originator’s drug patent may be considered a violation of the patent owner’s rights, according to Article 9 of the Ukrainian Law On Medicines. However, mere applications for an MA for generic drugs are usually not automatically declined by the Ministry of Health of Ukraine, which grants MAs (MOH).

The reason for this is that the MOH does not have something similar to the US Orange Book and does not check whether an application for an MA of a generic pharmaceutical refers to the respective original pharmaceutical patent granted in Ukraine. A generic applicant has to file a guarantee within the MA application stating that patent rights of any third parties are not infringed by the generic product applied thereby for state registration. However, not all generic applicants act in good faith. An MA application for a generic product may be rejected by the MOH if such product infringes patents through its manufacturing, use, sale, etc. Yet, in practice, infringing MAs for generic products are often granted by the MOH, and patent owners have to file patent infringement actions each time they reveal the respective MA for the infringing product, along with a request to cancel the respective MA. The local court may also cancel the MA for a generic product if a patent infringement is proven.

Legal regulation

Ukrainian legislation introduces a procedure similar to patent linkage that can be deduced from the legal framework.

According to Article 9 of the Ukrainian Law On Medicines, an MA can be cancelled if such MA results in a violation of valid patent rights, including by way of production, use and sale of such a pharmaceutical product. This subsequently means that patent infringement is also a basis for cancellation of a respective MA.
**Proving patent infringement**

Part 2 of Article 28 of the Ukrainian Law On the Protection of Rights to Inventions and Utility Models stipulates that any product, the production process of which is protected by a patent for an invention, in the absence of evidence to the contrary, is considered to be manufactured using the patented invention, provided that at least one of the two requirements is met:

(a) The product, which was made using the process protected by the patent, is new; there are reasons to believe that the specified product is manufactured using this process.

(b) The patent holder is not able to determine by a reasonable effort the process which was used in the manufacturing of this product.

In such case, the requirement to prove that the process of manufacturing of a product is identical to the product manufactured using a process protected by a patent, or that it differs from the latter, lies with the person of whom there are reasonable grounds to believe that it violates the rights of the patent holder, as follows from *H. Lundbeck A/S v. Tripharma İlaç Sanayi Ve Ticaret A.Ş.*, decided by the High Commercial Court of Ukraine.

Consequently, any of the listed actions constitute use of a patented invention and patent infringement, with the following exemptions:

- Use of a patented invention (utility model) in the design or operation of a foreign vehicle that is temporarily or accidentally in the waters, airspace or in the territory of Ukraine, provided that the invention (utility model) is used exclusively for the purposes of the indicated vehicle
- Use of a patented invention (utility model) without a commercial purpose
- Use of a patented invention (utility model) for scientific or experimental purposes
- Use of a patented invention (utility model) in extraordinary circumstances (natural disaster, catastrophe, epidemic, etc.) provided that the owner of the patent is promptly notified and is paid appropriate compensation

**Enforcement**

According to Part 5 of Article 28 of the Ukrainian Law On the Protection of Rights to Inventions and Utility Models, a patent grants its owner an exclusive right to prohibit other persons from using the patented invention (utility model) without his/her permission, except for the cases when such use does not constitute patent infringement.

Article 34 of the Ukrainian Law On the Protection of Rights to Inventions and Utility Models stipulates that, at the request of a patent owner, any patent infringement should be ceased, and the infringer is obliged to compensate damages to the patent owner.

Therefore, based on Ukrainian legislation, manufacturing and selling of generic drugs prior to the expiration of the originator drug’s patent may be considered patent infringement.

However, whether an application for an MA in itself is violation of a patent is not clearly defined in the legislation of Ukraine and is the subject of diverse court practice. An application for an MA does not yet prove that the respective generic drugs are entered into commercial circulation in Ukraine, however, it may constitute preparation for such actions and the respective patent rights violation.
The obvious precondition for applying a patent linkage concept is the existence of a valid originator’s drug patent in Ukraine. However, in practice, a valid patent is not in itself a guarantee for refusing an MA for a respective generic drug by the MOH. In Ukraine, the patent linkage mechanism is not clearly implemented within the process of registration of MAs for pharmaceuticals, and patent owners have to monitor the situation with generic drugs filings for MAs and file patent infringement actions against generic drug applicants, as well as the MOH, with a request to cancel the respective MAs.

