IN-DEPTH

Pharmaceutical Intellectual Property And Competition

EDITION 5

Contributing editor
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Arnold & Porter

LEXOLOGY

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In-Depth: Pharmaceutical Intellectual Property and Competition (formerly The Pharmaceutical Intellectual Property and Competition Law Review) provides a practical overview of pharmaceutical intellectual property issues, including patent linkage and exclusivities, and related competition concerns. With a focus on recent developments, it is a useful tool for managing global risks in this area – analysing the key elements of the relevant legal and regulatory regimes across major jurisdictions worldwide.

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Editor's Preface

Daniel A Kracov

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The past year has continued to be a challenging one for the global pharmaceutical industry. Drug pricing, intellectual property, and competition issues remain a serious focus of governments worldwide. For example, adopting the Inflation Reduction Act drug price negotiation framework in the critical US market has altered the calculus for global product development priorities. Company business strategies continue to draw scrutiny, and regulatory and compliance burdens seem to inexorably grow in scope and complexity. With many companies operating globally across differing legal regimes and healthcare systems, it has become critical to rapidly understand and react to a wide array of developments and adapt to constant change.

Despite efforts at harmonisation in certain areas, the applicable rules vary around the world, and the nuances of these local frameworks require careful attention from both a planning and operational perspective to achieve business objectives across jurisdictions. Maximising the value of intellectual property and exclusivities in this environment can be the difference in deciding whether to pursue the development of an important new treatment and maintaining success in the marketplace. Similarly, failure to carefully manage risks in dealings with competitors, such as generic and biosimilar companies, can result in huge civil and criminal liabilities. As companies in the industry are all too familiar, this is an area of significant enforcement activity worldwide, with large fines being imposed and transactions thwarted if applicable legal constraints are not heeded. Moreover, the links between intellectual property strategies, competition and affordability are a constant source of political and legal challenges

Our objective in structuring this updated volume is to familiarise practitioners in the field with these critical issues across jurisdictions. It is hoped this book will reduce some of the burdens associated with bringing new treatments and cures to patients while achieving global business objectives. I would like to thank the authors for their renewed contributions to this edition of In-Depth:Pharmaceutical Intellectual Property and Competition; they have produced what we believe is a very useful tool for managing global risks in this area.

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Summary

Introduction

Pharmaceutical industry regulation in Australia comprises a number of regulatory frameworks administered by separate government departments or agencies. These include:

1. the framework for gaining marketing authorisation for pharmaceutical goods, including their entry on the Australian Register of Therapeutic Goods (ARTG) (administered by the Therapeutic Goods Administration (TGA));
2. the framework of the Pharmaceutical Benefits Scheme (PBS) under which the Australian government subsidises the supply of certain pharmaceutical goods to Australian citizens and residents (administered by Department of Health);
3. the framework for promoting competition and consumer protection as required by the Competition and Consumer Act 2010 (Cth) (CCA) (administered by the Australian Competition and Consumer Commission (ACCC) and other state agencies); and
4. the framework for extending the term of pharmaceutical patents, which is contained within the provisions of the Patents Act 1990 (Cth) (the Patents Act) (administered by the Australian Patent Office).

Year in review

The law affecting pharmaceutical patents continues to evolve in a number of important respects.

The Full Court of the Federal Court of Australia delivered its much anticipated judgment in Commonwealth of Australia v Sanofi [2023] FCAFC 97, dismissing the Commonwealth's claim for compensation against Sanofi and BMS under the usual undertaking as to damages given by the parties in return for the grant of interlocutory injunctions restraining the launch by Apotex of generic Plavix. The legal position, however, remains far from settled, with the High Court of Australia in December 2023 granting the Commonwealth special leave to appeal the Full Court decision, with the appeal hearing likely to be scheduled in the second half of 2024, and with a separate claim by the Commonwealth against Otsuka and BMS (in relation to the undertaking given in return for the grant of an injunction restraining the launch of generic Abilify by Generic Health) currently before the Federal Court of Australia.

The limited body of case law on support and sufficiency requirements under the Patents Act as amended by the Raising the Bar legislation has now received appellate attention in the Full Court's decision in Jusand Nominees Pty Ltd v. Rattlejack Innovations Pty Ltd [2023] FCAFC 178. The Full Court gave detailed consideration to the leading UK case on sufficiency (Regeneron Pharmaceuticals Ltd v. Kymab Ltd [2020] UKSC 27) and held inter alia that in the context of deciding whether a claimed range of options is sufficiently enabled by the specification, consideration ought to be given to the 'essence or core' of the

invention. The Court's decision confirms that the threshold for sufficiency and support is significantly raised post Raising the Bar.

The post Raising the Bar requirements for claiming 'priority' also received much needed judicial guidance in ToolGen Incorporated v. Fisher (No 2) [2023] FCA 794, with the Court holding that the document to which priority is claimed must disclose the claimed invention and in a manner that is clear enough and complete enough for the invention to be performed by the person skilled in the art, a significant departure from the pre-Raising the Bar requirement for priority.

The Federal Court's decision in Neurim Pharmaceuticals (1991) Ltd v. Generic Partners Pty Ltd (No 5) provided guidance including as to the conduct that will constitute direct infringement of Swiss-style claims, highlighting the importance of the language of the TGA approved indication and product information compared to that of the claims.[1]

The law on patentability of computer implemented invention also continues to develop with several Federal Court decisions[2] now grappling with the implications of the High Court's 3-3 split in Aristocrat v. Commissioner of Patents [2022] HCA 29. Although not the subject matter of these decisions, they clearly have potential significance in the medical technology sector.

On the regulatory front, it appears the TGA has at least temporarily abandoned a previously proposed regime to require generic and biosimilar manufacturers to provide patentees with early notification of their applications for marketing approval.[3]

There have also not been any further developments on the ACCC's proposed 'patents settlement register' though its implementation remains a possibility given the registers maintained by some international antitrust regulators including in the United States.

Legislative and regulatory framework

Authorisation

The Therapeutic Goods Act 1989 (Cth) (the TG Act) and the Therapeutic Goods Regulations 1990 (Cth) (the TG Regulations) establish the legal requirements for the import, export, manufacture and supply of therapeutic goods in Australia. They detail the requirements for listing, registering or including medicines, medical devices and biological products on the ARTG, as well as many other aspects of the law, including advertising, labelling, product appearance[4] and product recall.[5]

Unless it is exempt or otherwise authorised by the TGA,[6] a therapeutic good must be approved by the TGA and entered on the ARTG before it can be marketed or supplied in, or exported from, Australia.

State and territory legislation also imposes requirements relating to pharmaceutical substances, including the scheduling of substances and the safe storage of therapeutic goods.[7]

Pricing and public purchasing of pharmaceuticals

The PBS is a programme under which the government subsidises the supply of certain medicines to Australian citizens. All medicines that have been approved to be dispensed to patients at a government-subsidised price are listed on the PBS Schedule.

The Repatriation Pharmaceutical Benefits Scheme (RPBS), administered by the Department of Veterans Affairs, is a scheme that provides pharmaceutical benefits to eligible veterans and war widows and widowers.[8] Pricing and reimbursement arrangements for the supply of pharmaceutical benefits under the PBS are automatically translated across to the RPBS.[9]

The PBS legislative provisions relating to the supply and pricing of pharmaceutical benefits are located in Part VII of the National Health Act 1953 (Cth) (the NH Act) and include several provisions relating to the supply of pharmaceutical benefits (Division 2), payment for the supply of pharmaceutical benefits (Division 3), recovery of payments for the supply of pharmaceutical benefits (Division 3AA), price reductions for new brands of pharmaceutical items (including both single and combination items) (Division 3A, Subdivision A-D) and price disclosure price reductions (Division 3B, Subdivision A, B, D, E). In relation to the public purchasing of pharmaceuticals, Section 99 of the NH Act provides that a dispenser (pharmacist or approved medical practitioner) who has supplied a pharmaceutical benefit is entitled to be paid by the Commonwealth an amount equal to the Commonwealth price of the pharmaceutical benefit as at the time of the supply (or, if certain conditions are satisfied, an amount based on the Commonwealth price). The 'Commonwealth price' is defined in Section 84(1) of the NH Act.

In practice, patients pay an amount for a PBS-subsidised medicine (referred to as the patient co-payment), and the remainder of the cost is paid by the government directly to the dispenser. For general patients, the maximum cost for a pharmaceutical benefit item is A$31.60, while for concession card holders (e.g., RPBS patients), the maximum cost is A$7.70, together with any special patient contribution, brand premium or therapeutic group premium that is applicable.[10]

Patent duration

Australian patent law is governed by the Patents Act. There were two types of patents provided under the Patents Act: standard patents and innovation patents. A standard patent has a term of 20 years from its effective filing date,[11] while the term of an innovation patent is eight years from its effective filing date.[12]

Innovation patents are, however, being phased out, with new applications for innovation patents having ceased to be accepted from 26 August 2021.

Extension of term

Patent term extension is available for standard patents but not for innovation patents.

The term of a standard patent relating to pharmaceutical substances may be extended, in certain circumstances, for up to five years.[13] To qualify for patent term extension, the patent must contain at least one claim to one or more pharmaceutical substances per se, or pharmaceutical substances that are produced by a process involving the use of recombinant DNA technology, that is in substance disclosed in the complete specification

of the patent.[14] The available term of the extension is equivalent to the period between the filing date of the patent and the first regulatory approval date, which is the date any product containing the pharmaceutical substance is first listed on the ARTG, minus five years.[15]

The patent term cannot have been previously extended.

Two recent decisions of the Full Court of the Federal Court of Australia provided guidance regarding the operation of the provisions relating to the extension of the term of a patent (see 'Patent duration'). Both cases involved a scenario in which multiple products could have been relied upon for patent term extension. In both decisions, the Court took a literal view of the phrase 'first regulatory approval date', which appears in section 70(5) of the Patents Act.

In Commissioner of Patents v. Ono Pharmaceutical Co Ltd[16] the Court held that patentees must apply for any patent term extension within six months of the first inclusion of any product containing a pharmaceutical substance falling within the claims of the patent, even if the product was registered on the ARTG by a third party.

Similarly, in Merck Sharp & Dohme Corp v Sandoz Pty Ltd[17] the Court held that a patent term extension for a patent claiming more than one pharmaceutical substance must be calculated from the earliest regulatory approval date of any pharmaceutical substance disclosed in, and claimed by, the patent, even if that substance was not the substance relied upon for the patent term extension application.

Encouraging innovation in the pharmaceutical sector

The TG Act, the Patents Act and the NH Act all include provisions that encourage innovation. The patent term extension provisions in Section 70 of the Patents Act are, in part, in recognition of the fact that the patentee's reward for pharmaceutical patents may be diminished by reason of regulatory approval processes.

The data exclusivity provisions in Section 25A of the TG Act provide a five-year data exclusivity period commencing on the first day of the therapeutic product becoming registered. Within the exclusivity period, regulatory authorities cannot, without the permission of the innovator (in writing), use the preclinical and clinical data of the innovator's product to assess an application for registration of a generic or biosimilar. The data exclusivity provisions in the TG Act do not extend to protect information relating to a new indication or orphan drugs.

The NH Act provides that PBS-listed drugs are to be assigned to formularies identified as F1 or F2. The F1 formulary is for medicines for which only a single brand is listed, often because it is patented or an innovative medicine. In contrast, the F2 formulary contains medicines for which multiple brands are registered or for which a single brand medicine is registered that is interchangeable with multiple brand medicines at the patient level. The listing of a drug as F1 or F2 will affect its pricing.

When a new medicine is listed on the PBS as F1, its price is not linked to the price of any similar medicine in F2. Because F1 medicines are not interchangeable at the individual pharmacy level with other brands, the PBS price will not be affected by the pricing of other drugs until a bioequivalent or biosimilar brand is listed and upon which the medicine moves from F1 to F2.

Concessional tax treatment of eligible R&D expenditure under the R&D Tax Incentive remains available. Currently, companies with aggregated turnover of less than A$20 million can claim a refundable tax offset fixed at 18.5 per cent above the company's tax rate. Entities with aggregated turnover of at least A$20 million can claim a non-refundable tax offset between 8.5 to 16.5 per cent above the company's tax rate, depending upon its 'R&D intensity' (the portion of the company's total expenditure that is identified as being R&D expenditure).

The government announced in the 2024-25 Federal budget that it would not be proceeding with the 'Patent Box' proposal for concessional tax treatment of income associated with new patents in medicine and biotechnology, which had been proposed by the previous government.

Effect of competition laws on the pharmaceutical sector

The CCA is enforced and administered by the ACCC, an independent statutory authority.-[18] The ACCC is also the only national agency dealing generally with competition or antitrust matters. The CCA regulates the following types of conduct that are relevant to the pharmaceutical sector:

1. anticompetitive acquisitions;[19]
2. exclusive dealing and resale price maintenance;[20]
3. resale price maintenance;[21]
4. anticompetitive agreements, including concerted practices;[22]
5. misuse of market power;[23] and
6. cartel conduct, including price-fixing, output restrictions, market sharing and bid rigging.[24]

The following maximum civil penalties apply for breach of the provisions of the CCA relating to anticompetitive practices:[25]

1. for corporations, the greater of:
    - A$50 million;
    - three times the value of the benefit from the act or omission; or
    - where the benefit cannot be calculated, 30 per cent of the corporation's annual turnover in the preceding 12 months; and
2. for individuals, A$2.5 million.

Individuals found guilty of cartel conduct could face criminal or civil penalties, including up to 10 years in jail or fines of up to A$550,000 per criminal cartel offence, or both, and a pecuniary penalty of up to A$2.5 million per civil contravention.

It is illegal for a corporation to indemnify its officers against legal costs and any financial penalty. Other forms of relief relating to the cartel offence include injunctions, orders disqualifying a person from managing corporations and community service orders.

For corporations, the maximum fine or pecuniary penalty for each criminal cartel offence or civil contravention (whichever applies) is the same as penalties for anticompetitive conduct; that is, the greater of:

1. A$50 million;
2. three times the total value of the benefits obtained by one or more persons and that are reasonably attributable to the offence or contravention where benefits cannot be fully determined; or
3. 30 per cent of the annual turnover of the company (including related corporate bodies) in the preceding 12 months.[26]

New drugs and biologics – approval, incentives and rights

Drugs

The TGA has published guidelines to assist applicants (sponsors) in preparing their applications to register new medicines for human use in Australia, including the Australian Regulatory Guidelines for Prescription Medicines in relation to new prescription medicines[27] and the Australian Regulatory Guidelines for Biologicals in relation to new biologicals.[28]

Approval of new prescription medicine applications

The TGA registration process for new prescription medicine applications (including generic medicines) consists of eight phases with eight milestones, each milestone marking the completion of a phase.[29] The target time frame of a standard registration process is 255 working days from the date of acceptance for evaluation through to the date of the delegate's decision.[30]

Phase 1: pre-submission

Applications in Category 1 and Category 2 must go through a pre-submission phase,[31] which begins with the lodgement of a pre-submission planning form (PPF). A complete PPF provides the TGA with planning data, such as general submission information, information about the proposed application type and details of the quality, and nonclinical and clinical evidence that will be provided in the dossier. Once the TGA considers a PPF complete and acceptable, it begins arranging appropriate resourcing for the processing and evaluation of the application, including securing appropriate evaluators for the dossier.

Applicants must pay an application fee upon lodgment of a PPF. For applications submitted to the TGA from 1 July 2024, the application fee for a new chemical entity is A$56,844. For a new generic product, the application fee is A$21,923.[32] There is no application fee payable for applications made under Section 23 of the TG Act and involving a medicine that has been designated as an orphan drug.

Phase 2: submission

The submission phase involves the following TGA processing activities in preparation for evaluating the application:

1. confirming the dossier would be delivered by the expected lodgement date;
2. verifying that any fee has been paid;
3. workflow planning and IT administration;
4. considering the application against the TGA's regulatory requirements; and
5. issuing a notification letter and, if applicable, a notice of the evaluation fee payable.

An evaluation fee becomes due and payable when the applicant is notified that the application has been accepted for evaluation. For applications submitted to the TGA from 1 July 2024, for a new chemical entity, the evaluation fee is A$227,825; for a new generic product, the evaluation fee is A$87,016.[33]

Phases 3 to 6: assessments, response and review

During the first-round assessment phase (Phase 3), all data provided in the dossier are considered by evaluators and where there are issues or questions about any component of the application, a consolidated Section 31 request for information is sent to the applicant. The applicant must then prepare a response (Phase 4).

During the second-round assessment phase (Phase 5), evaluators consider the applicant's response to the Section 31 request (if applicable) and complete their evaluation of the data. When the assessment is complete, the evaluation reports are considered by the delegate (Phase 6). The delegate may seek independent advice on issues concerning the application, including from the Advisory Committee on Medicines (ACM), the main advisory group for prescription medicines.[34] The applicant's comments in relation to perceived errors of fact or major omissions in the second-round assessment reports of applications referred to the ACM are also considered.

Phases 7 and 8: decision and post-decision

The delegate determines whether to approve (possibly modify or vary) or reject the application (Phase 7). The applicant is notified in writing of the delegate's decision within 28 days of the decision being made. During the post-decision phase (Phase 8), administrative and regulatory activities are completed.

Priority review applications

The priority review pathway allows for faster assessment of vital and life-saving prescription medicines where data for a complete dossier is available.[35] The target time frame is 150 working days. A valid priority review designation must be held to access this pathway. The priority registration process, like the standard prescription medicines registration process, has eight phases, but with modifications made to reduce time frames.

For applications submitted to the TGA from 1 July 2024, the application fee for priority determination of a prescription medicine is A$14,805. The fee for a new prescription medicine application is A$60,234, and the evaluation fee is A$240,934. The fee for a new indications application is A$35,823, and the evaluation fee is A$143,295.[36]

Application and evaluation fee waivers apply to medicines with a valid orphan drug designation, provided that the priority therapeutic indication is identical to, or is a subset of, the orphan drug indication.

Provisional approval pathway

The TGA has an approval pathway for the provisional registration of prescription medicines on the ARTG for a limited duration based on preliminary clinical data demonstrating that there is potential for a substantial benefit to Australian patients.[37] A valid provisional determination must be held to access this pathway.

The provisional registration process, like the standard prescription medicines registration process, has eight phases, but with changes made to account for uncertainty associated with preliminary clinical data. The TGA specifies that the target time frame of the provisional registration process is 220 working days from the date of acceptance for evaluation through to the date of the delegate's decision.[38]

For applications submitted to the TGA from 1 July 2024, the application fee for a provisional determination of a prescription medicine is A$14,805. The fee for provisional registration of a new prescription medicine is A$56,956, and the evaluation fee is A$297,212. The fee for provisional registration of a new indications application is A$34,016, and the evaluation fee is A$196,070.[39]

Application and evaluation fee waivers apply to medicines with a valid orphan drug designation for the provisional registration process, provided that the therapeutic indication for provisional registration is identical to, or is a subset of, the orphan drug indication.

Biologics and biosimilars

Products regulated as biologicals must be a therapeutic good defined in Section 3 of the TG Act and either meet the definition of a biological or be specified by a legislative instrument to be a biological. A product is not regulated as a biological if it is an excluded good or a product regulated as a therapeutic good, but not as a biological.[40]

Certain autologous human cell and tissue products may be eligible for exemption from some regulatory requirements, provided the products meet specific eligibility criteria and fulfil specific regulatory obligations.[41]

Unapproved biologicals can be supplied through the following schemes, depending on whether the use is[42] part of a clinical trial (clinical trial schemes), for an individual patient (special access scheme) or by an individual practitioner for multiple patients (authorised prescriber scheme). Biologicals that are not otherwise exempt, approved or authorised must be included on the ARTG.

Classifying biologicals

A biological product must be classified before an application can be made to include it on the ARTG.[43] Classification of biologicals is based on whether it is mentioned in Schedule 16 of the TG Regulations (Class 1 and 4 biologicals) or based on the method of preparation and intended use of the product (Class 2 and 3 biologicals).