**Case law**

The patent linkage tool can be used (1) within the application procedure for an MA; and (2) after issuance of an MA and starting of generic drugs production and/or launch on the Ukrainian market. Whereas, the second option appears to be the more effective one.

Based on Ukrainian commercial court practice, cases regarding patent infringement are mostly filed after issuance of an MA by the MOH and starting of generic drugs production, as they have a higher success rate.

At the MA application stage, a patent infringement case may be considered by a local court as groundless, i.e., the court may decide that the application for an MA in itself is not patent infringement and find that the claimant (patent owner) lacks legal standing to maintain the lawsuit.

However, at the MA application stage, the patent owner may still claim a patent infringement and require cancellation of the MA, since the generic drug company, by filing the respective MA application, has started the procedure to prepare for the launch of a generic drug, while the originator’s patent was still in force, as it was considered in *H. Lundbeck A/S v. Farmak JSC*.

Local courts may satisfy requests for injunctions with respect to the actions to complete the MA process for generic drugs, filed by patent owners within the scope of a bigger patent infringement action. For instance, in *AbbVie Inc. v. NV Remedies Pvt. Ltd. and Hetero Labs Ltd.*, the local court issued an injunction against the production, sale and offering for sale of the generic drug, and against the completion of the respective MA process.

Another effective remedy against issuing an MA at application stage is to send a warning letter to the MOH and the Expert Center of the MOH informing them about the patent infringement and requesting them to reject issuing the respective MA. Though the MOH is not obliged to satisfy the requests in such warning letters, they may be used subsequently in court to prove that the MOH was notified of the patent infringement, and thus issued the respective MA in violation of the patent owner’s rights.

Consequently, the more common way is to initiate a patent infringement action after an MA for a generic drug is issued and the generic drug’s production and/or launch on the Ukrainian market has started. This option is more effective since it is easier to prove patent infringement and legal standing of the patent owner in such case. If the patent owner needs to prevent the infringement at an earlier stage, within the MA application process, a viable strategy may be to file an injunction request to the court, and support the patent infringement claim with an MA prevention request to the MOH.

**Summary and future developments**

There are no future changes to the above legislation planned as of the time of writing.

**Status:** Law stated as of July 2019
Introduction

The concept of patent linkage for pharmaceuticals was first introduced in the UAE in 2000 by Ministerial Resolution No. 404. The introduction contributed to the UAE being removed from the Special 301 Report Watch List of the Office of the United States Trade Representative (USTR). The Special 301 Report, published annually, identifies trade barriers to United States companies and products due to intellectual property laws in other countries. The report has played a significant role in the introduction and application of patent linkage in the UAE.

Before 2000, the UAE almost continuously appeared on the Watch List of the USTR. In 2000, Pharmaceutical Research and Manufacturers of America (PhRMA), the representative body of the biopharmaceutical industry in the United States, requested that the UAE be included in the Priority Watch List (one step up from inclusion in the Watch List) because of the UAE’s continued failure to protect patented pharmaceuticals. The request was dropped after the UAE government gave assurances and adopted Resolution No. 404 of 2000 concerning patent requirements for pharmaceutical product registration. The association even supported the UAE’s removal from the Watch List. However, later that year, PhRMA raised concerns that the UAE violated its commitments and registered generics which were infringing patent rights of originators and the UAE was placed back on the USTR Special Report Watch List in 2001. The UAE Ministry of Health (MOH) denied that any medicines were registered infringing patent rights of innovator drugs. The country was removed again in 2002 after the adoption of the 2002 UAE Patent Law, which included confirmation of the patent linkage concept with reference to the country-of-origin rule for a patent.

After a long period of absence, the UAE has been again included on the Watch List of the 2018 edition of the Report. USTR quotes recent policy changes that may weaken IP protection for pharmaceutical products as one of the reasons to place the country back on the list. According to the report, in April 2017 UAE officials allowed the domestic manufacture of generic versions of pharmaceutical products still under patent protection in the United States. The UAE claimed that country-of-origin patent protection for pharmaceuticals, as instituted by Ministerial Resolution No. 404, was no longer valid. Furthermore, it is unclear if the UAE continues to recognize GCC (Gulf Cooperation Council) patents. The situation required further monitoring.