A Class 1 biological product would be of low risk to public health and have an appropriate means of oversight, such as accreditation and a high level of practitioner oversight. To supply a Class 1 biological product, the product must comply with all applicable standards, be mentioned in Schedule 16 of the TG Regulations and be included on the ARTG.

Class 4 biologicals are high-risk products that are defined in Schedule 16 of the TG Regulations as:

1. biologicals that comprise or contain:
    - live animal cells;
    - live animal tissues; or
    - live animal organs;
2. biologicals to which both of the following paragraphs apply:
    - the biologicals comprise, contain or are derived from human cells or human tissues that have been modified to artificially introduce a function or functions of the cells or tissues; and
    - the artificially introduced function or functions were not intrinsic to the cells or tissues when they were collected from the donor;
3. pluripotent stem cells; and
4. biologicals derived from pluripotent stem cells.

Class 2 is restricted to biological products that have been subjected to minimal manipulation and are only for homologous use.

Class 3 includes biological products that are for homologous use but have been prepared using more than minimal manipulation or for non-homologous use, regardless of whether they have been prepared using minimal manipulation or more than minimal manipulation.

Inclusion of new biological products on the ARTG

There are eight phases to the standard process for acceptance and review of an application to include a new Class 2, 3 or 4 biological on the ARTG.[44]

Phases 1 and 2: pre-submission and submission

Pre-submission (Phase 1) involves a pre-submission meeting with the TGA and is recommended for applicants that are considering the supply of a biological product.

Following the pre-submission phase, applicants submit a biologicals application form, including supporting documentation required in the dossier, as specified in Sections 32DDA(9) and (10) of the TG Act, and payment of an application fee (Phase 2). The application then proceeds to preliminary screening, which also entails payment of an evaluation fee.

For applications submitted to the TGA from 1 July 2024, the application fee for Classes 1, 2, 3 and 4 biologicals is A$1,231. The evaluation fee is A$85,772 for Class 2 biologicals, A$171,659 for Class 3 and A$78,904 for Class 4 (the priority evaluation fees for Class 2, 3 and 4 biologicals are A$89,655, A$179,752 and A$290,462, respectively).[45] A reduction or waiver of the evaluation fee is possible for applications submitted as a single submission or if an application only requires an abridged assessment.

Phases 3 to 6: evaluation and expert advisory review

During the first round of evaluation (Phase 3), the application is reviewed by a number of specialist disciplines within the TGA, including quality, infectious disease safety, microbiology, toxicology and clinical areas, to ensure:

1. the quality, safety and efficacy of the biological product is satisfactorily established for the proposed use or uses;
2. the presentation of the biological is acceptable;
3. the biological conforms to all applicable standards;
4. if a step in the manufacture of the biological has been performed outside Australia and the biological is not exempt from the operation of Part 3-3 of the TG Act, the manufacturing and quality control procedures used in the step are acceptable;
5. the biological does not contain substances that are prohibited imports for the purposes of the Customs Act 1901;
6. all the manufacturers of the biological product are nominated as manufacturers of the biological in the application; and
7. other matters that the Secretary of the Department of Health (the Secretary) considers relevant.

The applicant is sent a consolidated letter under Section 32JA of the TG Act if additional information is required (Phase 4).

Evaluation is resumed in a second round (phase 5) and if further information is required, the applicant is again sent a consolidated letter under Section 32JA of the TG Act (Phase 5a). In the third evaluation round (Phase 5b), reports are finalised by each evaluation area and provided to the delegate for consideration. The TGA may work closely with the applicant

to resolve any outstanding issues following evaluation of the applicant's responses during the review and decision phase, or the TGA may highlight them for the delegate to consider.

The delegate will review the evaluation reports and where required, may seek advice from the Advisory Committee on Biologicals (Phase 6).

Phases 7 and 8: decision and post-decision

The delegate may liaise directly with the applicant to resolve any outstanding issues before finalising its decision. Once a decision is made, the applicant is provided written notification. If the decision is to include the biological product on the ARTG, the decision letter will outline any specific conditions that apply. If the decision is not to include the biological product on the ARTG, the decision letter will outline the reasons and provide information on the applicant's rights to seek a review of the decision.

In relation to inclusion of Class 1 biologicals on the ARTG, applicants are required to submit a statement of compliance (a written certification) confirming that the biological product:-[46]

1. is a Class 1 biological;
2. is safe for the purposes for which it is to be used;
3. conforms with any relevant mandatory standards; and
4. does not contain substances that are prohibited imports for the purposes of the Customs Act 1901.

Biosimilar medicines

Applications to register biosimilar medicines must meet the same requirements as for prescription medicines. Biosimilar medicines are evaluated through the standard prescription medicines registration process, and applications must meet the same requirements and guidelines as those for prescription medicines (see 'Approval of new prescription medicine applications').[47]

For a biosimilar medicine to be registered in Australia, a number of laboratory and clinical studies must be performed to demonstrate the comparability or biosimilarity of the biosimilar to the reference biological medicine that is already registered in Australia.

Biosimilar medicines must have similar physicochemical, biological, immunological, efficacy and safety characteristics to its reference biological medicine, demonstrated using comprehensive comparability studies.

A number of European guidelines that outline the quality, non-clinical and clinical data requirements specific to biosimilar medicines have been adopted by the TGA. The TGA has also adopted the guideline of the International Council for Harmonisation of Technical Requirements for Pharmaceuticals for Human Use on the assessment of comparability.

The TGA notes that Common Technical Document Module 3 of the dossier, which describes the format and organisation of the chemical, pharmaceutical and biological

data relevant to the application, will require significant modification from the EU dossier, including in relation to:

1. in-house standard;
2. bridging comparability studies;
3. shipping stability; and
4. labelling.

Data exclusivity

Innovators enjoy a period of data exclusivity with respect to confidential information that they submit to the TGA to obtain regulatory approval of a new product containing a pharmaceutically active ingredient for human use.

During the data exclusivity period, the TGA cannot use this confidential information to evaluate an application to register therapeutic goods on the ARTG without first obtaining the written consent of the first sponsor. Section 25A of the TG Act provides that certain information is protected if:

1. the information is to an active component (not being a device) that is contained in an application to register a therapeutic good;
2. the information is not available to the public;
3. the sponsor has not given written permission for the Secretary to use the information;
4. at the time the application for regulatory approval was lodged, no other therapeutic goods containing the active ingredient were (or had ever been) included on the ARTG; and
5. the therapeutic good has been included on the ARTG for less than five years.

The period in which data is protected for new prescription products and biological products is five years from the date the new product is registered.

Patent linkage

Patent linkage is a term used to describe mechanisms that may be used to provide notice to a patentee, usually the innovator of the patented medicine, that a manufacturer is seeking to enter the market with a generic version or biosimilar of the patented medicine.

At present, there is no mechanism for notification to a patentee of the marketing authorisation applications submitted to the TGA by manufacturers in relation to generic or biosimilar medicines. While a certification process is mandated by the TG Act, this does not require notification to the patentee in all circumstances.

Between February 2019 and June 2020, the TGA conducted an extensive public and targeted stakeholder consultation regarding potential measures to require generic and biosimilar companies to provide patentees with early notification of their applications for marketing approval. This would have required applicants for first generic and first biosimilar medicines notifying the patent holder upon acceptance of their application for evaluation by the TGA under Section 25 of the TG Act, and before the TGA commenced its evaluation. These measures did not proceed (and appear to have been abandoned).[48]

In January 2021, the TGA did however implement a separate process involving the early publication (on the TGA's website)[49] of applications for new medicines and new uses for existing medicines once they have been accepted by the TGA for evaluation under Section 25 of the TG Act. The TGA website identifies the product sponsor, product name, active ingredients, proposed indication or indications and the application type (new medicines, new combination of medicines, new indications for existing medicines).

Under Section 26B of the TG Act, applicants for marketing approval must certify to the secretary either that their product would not infringe a valid patent claim or that the patentee has been notified of the application. In practice, intending generics almost universally notify the secretary that in their opinion, the sale of the generic would not infringe a 'valid' patent, thereby bypassing the need to notify the patentee.

Where a generic manufacturer seeks to enter the market and the patentee decides to institute patent infringement proceedings, the patentee must first certify that the proceedings are being commenced in good faith, have reasonable prospects of success and will be conducted without unreasonable delay. As at 1 July 2024, fines of up to A$330,000 may be imposed for false or misleading information in a certificate and the Commonwealth Attorney General may join the action to recover losses to the PBS.

If an interlocutory injunction is contemplated, Section 26D(2) of the TG Act requires that the Attorney General of the Commonwealth, or of a state or of a territory be notified in writing of the interlocutory injunction application.

The TGA can proceed to register the generic or biosimilar even though the relevant patent has not yet expired. A generic manufacturer may then apply for listing on the PBS for its medicine at any time. The application for listing on the PBS by the generic, of itself, does not constitute patent infringement.

PBS listing of a generic or biosimilar medicine will trigger a 25 per cent reduction in the subsidised price of the innovator's medicine (and the further price reductions resulting from ongoing price disclosure obligations) and result in the transfer of the innovator's medicine from the F1 formulary to the F2 formulary.

Preventing market entry of generic medicines – injunctions

Having regard to the matters discussed above, innovators will have no notice of an application for TGA approval and only a brief period of notice of an application for PBS listing. A patentee concerned that a newly registered generic or biosimilar will infringe its patent must therefore act swiftly if it wishes to seek to prevent the launch of generic or biosimilar products upon becoming aware of the grant of marketing approval.

In urgent situations, a patentee may seek an interlocutory injunction to prevent the launch of the generic or biosimilar product. In such an application, the patentee must demonstrate

to the court that there is a prima facie case of infringement and that the balance of convenience favours the grant of the injunction. A key factor in the grant of interlocutory relief is whether the applicant can demonstrate that it will suffer irreparable harm (for which monetary damages are an inadequate remedy) if the injunction is not granted.

In the application, the question will often arise regarding how validity issues are to be weighed in determining whether the applicant has discharged the onus of establishing a prima facie case of infringement. This requires the court to make a preliminary assessment of validity issues in determining the question of prima facie case.