Legal regulation

Ministerial Resolution No. 404 concerning patent requirements for pharmaceutical product registration regulates patent linkage in the UAE. Article 1 of the Resolution provides that the registration of any medicine or pharmaceutical composition which is not patent protected shall be prohibited. Article 2 provides exceptions to such general rule. It states that besides essential medicines on the list of the World Health Organization, the general rule does not apply to medicines and compositions of which the period of patent protection for the original product has expired. This means that generics or biosimilars can be registered only after the period of patent protection of the originator has expired.
Ministerial Resolution No. 404 does not specify which patent is used as a reference for the patent protection period. However, Article 71 (3) of Federal Law No. 17 of 2002 Regulating and Protecting Industrial Property Rights for Patents and Industrial Designs and Models ("2002 Patent Law") includes specific reference to country-of-origin patent protection in relation to pharmaceuticals:

Article 71 (3) provides:

… If a patent is granted in one of the states which is a member of the World Trade Organization for the protection of the subject of one of said applications, and the holder thereof is licensed to market his invention on a commercial basis in such state, then the applicant shall have the exclusive right to market such invention as from the date of the license granted to the applicant by the concerned bodies in the State to market his invention on a commercial basis.

Until recently, the patent in the country of origin of the marketing authorization holder was used for the purposes of patent linkage. Since the 2017 incident reported by USTR in their 2018 Special 301 Report, there has been uncertainty among innovators on how patent linkage will be applied by the UAE MOH going forward: It appears that (at least in certain cases) patents in the country of origin are no longer considered for the purposes of patent linkage and the possibility to refer to other patents (GCC or UAE patents) is unclear. The UAE MOH denies any change of policy and states that it applies the country-of-origin rule. It does not normally consider GCC or UAE patents but it could do on a case-by-case basis. Companies are advised to closely monitor the situation and consult.

The concept of patent linkage is without prejudice to the provisions of Administrative Decision No. 71 of 2013, which lays down the UAE’s version of the Bolar Exemption and allows generic companies and local manufacturers to apply for marketing authorization within the last 24 months of the patent period. However, the marketing authorization will not be issued by the UAE MOH before the patent term expires.

**Case law**

We are not aware of any published patent (linkage) infringement cases in the UAE related to pharmaceuticals. In any event, it should be noted that UAE court decisions do not have the authority of binding precedent.

**Summary and future developments**

The uncertainty created by recent reports and, more specifically, the UAE MOH’s apparent rejection of country of origin patents for the purposes of patent linkage and its ambiguity in accepting GCC or even UAE patents, requires innovator companies to pro-actively consider their patent strategy and the need to file for additional patents.

Another particular challenge is to know if and when a generic or biosimilar application is submitted for registration. Different from other regulators, such as the European Medicines Agency, the UAE MOH does not publish the fact that it has received an application for registration of a medicinal product and it is unlikely to disclose any such information on request. It would not be unusual to find out about the registration of a generic or biosimilar when receiving notice that the price of the originator drug is reduced. At that moment, in case of infringement, time is of the essence in deciding on a defense strategy and it is very helpful if all essential information around patent registration, regulatory process and litigation options that inform such strategy is readily available.

Status: Law stated as of July 2019
Introduction

Consistent with other EU jurisdictions, there is no patent linkage system in operation in the UK. For further information on the EU regulations, see the EU chapter.

Legal regulation

EU law provides for a Bolar Exemption from patent infringement for certain activities relating to regulatory approvals, suggesting a further separation of the link between the patent and regulatory systems. The directive excludes (as a minimum) from patent infringement any studies or trials conducted with a view to an abbreviated marketing authorization application. The UK implementation of the directive now goes further to exclude activities relating to any application for marketing authorizations (and not just abbreviated generic applications) and covers applications for health technology assessment bodies, such as NICE.

Case law

Nevertheless, the English courts are well versed and experienced in dealing with patent cases in the life science industry, including addressing issues that overlap with the pharmaceutical regulatory systems.