A significant issue that arises on the determination of the balance of convenience is the relative positions of the patentee and generic with respect to the calculation of damages. The patentee will have an established market position in the therapeutic field and will often have the benefit of the PBS price for its product. The PBS listing of a generic or biosimilar will result in mandated price reductions for the patentee's product (see 'Encouraging innovation in the pharmaceutical sector').

Notwithstanding the impact of such mandated price reductions on the patentee, judicial dicta in cases involving the calculation of damages claimed to have resulted from an interlocutory injunction are to the effect that the calculation of damages flowing to a generic from the grant of an interlocutory injunction may present greater difficulty than the calculation of damages to the patentee from refusing the grant of an injunction.[50] Turning the tide on a decade or so of the Federal Court's granting of multiple interlocutory injunctions in pharmaceutical patent cases, there has not been a successful application for interim relief in a patent case in the past five years. This reflects the Federal Court's view as to the difficulty in calculating generic/biosimilar damage, however, questions of patent validity were also material factors in the refusal to grant the interlocutory relief. It remains that each application for injunctive relief is to be assessed on its own facts.

An important point that arises in the determination of the balance of convenience is whether, if the court refuses an interlocutory injunction but later grants final injunctive relief, the mandated price reductions under the NH Act would be reversed to restore the patentee's price. This would involve reversing the 25 per cent price reduction and the further price reductions resulting from ongoing price disclosure obligations. This is a matter that is completely within the discretion of the Minister for Health and Aged Care and poses considerable uncertainty for the court.

Before the grant of an interlocutory injunction, the patentee must undertake to the Court to compensate any person affected by the operation of the order or undertaking.

A significant issue that arises under the undertaking as to damages is whether, if it is later held that the injunction was improperly granted, the Commonwealth government is entitled to claim damage in the form of difference between the cost to it of the PBS subsidy while the injunction was in place and the cost of the subsidy it would have borne if no injunction had been granted.

The complexities of such a claim were recently demonstrated in Commonwealth of Australia v. Sanofi (No. 5) [2020] FCA 543. In that case, the Federal Court dismissed a claim by the Commonwealth government for compensation from Sanofi on the usual undertakings regarding damages. The decision was upheld on appeal to the Full Court of Federal Court (Commonwealth of Australia v. Sanofi [2023] FCAFC 97). The Commonwealth has been granted special leave to appeal to the High Court of Australia.

The Commonwealth's right to compensation under the usual undertaking as to damages is also currently the subject of first instance Federal Court of Australia proceedings between the Commonwealth and Otsuka / BMS concerning Abilify.

Delaying market entry of generic medicines – settlement

Parties, or prospective parties to patent litigation, may settle disputes; however, any such settlement will always be subject to oversight by the CCA.

The potential for liability under the CCA mainly arises in relation to a 'pay for delay' settlement whereby a generic or biosimilar company who is challenging an originator's patent decides to abandon litigation or market entry in exchange for a monetary award. Pay-for-delay arrangements may be impugnable under several provisions of the CCA, including the cartel conduct prohibitions and offences (Sections 45AF, 45AG, 45AJ and 45AK), anticompetitive agreements and concerted practices (Section 45), misuse of market power (Section 46) and exclusive dealing (Section 47). Concerning cartel conduct, the ACCC will likely give particular attention to provisions of a contract, arrangement or understanding (CAU) that have the purpose of preventing, restricting or limiting the supply, or likely supply, of goods to persons or classes of persons by the generic company.[51]

The key question that must be asked is whether, absent the settlement, there was a real possibility that the generic or biosimilar company would otherwise have supplied its version of the medicine to the Australian market at an earlier date?

Answering this question requires an assessment of whether the generic or biosimilar company's patent challenge would have succeeded and an evaluation of the purposes of the patent holder at the time of settlement. Accordingly, the ACCC must conduct appropriate due diligence to understand the purpose and impact of a settlement on the pharmaceutical sector – this information often only being known by the parties to such arrangements and their representatives.

Although, at present, the ACCC or jurisprudence has not provided any indication of how this question will be answered, a recent joined judgment of the European Court of Justice may provide some guidance.[52] In those circumstances, which concerned pay-for-delay settlements, the European Court of Justice determined the relevant considerations to be that:

1. uncertainty of a patent's validity of a patent is a central aspect that characterises the pharmaceutical sector;
2. patents do not wholly prevent actions that contest validity and these actions are commonplace;
3. potential competition in the pharmaceutical sector could be exerted before a patent's expiry as the manufacturer of a generic or biosimilar will want to prepare themselves to enter the market on the expiry of that patent; and
4. the fact that a genuine dispute exists between the parties does not preclude the presence of competition but, conversely, serves as evidence of the existence of potential competition between those parties.

Competition enforcers

Competition enforcers in Australia

The primary responsibility of the ACCC is to ensure that individuals and businesses comply with the CCA. The following powers and remedies are available to the ACCC:[53]

1. compulsory information-gathering powers;[54]
2. search warrant and seizure powers (i.e., dawn raid powers) to gather evidential material – pursuant to a search warrant, the ACCC may also require any person on the premises to answer questions and produce documents that relate to the ACCC's entry to the premises;[55]
3. request that parties voluntarily provide information and documents to the ACCC in response to an investigation;
4. issue infringement notices;[56]
5. accept court-enforceable undertakings from a party under Section 87B of the CCA; and
6. institute legal proceedings if the ACCC considers it appropriate. A number of remedies and penalties available to the ACCC by way of a court order include declarations, injunctions, pecuniary penalties and other remedial orders.

The ACCC also continues important residual work in areas previously identified as priority areas, such as healthcare.

Each year, the ACCC releases its Compliance and Enforcement Policy,[57] which identifies the industries and behaviours it will be focusing on. The ACCC also has in place a set of enduring priorities that covers forms of conduct that it considers are so detrimental to consumer welfare and the competitive process that they should always be a priority.

Although the 2024–25 priorities are not directly relevant to the pharmaceutical sector, the enduring priorities are relevant and include the following:[58]

1. cartel conduct;
2. anticompetitive conduct;
3. product safety;
4. vulnerable and disadvantaged consumers; and
5. conduct impacting indigenous Australians.

Merger control

Merger authorisation

Acquisitions that would have the effect or be likely to have the effect of substantially lessening competition in any market are prohibited by Section 50 of the CCA.[59] Acquisitions are subject to the CCA and must be authorised by the ACCC.

Merger authorisation allows merger parties to seek statutory protection for a proposed acquisition from legal action under Section 50 of the CCA.

The ACCC can grant a merger authorisation if it is satisfied that either the proposed acquisition would not have the effect, or would not be likely to have the effect, of substantially lessening competition; or that the proposed acquisition would result, or be likely to result, in a benefit to the public, and the benefit would outweigh the detriment to the public that would result, or be likely to result, from the acquisition.[60] The ACCC's Merger Authorisation Guidelines reflect the proposed approach of the ACCC in assessing applications for authorisation, including the likely competition effects of proposed acquisitions under the CCA.[61]

The merger authorisation process is open to the public, and applications for merger authorisation, all related submissions by the applicant and interested parties, and the ACCC's determinations are stored on the merger authorisations public register.

To date, there have been no final decisions by the ACCC or ACT in relation to the pharmaceutical sector.

The merger authorisation process is an alternative to the informal merger review process. Previously parties could seek authorisation for mergers directly from the ACT; however, currently, applications must first be made to the ACCC, and reviews are made to the ACT. The informal merger review regime is set out in the ACCC's Informal Merger Review Process Guidelines.[62]

Informal merger reviews

The ACCC's informal review process is not mandated by the CCA or other legislation; rather the process has developed over time to provide an avenue for parties to seek the ACCC's informal view prior to completion of an acquisition. An informal view by the ACCC not to oppose a merger does not protect merger parties from legal action by the ACCC or other parties.

Recent examples of the ACCC's informal merger review process concern:

1. iNova Pharmaceuticals Australia's proposed acquisition of Juno PC Holdings (withdrawn on 6 January 2020);[63]
2. Elanco Animal Health Incorporated's acquisition of Bayer Aktiengesellschaft's animal health business in July 2020; and
3. The proposed merger of Mylan NV and Pfizer's Upjohn Inc division (not opposed subject to undertakings on 10 September 2020).[64]
4. Sigma Healthcare Limited’s proposed acquisition of Chemist Warehouse Group Holdings under assessment at the time of writing.[65]

Another recent example is the ACCC's decision on 11 February 2022 not to oppose Wesfarmers Limited's (Wesfarmers) proposed acquisition of Australian Pharmaceutical Industries Limited (API).[66] Wesfarmers is a conglomerate that operates businesses including Bunnings (hardware), Officeworks (stationery), Kmart (retail department store), Target (retail department store) and Catch (online business model offering branded products on a first-party basis and a third-party online marketplace). API is a pharmaceutical distribution, health and beauty company that operates the Priceline retail business and is the franchisor for, and distributes products to, independently owned Priceline pharmacies.

The ACCC considered the likely impact of the proposed acquisition in Australian retail markets for over-the-counter pharmaceutical products and beauty and personal care products. It found that Wesfarmers and API were not close competitors in the relevant markets, and existing retailers in those markets would compete strongly with Wesfarmers after the acquisition.

Further, on 15 September 2022, the ACCC decided not to oppose the proposed acquisition by Zoetis Australia Research and Manufacturing Pty Ltd of Betrola Pty Ltd.[67] In Australia, subsidiaries of both companies were involved in the development, manufacture and marketing of animal health products for companion animals and livestock. The ACCC's decision not to oppose the proposed acquisition was subject to a Section 87B undertaking being offered by Zoetis, which was accepted by the ACCC (the 'Zoetis Undertaking'). The ACCC had concluded that, in the absence of the Zoetis Undertaking, the proposed acquisition would have the effect, or be likely to have the effect, of substantially lessening competition in the markets for the supply in Australia of intramammary antibiotics for lactating cows, intramammary antibiotics for dry cows and teat sealants, including because Zoetis would have the ability and incentive to increase prices in each of the relevant markets.

Finally, on 13 June 2024, the ACCC released a Statement of Issues concerning its assessment of the application for authorisation of the proposed acquisition by Sigma Healthcare's of Chemist Warehouse Group Holdings. Sigma is a publicly listed Australian company with wholesale, distribution and retail pharmaceutical operations. Chemist Warehouse is an unlisted Australian public company that is the franchisor of around 600 pharmacies. The entities are therefore in both horizontal and vertical relationships. The ACCC noted five 'issues that may raise concern' under the CCA, which include: (1) raising barriers of entry due to the extent of vertical integration; (2) reduction in competition in pharmacy retailing; (3) foreclosure of retail pharmacies; (4) further reduction of retail pharmacy competition through access and use of Sigma-supplied independent pharmacies' data, and; (5) foreclosure of rival suppliers. The ACCC has invited interested parties to make submissions addressing the foregoing concerns.

The ACCC's informal merger reviews register[68] contains a list of all public informal merger reviews by the ACCC that are under consideration or completed.

To date, there are no Federal Court decisions in respect of merger authorisations under Section 50 of the CCA.

Merger reforms: a mandatory, suspensory regime

A mandatory, suspensory regime is proposed to come into effect in Australia on 1 January 2026, replacing Sections 50, 50A, 88 and 90(7) of the CCA.[69] Under this new merger clearance model, it is proposed that transactions meeting certain thresholds will be required to be notified to the ACCC[70] and will require the regulator's approval before they can proceed.

Under this proposal, announced by the Australian Federal Treasurer in early 2024, the ACCC's role will shift from purely advisory to administrative, becoming the primary decision-maker on merger approvals with legally binding authority, eliminating the need for Federal Court injunctions to halt mergers.

Following the enactment of the reforms, it is proposed that the merger review model will be divided into two phases. In PhaseI it is proposed that the ACCC will assess any likely anticompetitive effects arising from the merger; the 'substantial lessening of competition' test will be enhanced by the inclusion of 'creates, strengthens or entrenches a position of substantial market power'. This acknowledges the nexus between mergers and misuse of market power, emphasising the necessity to evaluate a market's competitive structure when assessing the overall effects of a merger.[71] The proposed reform will replace the current 'merger factors' under Section 50(3) with principles aimed at preserving competitive markets, and promoting consumer-friendly technical and economic progress, without hindering competition. In applying these principles, the ACCC will account for market structures; competitive conditions; actual and potential competition from businesses in Australia; the market position of the relevant enterprises and their economic and financial power. The substantial public benefits test is proposed to remain, but its assessment is proposed to be conducted separately in Phase II. This sequential approach will offer merger parties an additional exit point, whilst enhancing ACCC's determination on competition considerations.[72]

Subject to further consultation papers to be released in the course of mid to late 2024–25, the proposed reforms (in their current form) herald significant impacts on future mergers in Australia. First, though the appropriate thresholds remain to be determined by the Treasury, the introduction of financial and market share thresholds is expected to expand the scope of mergers subject to mandatory scrutiny. The ACCC's focus on serial or 'creeping' acquisitions and its newfound capacity to consider the cumulative effects of past deals means that companies will need to review their M&A activity from 1 January 2023 when contemplating post-reform mergers. Additionally, the front-loaded approach will necessitate increased legal costs and resources from parties preparing for merger filings. As notifiable mergers will no longer be finalised without the ACCC's approval, the relevant enterprises must exercise heightened caution to avoid gun-jumping risks and corollary penalties. Lastly, market participants may experience increased challenges in obtaining market power via integration or in altering existing market structures and dynamics.

Anticompetitive behaviour

As discussed in 'Effect of competition laws on the pharmaceutical sector', conduct involving intellectual property rights previously exempt from the anticompetitive conduct prohibitions in the CCA is now subject to those prohibitions. Two cases in which legal

action was taken by the ACCC to enforce the CCA are ACCC v. Pfizer[73] and ACCC v. Ramsay.[74]

ACCC v. Pfizer concerned the provisions of the CCA prior to the amendments made by the Competition and Consumer Amendment (Competition Policy Reform) Act 2017 and the Competition and Consumer Amendment (Misuse of Market Power) Act 2017 (the Amendments), which came into effect on 6 November 2017. This case was the first instance where the ACCC brought proceedings against a pharmaceutical company concerning misuse of market power and exclusive dealing.

In ACCC v. Ramsay, the ACCC brought proceedings against a pharmaceutical company regarding misuse of market power and exclusive dealing issues under the provisions of the CCA prior to the Amendments.

Anticompetitive conduct authorisations

On the application by one or more entities, the ACCC is empowered under Subsection 88(1) of the CCA to provide authorisations, thereby proving legal protection for conduct that would otherwise contravene the CCA. The test for granting those authorisations is the same as that applicable to formal merger authorisations (see 'Merger authorisation'). The type of arrangements for which authorisation is usually sought includes collective bargaining, industry levies and joint ventures or alliances.[75]

The ACCC made a concerted effort to grant such authorisations for pharmaceutical companies during the covid-19 pandemic to maintain the viability of the industry and ensure the availability of essential pharmaceuticals. For example, on 17 September 2020, the ACCC authorised the National Pharmaceutical Services Association to temporarily coordinate arrangements and associated conduct between its members and Community Service Obligation distributors for 'facilitating the supply of, and access to, medicines and pharmacy products'.[76]

The ACCC re-authorised the above conduct on 17 February 2022 and expanded the authorisation to allow collective bargaining in relation to possible vaccine distribution arrangements with the government.[77] As a condition of the authorisation, the ACCC included a monthly reporting requirement to maintain oversight over those arrangements until expiry of the authorisation on 28 February 2023. The authorisation was not renewed.-[78]

Outside of covid-19-related matters, the ACCC has taken a literal approach to the 'must not grant' language in the CCA and has sought to grant authorisations only where satisfied that the proposed conduct would not have the effect of substantially lessening competition or would otherwise result in a benefit that outweighs the detriment to the public. In this regard, the ACCC has emphasised the need for evidence establishing a proper basis to grant authorisations. It will also look to the parties to provide all the necessary evidence in support of an application for authorisation.

Cartel conduct

As discussed in 'Effect of competition laws on the pharmaceutical sector', participants in the pharmaceutical industry are liable for cartel conduct should they enter into a contract, arrangement or understanding to cooperate and, therefore, inhibit the competitive process.

Common examples of cartel conduct include price-fixing, coordinating output restrictions, market sharing and bid rigging.

A recent example is the prosecution of Alkaloids of Australia Pty Ltd (Alkaloids), an Australian producer and supplier of the active pharmaceutical ingredient in antispasmodic medications (SNBB), and its former export manager, Christopher Kenneth Joyce. On 26 October 2021 and 16 November 2021, Joyce and Alkaloids, respectively, pleaded guilty to numerous charges brought by the Commonwealth Director of Public Prosecutions and admitted to further offences relating to their conduct, including price-fixing, bid rigging and market allocation cartel arrangements between Alkaloids and other overseas SNBB suppliers over a near 10-year period.[79] On 29 November 2022, the Federal Court of Australia handed down approximately A$2 million in fines to Alkaloids and sentenced Joyce to 32 months' imprisonment to be served by way of intensive correction in the community, 400 hours of community service, a fine of A$50,000 and disqualification from managing a company for five years.[80]

Outlook and conclusions

The law affecting pharmaceutical patents continues to evolve in a number of important respects, including with regard to:

1. the law on support, sufficiency and priority under amendments to the Patents Act made by the Raising the Bar legislation;[81]
2. the elucidation of the principles applicable to the construction, infringement and validity of Swiss-style claims and method of treatment claims;[82] and the law of novelty relevant to method of treatment claims;[83]
3. the practical application of the principles relating to the grant of interlocutory injunctions;[84]
4. the principles applicable to determining claims to damages in patent infringement cases that in turn affect the consideration of the balance of convenience in applications for interlocutory injunctions;[85]
5. the right of the Commonwealth to compensation from the patentee under the usual undertaking as to damages given in return for the grant of an interlocutory patent injunction; [86] and
6. the law on the patentability of computer-implemented inventions with potential implications for the development of medical technology[87].

At the same time, regulatory changes may significantly affect the litigation landscape, including in particular any generic/biosimilar early patentee notification regime and patent settlement register that may be introduced.

In addition, recent changes to the CCA have brought the settlement of intellectual property law disputes into sharper focus, involving, as such settlements often do, agreements between actual or potential competitors. Careful analysis of the competitive situation is warranted. The potential for those changes to affect behaviour in the pharmaceutical

sector is significant given the pivotal role of patents in creating exclusive rights for significant products in important therapeutic areas.

Endnotes

1 The recent Federal Court decision in Zoetis Services LLC v Boehringer Ingelheim Vetmedica GmbH [2024] APO 4 also addressed method of treatment claims. Back to section

2 Aristocrat Technologies Australia Pty Ltd v Commissioner of Patents (No 3)[2024] FCA 212; UbiPark Pty Ltd v TMA Capital Australia Pty Ltd (No 2) [2023] FCA 885; Motorola Solutions, Inc. v Hytera Communications Corporation Ltd (Liability) [2022] FCA 1585. Back to section

3 The TGA's website notes in respect of this measure "None of the options canvassed during consultation received consensus support and therefore the proposed measure…was not progressed". Back to section

4 Therapeutic Goods Administration (TGA), 'Overview of supplying therapeutic goods in Australia' (28 August 2020). Back to section

5 See Sections 30EA, 32HA, 41KA and 42V TGA Act. Recall provisions under the Consumer Law apply when a therapeutic good is a consumer good; however, therapeutic goods that do not meet the definition of consumer goods (i.e., goods intended for personal, domestic or household use) are not subject to the Consumer Law. These include medical devices used in hospitals and goods used strictly in the practice of medicine and not supplied directly to consumers for personal, domestic or household use. See Section 2, Schedule 2 of the Consumer Law in the Competition and Consumer Act 2010 (Cth) (CCA). Back to section