Interim injunctions in patent cases, although quite rare in general, are available in pharmaceutical/biotech cases. Applications for interim injunctions are usually decided based on the existence of irreparable harm and, often, (especially in innovator v. generic cases) this is demonstrated by reference to an expected irreversible price-drop upon launch of the generic. In such circumstances, patentees are required to provide a cross undertaking in damages to the defendant. In a recent development, the patent court rules have been amended to require that a patentee seeking an interim injunction in a pharmaceutical case must also notify the Department of Health, to allow the Department of Health to consider applying to be a beneficiary of any cross undertaking offered.

With respect to timing, pharmaceutical/biotech companies seeking to launch a product that may be covered by a patent are expected (but not obliged) to take action to “clear the way” of third-party patents prior to a product launch. In support of this approach, the English courts have demonstrated significant flexibility in taking jurisdiction of patent disputes in the life sciences sector. Examples of this flexibility include the ability to bring infringement actions on a quia timet basis (if infringement is threatened, but not yet imminent); the permissibility of broad declaratory actions (for example, on issues such as whether a proposed product was obvious at the priority date of a patent); making orders for expedited trials if the launch of a product is expected in a certain time frame; and deciding on questions of infringement of non-UK patents.
In recent years, the English courts have been adaptable in addressing the interface between the patent and regulatory systems. By way of example, in cases of second medical-use patents, the courts have required public bodies to amend their prescribing guidelines to minimize the risk of unpatented uses of a medicine from encroaching into the sales for a patented indication.

**Summary and future developments**

We do not anticipate any change to the current regime.

Status: *Law stated as of July 2019*
United States
Introduction

There is patent linkage in the US.

Legal regulation and case law

The abbreviated new drug application

The process of marketing of generic drugs was statutorily enacted in the US as part of the Drug Price Competition and Patent Term Restoration Act of 1984 (as amended). The system of generic approval provided by this statute has largely been harmonized internationally. The original generic application, called a “paper” New Drug Application (NDA), had parameters that were subjectively determined by the US Food and Drug Administration (FDA) on a product-by-product basis. Further, there were no provisions for data exclusivity nor, in particular, bars to product approval based on a patent filed with the FDA. This statute provided for, among other things, an “abbreviated” process for approval of competitive generics after expiry of the patent and data exclusivity.

To give an idea of the scope of “abbreviation,” a typical full NDA is composed of two adequate and well-controlled clinical trials, formal statistical planning and analysis, human dose-ranging, pharmacokinetic and pharmacodynamic studies, absorption, distribution, metabolism and excretion studies, nonclinical safety pharmacology, pharmacology, pharmacokinetic, pharmacodynamic, genotoxicity, fertility and toxicology studies as well as a full description of the chemistry, manufacturing and controls (CMC). Additional clinical safety or efficacy studies that develop information on drug–drug interactions, humansafety pharmacology (QT prolongation) and special populations may also be required.

In contrast, an Abbreviated NDA (ANDA) is composed only of a pharmacokinetic comparison of the generic to the innovator or other reference drug that demonstrates bioequivalence, a copy of the innovator labeling revised to reflect changes in manufacturer and contact information, and the CMC section. The relevant reference drug is listed in the FDA’s Approved Drug Products with Therapeutic Equivalence Evaluations (“Orange Book”) and known as the “reference listed drug” or RLD.

Occasionally, especially with older drugs, the innovator may withdraw from the market. In that event, the FDA would designate another drug – typically one of the earlier generic drugs – as the Reference Standard (RS) in that setting in place of the RLD. New generics may then enter on comparison to that RS.

Bioequivalence data is generally gathered in a small study with between 25 and 100 healthy volunteers. The subjects are generally housed to permit frequent drug sampling.

In the US, the current review time for ANDAs is 18 months. The recently enacted Generic Drug User Fee Act and its successor, the FDA User Fee Reauthorization Act of 2017, provides for fee revenue to increase the
Office of Generic Drug’s resources. The FDA has committed to shortening the review time to a complete response to 10 months.

**The Orange Book for small molecule drugs**

**Orange Book patent listing**

By law, to take advantage of a bar to FDA approval of an ANDA during the patent term, an NDA holder must list each patent that claims the drug or a method of using the drug that is the subject of the NDA (or amendment or supplement to it) and with respect to which a claim of patent infringement could reasonably be asserted if a person not licensed by the owner of the patent engaged in the manufacture, use, or sale of the drug product. FDA regulations provide that, when filing an NDA, the applicant should include “patent[s] that claim the drug or a method of using the drug . . . [which] consist of drug substance (active ingredient) patents, drug product (formulation and composition) patents, and method-of-use patents.” The applicant should exclude “[p]rocess patents [and] patents claiming packaging.” 21 C.F.R. § 314.53(b)(1).

The statute also provides, separately, periods of data exclusivity for the new chemical entity or new method of use that runs concurrently – and thus, may expire before or after the patent. However, the period of data exclusivity is largely impervious to legal challenge.

**Challenging a patent that is listed in the Orange Book**

The NDA applicant attests to the accuracy of the patent information that it submits to the FDA for publication in the Orange Book. The FDA does not evaluate the accuracy of any information related to the patent listing. Instead, the law does not permit the FDA to accept, review or approve such an application if relevant periods of data exclusivity have expired. To be accepted for review, the ANDA applicant must challenge the claim by the NDA holder that the ANDA product would infringe by certifying to the FDA, and copying the patentee, that the ANDA product will not infringe either because the patent is invalid, unenforceable or the ANDA product does not infringe any valid and enforceable claim. Per the statute, the patent holder is then authorized to seek a judgment of infringement within 45 days of receiving the notice. If so, a 30-month stay is automatically applied to the approval of the ANDA (although review can be commenced).

An improper listing has not, as of yet, been successfully challenged as outside the scope of authorization for listing. To that end, on 10 January 2018, the US District Court of Massachusetts dismissed a case that alleged that certain patents should not have been listed in the Orange Book and doing so caused an improper delay of entry into the market of a competitive product. The basis for the allegation was that the FDA had been informed that a number of drug manufacturers were listing their drug delivery systems in the Orange Book, but the FDA had been unable to reach a decision on whether such a listing was proper. Given this, the issue remained an open question, and the court found that listing the patents was reasonable and dismissed the case.

That said, one potential avenue for challenging Orange Book listings has been through a counterclaim in response to a patent infringement suit filed by the patent holder as part of a declaratory judgment following the certification of non-infringement notice. In one such case, a generic applicant filed a counterclaim seeking to delist a patent on the basis that the patent did not claim or disclose either the drug substance, drug product, or method of use. The case was dismissed pursuant to a settlement agreement.
before the court ruled substantively. In 2012, the US Supreme Court permitted a generic drug manufacturer to assert a counterclaim alleging an improper use code listed in the Orange Book, in response to allegations that the generic manufacturer’s product infringed method-of-use claim.

The Purple Book for biologics

The Purple Book for biologics lists licensed biologics and their approved corresponding licensed biosimilars. In particular, the Purple Book enables users to see if biologics licensed under section 351(k) of the Public Health Service Act (“PHS Act”) have been determined to be biosimilar to or interchangeable with a brand-name product (also known as a reference biological product). Additionally, the Purple Book provides information on existing reference biological product exclusivity. Although the Purple Book includes exclusivity information, it does not include an expiration date for all biologics, and the lack of an expiration date does not mean a product is not eligible for statutory exclusivity. Moreover, the Purple Book does not list patents for biologics.

The disclosures to the branded company and their opportunity to sue

In an ANDA, an applicant seeking FDA approval of a generic RLD must make certain disclosures related to patents for the RLD. If an ANDA applicant seeks approval before a patent has expired on the basis that the patent is invalid, unenforceable, or not infringed, then the applicant must submit a paragraph IV certification to the FDA. When doing so, the applicant must also provide the NDA holder and the patent holder(s) notice of the paragraph IV certification. The notice must describe the factual and legal basis for the ANDA applicant’s claim that the patent is invalid, unenforceable, or not infringed.

Within 45 days of receiving such notice, the patent owner has an opportunity to sue the ANDA applicant for patent infringement. If the patent holder initiates a patent infringement lawsuit against the ANDA applicant, ANDA approval will be stayed for a period of time, generally 30 months from the later of when the NDA holder or patent owner(s) receives notice of the paragraph IV certification.