6 Regulations 12 and 12A, Schedule 5 and Schedule 5A TG Regulations. See also footnote 2. Back to section

7 TGA, 'Legislation & legislative instruments'. Back to section

8 Department of Veterans, 'Pharmacy information for providers' (29 June 2022). Back to section

9 Pharmaceutical Benefits Scheme (PBS), 'RPBS Explanatory Notes'. Back to section

10 PBS, Explanatory Notes, Section 1(4) Patient Charges. Back to section

11 Section 67 of the Patents Act. Back to section

12 Section 68 of the Patents Act. Back to section

13 Section 70 of the Patents Act. Back to section

14 Section 70(2) of the Patents Act. Back to section

15 Section 77 of the Patents Act. Back to section

16 [2022] FCAFC 39. Back to section

17 [2022] FCAFC 40. Back to section

18 Section 6A of the CCA. Back to section

19 Section 50 of the CCA. Back to section

20 Section 47 of the CCA. Back to section

21 Section 48 of the CCA. Back to section

22 Section 45 of the CCA. Back to section

23 Section 46 of the CCA. Back to section

24 Section 45AD of the CCA. Back to section

25 Section 224 of Schedule 2 of the CCA. Back to section

26 Section 45AF of the CCA. Back to section

27 TGA, 'Australian Regulatory Guidelines for Prescription Medicines (ARGPM)'. Back to section

28 TGA, 'Australian regulatory guidelines for biologicals (ARGB)' (24 November 2021). Back to section

29 TGA, 'Prescription medicines registration process' (12 August 2021). Back to section

30 Regulation 16C(3) TG Regulations. Back to section

31 But this excludes requests for additional trade names. Back to section

32 TGA, 'Fees and charges: summary From 1 July 2024' (Version 1, July 2024). Back to section

33 ibid. Back to section

34 Specific issues may also be referred to the Pharmaceutical Subcommittee of the Advisory Committee on Medicines. Back to section

35 TGA, 'Priority registration process: For prescription medicines with priority determination' (Version 1.2, August 2018). Back to section

36 See footnote 32. Back to section

37 TGA, 'Provisional registration process: For prescription medicines with provisional determination' (Version 1.1, August 2018). Back to section

38 The statutory time frame for provisional registration is 255 working days (Reg 16C(3) TG Regulations). Back to section

39 See footnote 32. Back to section

40 Section 32A of the Therapeutic Goods Act 1989 (Cth): the Secretary may determine that a specified thing is or is not a biological. See TGA, 'What is regulated as a biological Australian Regulatory Guidelines for Biologicals (ARGB)' (Version 3.0, January 2020).- Back to section

41 TGA, 'Pathways for supply of biologicals: Australian Regulatory Guidelines for Biologicals (ARGB)' (Version 1.0, July 2018). Back to section

42 ibid. Back to section

43 TGA, 'Classification of biologicals: Australian Regulatory Guidelines for Biologicals (ARGB)' (Version 2.1, November 2020). Back to section

44 TGA, 'Applying for inclusion of a Class 2, 3 or 4 biological on the ARTG – a step-by-step guide' (Version 1.1, November 2020). Back to section

45 See footnote 32. Back to section

46 TGA, 'Applying for inclusion of a Class 1 biological in the ARTG' (23 June 2021). Back to section

47 TGA, 'Biosimilar medicines regulation' (Version 2.2, April 2018). Back to section

48 The TGA's website at https://www.tga.gov.au/submissions-received-and-tga-response-transparency-measures-prescription-medicine stating in respect of these measures "None of the options canvassed during consultation received consensus support and therefore the proposed measure…was not progressed". Back to section

49 At https://www.tga.gov.au/resources/prescription-medicines-under-evaluation Back to section

50 Sigma Pharmaceuticals (Australia) Pty Ltd v. Wyeth [2018] FCA 1556; H. Lundbeck A/S v Sandoz Pty Ltd [2018] FCA 1797; Sanofi-Aventis Deutschland GmbH v Alphapharm Pty Ltd (No 3) [2018] FCA 2060; Biogen International GmbH & Anor v. Pharmacor Pty Limited [2021] FCA 1591; Mylan Health Pty Ltd v Sun Pharma ANZ Pty Ltd (No 2) [2019] FCA 505 and Mylan Health Pty Ltd v Cipla Australia Pty Ltd [2019] FCA 506. Back to section

51 Diana Biscoe, Rosie Finalyson and Andrew Christopher, '"Pay-for-delay" Arrangements in the Pharmaceutical Industry: How will They Be Treated under Australian Competition Law?' (2023) 31(2) Australian Journal of Competition and Consumer Law 111, 121. Back to section

52 Joined Cases C-501/06P, C-515/06P and C-519/06P, GlaxoSmithKline Services Unlimited, formerly Glaxo Wellcome plc v. Commission and Commission, EAEPC and Aseprofar v. GlaxoSmithKline Services Unlimited, formerly Glaxo Wellcome plc. Back to section

53 Australian Competition and Consumer Commission (ACCC), 'Compliance & enforcement policy and priorities'. Back to section

54 Section 155 of the CCA. Back to section

55 Division 6 of the CCA. Back to section

56 Infringement notices are issued where the ACCC believes that a contravention of the CCA requires a more formal sanction, rather than an administrative resolution, but where legal action is not required. Back to section

57 ACCC, '2024–25 Compliance and Enforcement Priorities'. Back to section

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59 ACCC, 'Merger authorisation Guidelines' (October 2018). Back to section

60 Section 90(7) of the CCA. Back to section

61 ACCC, 'Merger Authorisation Guidelines' (October 2018). Back to section

62 ACCC, 'Informal Merger Review Process Guidelines 2013', (7 November 2017). Back to section

63 ACCC, 'iNova Pharmaceuticals (Australia) Pty Ltd – Juno PC Holdings Pty Ltd' Back to section

64 ACCC media release, 'Divestments overcome strong competition concerns with pharmaceutical merger' (10 September 2020) Back to section

65 ACCC, 'Sigma Healthcare Limited – Chemist Warehouse Group Holdings' Back to section

66 ACCC, 'Wesfarmers Limited – Australian Pharmaceutical Industries Limited'. Back to section

67 ACCC, 'Zoetis Australia Research and Manufacturing Pty Ltd – Betrola Pty Ltd (including Jurox Pty Ltd)'. Back to section

68 ACCC, 'Public Informal merger reviews'. Back to section

69 The Treasury, 'Merger Reform: A Faster, Stronger and Simpler System for a More Competitive Economy' (10 April 2024). Back to section

70 Ibid. Monetary thresholds: the acquirer or target has an annual turnover of A$400 million or more, or if the global transaction value is A$35 million or more. A market share threshold capturing anti-competitive deals with lower revenue is currently under consultation at the Treasury. Back to section

71 Ibid 9. Back to section

72 Ibid 10. Back to section

73 Australian Competition and Consumer Commission v. Pfizer Australia Pty Ltd [2015] FCA 113. Back to section

74 Australian Competition and Consumer Commission v. Ramsay Health Care Australia Pty Limited [2020] FCA 308. Back to section

75 ACCC, 'Authorisation'. Back to section

76 ACCC, 'National Pharmaceutical Services Association (NPSA)'. Back to section

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78 ACCC, 'National Pharmaceutical Services Association Limited (NPSA) and Ors'. Back to section

79 ACCC, 'Former export manager of pharmaceutical ingredient company pleads guilty to criminal cartel charges' (26 October 2021). Back to section

80 Commonwealth Director of Public Prosecutions v. Alkaloids of Australia Pty Ltd [2022] FCA 1424; Commonwealth Director of Public Prosecutions v. Joyce [2022] FCA 1423. Back to section

81 Merck Sharp & Dohme Corporation v Wyeth LLC (No 3) [2020] FCA 1477; Cytec Industries Inc. v Nalco Company [2021] FCA 970; Jusand Nominees Pty Ltd v Rattlejack Innovations Pty Ltd [2022] FCA 540; Jusand Nominees Pty Ltd v Rattlejack Innovations Pty Ltd [2023] FCAFC 178; ToolGen Incorporated v Fisher (No 2) [2023] FCA 794. Back to section

82 Mylan Health Pty Ltd v. Sun Pharma ANZ Pty Ltd [2020] FCAFC 116;Neurim Pharmaceuticals (1991) Ltd v Generic Partners Pty Ltd (No 5) [2024] FCA 360. Back to section

83 ibid. Back to section

84 ibid. See also Sanofi-AventisDeutschland GmbH v. Alphapharm Pty Ltd (No. 3) [2018] FCA 2060 and Biogen International GmbH & Anor v. Pharmacor Pty Limited [2021] FCA 1591. Back to section

85 Commonwealth of Australia v. Sanofi (No. 5) [2020] FCA 543; Sigma Pharmaceuticals (Australia) Pty Ltd v. Wyeth [2018] FCA 1556; Lundbeck in H Lundbeck A/S v. Sandoz Pty Ltd [2018] FCA 1797; and Generic Health Pty Ltd v. Bayer Pharma Aktiengesellschaft [2018] FCAFC 183. Back to section

86 Commonwealth of Australia v. Sanofi [2023] FCAFC 97; Federal Court of Australia Proceedings No. NSD 121 of 2012 Back to section

87 Aristocrat v Commissioner of Patents [2022] HCA 29; Aristocrat Technologies Australia Pty Ltd v Commissioner of Patents (No 3)[2024] FCA 212 UbiPark Pty Ltd v TMA Capital Australia Pty Ltd (No 2) [2023] FCA 885; Motorola Solutions, Inc. v Hytera Communications Corporation Ltd (Liability) [2022] FCA 1585. Back to section

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Summary

Introduction

Articles 6 and 196 of the Constitution establish that access to healthcare, including related products and services, is the duty of the government and the right of every Brazilian citizen. Following this constitutional principle, the government created the Unified Health System (SUS) through the enactment of Law No. 8,080 of 1990.

According to Article 199, Section 1 of the Constitution, private entities can have supplemental participation in the SUS, meaning that every Brazilian citizen can use both public and private healthcare services.

The Brazilian Ministry of Health (MoH) was entrusted by the Constitution with the duty to provide public healthcare and to coordinate SUS activities. It is also responsible for public healthcare policies and clinical protocols, as well as the regulation of medical treatments. The Brazilian Heath Regulatory Agency (ANVISA), a regulatory agency created by Law No. 9,782 of 1999 and subject to the MoH, has a mandate to monitor, control and regulate public health issues and has powers to regulate and supervise the registration, manufacture, distribution and dispensation of drugs (and, thus, ensure the health and safety of consumers). Together with the state and municipal health offices, ANVISA's role is to oversee the production and distribution of pharmaceutical products and to ensure their quality and safety to protect the health and welfare of consumers.