The 180-day exclusivity prize the first generic wins

The first ANDA applicant to file a paragraph IV certification is awarded exclusivity vis-à-vis other ANDA applicants for a 180-day exclusivity period. This exclusivity period is given to the first ANDA applicant in exchange for the ANDA applicant risking exposure to patent litigation by filing a paragraph IV certification and giving the requisite notice to the NDA holder and patent owner(s). An ANDA applicant does not need to win a patent infringement suit to retain eligibility for the 180-day exclusivity period. See Mova Pharms. Corp. v. Shalala, 140 F.3d 1060 (D.C. Cir. 1998).

Challenging patents using the USPTO’s inter partes review proceedings

Inter partes review (IPR) is a type of proceeding before the Patent Trial and Appeal Board (PTAB) that allows parties to challenge claims in a granted patent based on prior art and printed publications. Introduced in 2012 under the America Invents Act (AIA), IPR is now the most utilized mechanism for challenging patents in post-grant proceedings at the PTAB. Adjudicated by a three-judge panel of the PTAB, IPRs have a resolution deadline of just 18 months, requiring careful preparation by the challenger and swift responses from the patent owner.

According to statistics provided by the US Patent and Trademark Office (USPTO), a total of 7,429 IPR petitions were filed from September 2012 through August 2017. Of these petitions, 51% (3,774) were instituted. While the institution rate has been decreasing, and the overall rate appears low, the institution rate is still above 60% when viewed on an annual basis.
This means that a well-drafted petition will more likely than not result in an institution of at least one ground asserted in the petition. More importantly, of the instituted petitions that resulted in final written decisions, 81% of the final written decisions found at least one instituted claim to be invalid, while 65% found all of the instituted claims to be invalid. This means that, if a petition is instituted, at least one asserted claim will very likely be invalidated, if not all of the asserted claims. Therefore, an institution will put a heavy burden on the patent owner as to whether the IPR should proceed to trial.

However, drug patents have fared much better than other types of patents in IPR proceedings. As of July 2017, in IPRs involving Orange Book patents, only 44% were instituted, only 16% resulted in final written decisions finding all instituted claims invalid, and all claims were upheld in 50% of final written decisions.

**The substantial absence of a device patent linkage system**

For patents granted by the USPTO after 8 June 1995, in general, there is a 20-year patent life term from the date of the first patent application filing. Having said this, the effective patent life term is often less than 20 years because patents are often granted well before a product’s actual commercial marketing.

Many factors affect the effective patent term length, including the premarket approval requirements applied to certain products regulated under the Federal Food, Drug and Cosmetic (FDC) Act. Frequently, these products must undergo extensive testing in humans (and possibly animals) to demonstrate their safety and efficacy to the FDA before the agency will approve the product for commercial marketing.

As a result, to promote product development and innovation, in 1984, Congress chose to enact legislation affording the opportunity to extend patent terms under certain circumstances to compensate patent holders for patent time lost while developing a product and awaiting FDA premarket approval. The legislation allows these patent holders to gain back some of the lost patent time. See Title II of the Drug Price Competition and Patent Term Restoration Act (Public Law 98-417).

While there is much focus given to patent term restoration issues for pharmaceuticals, often little attention is given to medical devices in this regard. However, a subset of medical devices, Class III devices subject to premarket approval under Section 515 of the FDC Act, can qualify for patent term restoration based on the development and pre-approval process requirements established by the FDA for them.

In the relevant part, under the patent term extension statute at 35 USC. § 156, the owner of record of a patent (or its agent) must submit to PTO an extension request within the 60-day period beginning on the date the Class III medical device received approval for commercial marketing. For purposes of an extension
request for a Class III device subject to premarket approval, the “regulatory review period” that can be recouped is defined as the sum of the following:

- The period beginning on the date a clinical investigation on humans involving the device was begun and ending on the date a premarket approval application was initially submitted with respect to the device to the FDA.
- The period beginning on the date the application was initially submitted with respect to the device to the FDA and ending on the date such application was approved by the FDA.

**Summary and future developments**

There are no relevant developments to report.

**Status:** Law stated as of July 2019
Venezuela
Introduction

There is no patent linkage in the Venezuelan system. In fact, pharmaceutical patents are expressly prohibited under current legislation. Furthermore, the Venezuelan Industrial Property Registry has not granted a patent for over ten years. In spite of this situation, a number of global pharmaceutical companies continue filing patent applications.

Status: Law stated as of July 2019
Introduction

Patent linkage refers to the system or process where drug marketing authorization (MA) of generic drugs is made dependent on the status of the patents corresponding to the originator products. Accordingly, any generic drug manufacturer will not be granted MA unless (i) that drug has not been patented; (ii) the patent term has expired; (iii) the competent authorities determine that the patent is not invalid and will not be infringed; or (iv) consent is given by the patent owner.

For applicants of MA, they have a duty to establish that the drug is not protected by a patent.

For national regulatory authorities, they have a duty to prevent registration and marketing of generic pharmaceutical that may infringe the rights of patent owners.

Patent linkage helps to ensure product exclusivity for better IP protection. The process of drug research and development is highly expensive, risky and time-consuming, and generally has a very low success rate. It takes about 12–15 years for a new drug to be developed and commercialized. 1/5000 is the rate of new drugs that pass human testing and are approved for human usage. Therefore, effective patent protection is crucial for any pharmaceutical companies to recover their expenses, make revenue and further develop their R&D. Patent linkage becomes particularly relevant in this regard.

Legal regulation

Pursuant to Article 126 of Vietnam’s 2005 Intellectual Property Law, amended in 2009 and 2019 (“IP Law”), the act of using a protected invention (i.e., under a patent) during the effective term of the patent, without permission from the patent owner, shall be regarded as patent infringement. An act of patent use includes the following (Article 124.1 of the IP Law):

(a) Manufacturing the protected product
(b) Applying the protected process
(c) Exploiting the uses of the protected product or a product obtained by a protected process
(d) Distributing, advertising, offering for sale, or stocking for circulation the products mentioned in item (c)
(e) Importing the products mentioned in item (c)

Applying for/obtaining MA in Vietnam does not fall within the ambit of an act of patent use. Therefore, applying for/obtaining MA in Vietnam does not constitute patent infringement in Vietnam.
Please also note that the following acts shall not constitute patent infringement (Article 125.2 of the IP Law):

(a) Using the patent for personal needs or non-commercial purposes, or for evaluation, analysis, research or teaching, testing, pilot production or for obtaining information to carry out procedures for licensing/approval of production, importation or marketing of products

(b) Circulating, importing, and exploiting the uses of products that have been legally placed into the stream of commerce, including foreign markets (i.e., international exhaustion of rights)

(d) Using the patent only for the purpose of maintaining the operation of a foreign vehicle in transit or one that is temporarily in the territory of Vietnam

(e) Using the patent by a person with prior use right

(f) Using the patent by a person under authorization of a competent state authority (i.e., compulsory license)

Article 58 of the 2016 Law on Pharmacy (“Law on Pharmacy”) sets out seven cases where an MA shall be revoked:

(a) The drug is recalled due to a first-degree violation.

(b) Two batches of the drug are recalled within 60 months due to a second-degree violation, or three batches of the drug are of poor quality.

(c) The certificate of pharmaceutical product of an imported drug, which is the basis for the Ministry of Health to issue the certificate of free sale in Vietnam, is revoked by a foreign competent authority.

(d) The market authorization is issued based on counterfeited documents.

(e) The drug/medicinal ingredient is not manufactured at the registered address.

(f) The active ingredients, herbal ingredients or drug contains active ingredients, or herbal ingredients that are not recommended by WHO or a Vietnamese competent authority or its country of origin in terms of safety and efficacy.

(g) The manufacturer or applicant requests the revocation of the market authorization.

This provision only addresses issues of quality, safety and efficacy, without any mention of intellectual property or patent violations. Furthermore, this appears to be an exhaustive list, as there is no “catch-all” provision, typically found in Vietnamese law, allowing the revocation of marketing authorizations and drugs for “other cases prescribed by law.”

Given the above, in brief, currently a “patent linkage” system does not exist in Vietnam.

Case law

There is no relevant case law.
Future developments

There are no relevant developments to report.

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