From a patent perspective, the National Industrial Property Institute (INPI) has primary legal jurisdiction to review patent applications. Previously, applications that referred to a pharmaceutical patent were subject to ANVISA's prior consent; however, this requirement was revoked by Law No. 14,195/2021. Accordingly, ANVISA no longer interferes in the patent registration process of pharmaceuticals. The roles of both authorities in the examination of pharmaceutical patents have historically been disputed in Brazil.

The Administrative Council for Economic Defense (CADE) is responsible for analysing and approving merger cases and investigating alleged anticompetitive practices in all economic areas, including the pharmaceutical industry, which has always been under close observation by the Brazilian antitrust authorities and authorities globally. Within its activities, CADE is entitled to investigate concentrations or anticompetitive conduct that could actually or potentially harm competition.

Year in review

From an antitrust standpoint, in a post-covid-19 scenario, last year we witnessed CADE acting more confidently in relation to the markets involved by the pharmaceutical industry, which is demonstrated by the confirmation of the traditional parameters and metrics for the analysis of these markets. For the competition authority, in the area of merger control, 2023 was marked by the consolidation of a relevant player in the onco-hermato and high-complexity drug sectors, which occurred as a result of the unrestricted approval of the transaction between Blau Farmacêutica and Laboratório Químico Farmacêutico Bergamo.

On the subject of repressing anticompetitive conduct, specifically in the pharmaceutical industry, we highlight CADE's decision in the Astellas/Apsen case – an example of the

authority's position on sham litigation investigations. CADE's decision to close this case highlights the difficulty in convincing the authority that an agent is practising sham litigation, especially in patent matters, which are often subject to a delicate balance of competences between CADE and the INPI. The Astellas/Apsen case points to the fact that the Brazilian competition authority needs a robust body of evidence to proceed in such situations – among other cases, this one also joins the list of sham litigation investigations that were prematurely closed, namely, not effectively converted into an administrative proceeding.

With respect to the industrial property field, some players of the pharmaceutical industry still try to maintain, in court, the extension of the validity term of some patents granted under the sole paragraph of Article 40 of the Brazilian Industrial Property Law, judged unconstitutional by Supreme Court in 2021. So far, more than 50 actions have been filed, but the majority of them were denied on the merits.

Legislative and regulatory framework

Health regulation by ANVISA

Pharmaceutical regulations are under the jurisdiction of ANVISA. Among its activities, ANVISA is in charge of the approval process required as a condition for pharmaceuticals to be commercialised in Brazil (either through local manufacturing or imports), pursuant to general rules provided under Law No. 5,991 of 1973 and Law No. 6,360 of 1976, and specific requirements provided under ANVISA's regulation for each category of pharmaceutical, notably Resolution RDC No. 753 of 2022, for synthetic pharmaceuticals.

All pharmaceutical products require registration, except those posing lower risks to health,[1] such as pharmaceuticals with specific concentrations of acids and calcium carbohydrate-based medications,[2] which are subject to notification only (and not approval).

ANVISA is also responsible for the certification and inspection of manufacturing plants in Brazil and abroad[3] and for post-marketing surveillance of pharmaceuticals (e.g., recall).-[4] Further, ANVISA and the state and municipal health authorities are responsible for issuing federal, and state and municipal healthcare licences, respectively, for companies to operate.[5]

Price control

Most pharmaceuticals are subject to price control, pursuant to mechanisms defined by ANVISA's Drug Market Regulation Chamber (CMED), created under Law No. 10,742 of 2003. In the case of pharmaceutical products that were not clearly exempted from CMED's control, a registration holder must obtain the CMED's approval for the respective price after approval and registration before ANVISA and before the launch of the product in the market. The CMED-approved price is the maximum selling price in the private market.

For pharmaceuticals under the CMED's control, the Chamber defines the final price for consumers and mandatory discounts for the public market.

Disputes around CMED pricing decisions are not uncommon, in particular because the CMED's parameters have been steady over the past years and poorly reflect an appropriate pricing regime to innovative pharmaceuticals, as consistently claimed by the pharmaceutical industry. A draft regulation to redefine the pricing mechanisms in place was published for public consultation from July to September 2021 in response to the sector demands for a more dynamic and investment-attractive environment, but it was likewise scrutinised and has not been converted into regulation so far. CADE's Department of Economic Studies (DEE/CADE) responded to this consultation, emphasising the need to carry out a broad review of the pricing methodology to ensure equality among players.

With the nomination of CMED's new Secretary Executive in August 2023, the expectation for the sector is that 2024 will be quite busy, considering the possible resumption of the review of the criteria for defining the prices of new products and new presentations and the need to provide specific rules for the price definition of advanced therapies.

Public purchases

Because access to health is a government duty under the Constitution, the government is one of the main purchasers of pharmaceuticals in the country. As a general rule, only pharmaceuticals incorporated in the MoH's formulary can be purchased by the government. The incorporation process is the responsibility of the National Commission for Technology Incorporation (CONITEC) and is mainly regulated under Law No. 9,784 of 1999, Law No. 12,401 of 2011 and Decree No. 7,646 of 2011, which was amended by Decree No. 11,161 of 2022, to update and reorganise CONITEC's internal operations and procedures and define the criteria to incorporate off label indications of pharmaceuticals registered with ANVISA into the public health system.

Sales of pharmaceuticals to government entities must follow the Brazilian public procurement laws and principles. These are provided under Law No. 14,133/2021, as well as Decree No. 10,024/2019, which set forth public tenders and public contract requirements at the federal level.

Given the decentralised structure of the Brazilian healthcare system, states, and municipalities, as purchasers of pharmaceutical products, are subject to specific local laws and regulations. Generally, public purchases are subject to strict transparency and publicity rules and must be guided by a balanced analysis involving quality and price criteria.

Intellectual property

From an intellectual property perspective, pursuant to Law No. 9,279 of 1996, patent protection is valid for 20 years (15 years for a utility model patent, which is defined by Law No. 9,279 of 1996 as an item of practical use, or any part thereof, provided that it is capable of industrial use, presents a new shape or layout and involves an inventive act that results in functional improvement in terms of use or manufacture thereof), counted from the filing date; however, the term for an invention patent cannot be fewer than 10 years (seven years for a utility model patent) counted from the granting date in Brazil.[6] The minimum term for patents was created to compensate for the time taken for the authorities to grant patents.

Pharmaceutical patent application used to require not only the INPI's review but also the prior consent of ANVISA, as previously provided in Article 229-C of the Industrial Property Law No. 9,279 of 1996 (LPI); however, in August 2021, Law 14,195/2021 revoked Article 229-C of the LPI, therefore abolishing the need for ANVISA's prior consent as a condition for granting a pharmaceutical patent.

In May 2021, the Brazilian Federal Supreme Court considered the sole paragraph of Article 40 of the LPI to be unconstitutional; therefore, it ruled that, as from the publication of its ruling, the legal provision establishing a minimum patent protection term of 10 years (for inventions) and seven years (for utility models), counted from the respective date of granting by the INPI, will not apply to patent applications of any kind.

Patents granted in reliance on the aforementioned legal provision remain intact, except (1) patents involving pharmaceutical products and processes, as well as health devices or materials; and (2) ongoing lawsuits filed until 7 April 2021 revolving around the constitutionality of the sole paragraph in Article 40 of the LPI. In those cases, the declaration of unconstitutionality will have retrospective effects (ex tunc).

The concrete effects already ensuing from the validity of patents on medications and health materials for periods longer than those set out in the main section of Article 40 are safeguarded, thus avoiding a review of contracts signed and existing before the Federal Supreme Court's determination.

The INPI estimated that within the 30,648 patents that at the time were effective under the aegis of the sole paragraph of Article 40 of the LPI, 3,435 patents (11.21 per cent) related to medications and health products would be directly affected by this decision.

The Competition Law

The main legal source for competition in Brazil is the Competition Law No. 12,529/11, which came into effect on 28 May 2012, replacing Law No. 8,884/94, and introducing several important changes to the Brazilian competition system. The Competition Law reshaped the Brazilian system for protection of competition and empowered CADE with relevant investigative and decision-making powers, as well as the necessary independence to comply with its legal obligations.

In this context, the Competition Law also sets forth the general rules for the mandatory merger control system and clarifies important definitions of anticompetitive conduct and applicable penalties and fines. To guide its decisions, CADE takes into account several resolutions and guidelines.

Innovation

The pharmaceutical market is driven by innovation, which is a key factor in the development of the sector. The pace of innovation usually outstrips updates in regulations, and the Brazilian healthcare market is no different in this regard.

Nonetheless, owing to the adverse effects of the covid-19 pandemic, the Brazilian regulatory framework has had to adapt quickly to respond to the demands of the emergency state of affairs and to promote access to vaccines and pharmaceuticals.

After prolonged debate, the Federal Physicians Council has published the long-awaited regulation on remote access to medical services, which was accompanied by the approval of Federal Law No. 14,510/2022, which authorised and regulated the practice of telehealth services across the country.

In May 2024, Brazil witnessed the sanctioning of Law No. 14.784/2024, which marked the first legal framework on the subject in the country and introduced new regulations for the prevailing ethical analysis process in clinical research involving human beings, post-research access standards, management of biological materials, and personal data treatment. These legislative changes are expected to foster incentives and increase investments in future research endeavours within the country. Brazil has the potential to be a major player in clinical research, due to its diverse multi-ethnic population for pharmacogenomic studies, a strong healthcare system with established health regulations, and a competitive advantage in terms of cost compared to other countries.

New drugs and biologics – approval, incentives and rights

Drugs

Only pharmaceuticals registered before ANVISA can be manufactured, imported and commercialised in Brazil,[7] and the application for registration of new pharmaceuticals can only be made by legal entities properly incorporated in Brazil and licensed according to the appropriate regulations.

As a rule, the registration application must be supported by a complete dossier, in which the data on the development, production, quality control and non-clinical and clinical data of the product must demonstrate the quality, efficacy and safety of the product.[8] Under exceptional circumstances provided under specific regulation (as is the case for medication for rare or highly severe diseases, genetic therapies or as needed to fight the covid-19 pandemic), ANVISA may accept a partially complete technical dossier of the product, provided that the applicant provides a formal commitment to further supplement data and evidence.

The application request for registration of pharmaceuticals will be reviewed by ANVISA. Depending on the technical complexity of the product and its clinical, economic and social benefits, ANVISA will classify the product into either the priority or ordinary category, which is important for defining the terms in which ANVISA must review and approve the pharmaceuticals.[9] Pharmaceuticals for neglected, emerging or re-emerging diseases, public health emergencies or serious debilitating conditions are classified under the priority category.[10]

For pharmaceuticals under ordinary classification, ANVISA must decide on the request within 365 days of the application date and, in the case of priority classification, within 120 days, with an extension being allowed for an additional period of one-third of the original term by a justifiable decision issued by ANVISA.[11] In the case of new pharmaceuticals

for rare diseases, ANVISA must approve or deny the application within 60 days of the application date[12]. Ifapproved , the registration must be published within 30 days.

Applicants must pay ANVISA's fees for registration of new pharmaceuticals. The fees are calculated based on the revenue of the applicant company. For registration of new pharmaceuticals, ANVISA's fees vary from 7,870.80 reais to 157,416 reais.[13] Fees apply regardless of the category of product.

Regarding regulatory exclusivity, there is no data exclusivity protection for pharmaceuticals in Brazil. Dossier data is protected by confidentiality obligations and under the unfair competition rules. As a rule, ANVISA must keep non-public data confidential until it falls into the public domain.

Generic and follow-on pharmaceuticals

Generic pharmaceuticals are defined as unbranded drugs that are similar to and intended to be interchangeable with a reference or innovative product, and that are generally produced after the termination of patent protection or other exclusivity rights, with proven efficacy, safety and quality. For new pharmaceuticals, only entities incorporated in Brazil and bearing the applicable licences can apply for registration of generics.

To apply for the registration of generics, the product must be therapeutically equivalent to a new pharmaceutical product and proven to produce essentially the same effects of efficacy and safety, as evidenced through bioequivalence and bioavailability studies.

There are no exclusivity rights granted to successful generic pharmaceutical applicants.

Biologics and biosimilars

The approval processes for new biologic products are the same as those for new pharmaceuticals. The application must also be supported by a complete technical and scientific registration dossier. Application of biosimilars, however, may follow either the comparative development pathway (based on similarity with the innovator) or the individual full-development pathway.[14] In sum, in the individual development pathway, the applicant must provide ANVISA with a complete technical and scientific registration dossier, including clinical and non-clinical data and immunogenicity studies.

In the comparability pathway, the biosimilar is approved upon comparison of its efficacy and safety attributes with a comparator product already approved by ANVISA and requires comparative preclinical and clinical studies to evidence the bio similarity between the comparator and the originator biologic product. In 2024, ANVISA published Resolution RDC No. 875/2024, which provides new rules to simplify the procedure of registration of biosimilar drugs through the comparative development pathway. Resolution RDC No. 875/2024 aims at modernising and accelerating the development and availability of such drugs in the country by exempting the performance of clinical and non-clinical studies in some cases and enabling the use of a reference biological drug registered with an equivalent foreign regulatory authority recognised by ANVISA.[15]

Regarding new pharmaceuticals that are intended to be used in the treatment of severe or high-mortality diseases, companies can apply for registration of new biologics for severe diseases or diseases with high mortality, with Phase II clinical trials (conducted with a

small group of patients) concluded and Phase III (with a bigger group of patients) ongoing, provided that the company demonstrates a high therapeutic efficacy or there is not an alternative treatment available in the market, or both.[16]

The registration of new biologic products or biosimilar products manufactured abroad may only be granted by ANVISA if the product is approved and released for use in its manufacturing country. Exceptionally, new biologic products and biosimilar products not registered in the manufacturing country can be registered before ANVISA because of epidemiological necessity. No exclusivity rights are granted to successful biologic or biosimilar applicants.

Patent linkage

Under Law No. 9,279 of 1996, any patent application remains confidential for 18 months from filing. After this period, any interested party may present documents and information to assist the INPI with the patent examination.

If the patent is ultimately granted, any interested party may file an administrative appeal or file a nullity action either to limit the scope of the patent or to declare its nullity. It is not common to have patent application discussions in pre-litigious mediation proceedings. Although this dispute resolution method is perfectly valid in Brazil and its use has been increasing in recent years, it is not often used for patent disputes.

Law No. 9,279 of 1996 provides for a compulsory licence mechanism by which a patent licence is granted to third parties without the consent of the holder. Compulsory licences can be applied against a patent granted in Brazil in the following scenarios:

1. abusive exercise of the patent rights or abusive exercise of economic power duly evidenced and declared by an administrative or judicial decision;
2. lack of exploitation of the patent in Brazil (except in the case of economical infeasibility to do so, a situation in which the importation of the product will be authorised);
3. insufficient commercialisation to meet market demand;
4. a situation involving dependent patents; and
5. national or international emergency, state of public calamity or public interest events declared by the government.

The case in point (e) was an amendment provided by Law 14,200/2021, which altered Article 71 of the LPI, providing for the inclusion of international emergency scenarios as events that justify compulsory licences, state of public calamity as an event that justifies compulsory licences and other specific guidelines for the application of these new scenarios. The amendment is a direct result of the covid-19 pandemic, since, in theory, compulsory licences would enable more companies to provide vaccines and, therefore, contribute to public welfare.

Competition enforcers

CADE is the primary competition authority in Brazil. Its structure comprises two main entities: the Administrative Tribunal, composed of a president and six commissioners, and the General Superintendence.

The General Superintendence is the authority that first receives and analyses merger cases in Brazil. It may issue either a definitive decision to approve the transaction or a non-binding decision referring more complex transactions to the Administrative Tribunal for further investigation and issuance of a final decision.

In relation to anticompetitive conduct, the General Superintendence is responsible for conducting a fact-finding and investigating the case to provide the Administrative Tribunal with a complete report and suggestions on how to rule the case. The Administrative Tribunal is ultimately responsible for deciding on the existence of anticompetitive conduct and defining and imposing the applicable penalties.

The Administrative Tribunal is also responsible for the analysis of merger cases referred by the General Superintendence and cases in which third parties appeal the General Superintendence's approval decisions. The Administrative Tribunal may also request to review transactions approved by the General Superintendence.

Sensitive markets, such as the pharmaceutical market, have historically occupied an important position in CADE's agenda. Regarding merger control, CADE has developed cautious analysis on transactions submitted for review, requiring merger remedies in more complex cases to avoid concentrations that could reduce competition. More recently, it has also indicated its concerns regarding acquisitions of small entrants by incumbents to identify and prevent possible 'killer acquisitions'.

Regarding anticompetitive behaviour, CADE has conducted a number of investigations into the pharmaceutical industry, especially related to sham litigation, collusive practices on commercialisation of inputs and final products, and bid rigging in both the private and public sectors. It has also expressed concerns about disclosing tables on drug prices and possible price abuses in the context of the covid-19 pandemic.

Merger control

The Competition Law adopts a pre-merger control regime, pursuant to which competition approval is a condition precedent for the closing of a transaction for which filing is mandatory. Any acts of consummation carried out before CADE's approval are subject to fines and other penalties.

Certain types of transactions (e.g., mergers, acquisitions, joint ventures and associative agreements)[17] are subject to mandatory notification to CADE when:

1. at least one of the involved economic groups[18] registered gross revenues or volume of businesses equal to or exceeding 750 million reais in the year preceding the transaction in Brazil; and

2. at least one other involved economic group registered gross revenues or volume of businesses equal to or exceeding 75 million reais in the year preceding the transaction in Brazil.

There are no specific rules for transactions in the pharmaceutical industry.

The definition of relevant markets

Relevant product market

The relevant product markets related to the pharmaceutical industry, more specifically in relation to drugs for human health, take into consideration the Anatomical Therapeutic Chemical (ATC) classification system – usually levels 3 and 4 – and the therapeutic indication of each drug.[19] The ATC system, developed by the European Pharmaceutical Marketing Research Association and by the Intercontinental Medical Statistics, classifies drugs into four levels, indicating the level of substitutability between products, based on the similarities in each of those categories.

CADE recognises that, in certain cases, the ATC classification can be either too broad, encompassing non-substitute products designed for distinct uses, or, in other cases, too strict, when it sets aside important substitutes for the drug under scrutiny.

Considering these difficulties when adopting a market definition solely based on the ATC, CADE may also rely on the therapeutic prescriptions of the drug (identifying treatment protocols used in Brazil or abroad). Under this approach, it may find actual substitutes for the drug, based on the market perception and practice.[20]

A third criterion already discussed in past rulings issued by CADE is the distinction between over-the-counter drugs and drugs that demand medical prescription. This differentiation is relevant in distinguishing the level of choice of consumers, considering that prescription drugs usually have limited advertising and have the prescription as a choice-limiting factor.[21]

Geographic relevant market

CADE's settled precedents confirm that the scope of the geographic market is national, to the extent that drugs registration with ANVISA is granted to firms established in Brazil.[22] CADE has also considered drugs distributors to be capable of reaching the entire national territory.[23]

Barriers to entry

It has already been recognised by CADE that the pharmaceutical market has relevant regulatory barriers to entry to the extent that the process for development of a drug and the issuance of requisite registrations by the competent bodies take time and involve considerable costs. CADE has described factors that constitute market entry barriers, including high investment costs, the time required for registration at ANVISA, the

minimum time required for an entrant to initiate its activities and the existence of patent requirements.[24]

Relevant cases

GSK/Novartis

The first transaction conditioned to merger remedies in the pharmaceutical market after Law 12,529/2011 was the creation of a joint venture between GlaxoSmithKline plc (GSK) and Novartis AG (focused on over-the-counter healthcare products).[25] CADE understood that the merger could raise high concentrations in the anti-smoking drugs market.

To mitigate this concern, the companies committed to a structural remedy in the form of the divestment of a package of assets related to its main anti-smoking product, including tangible and intangible assets, such as intellectual property rights, licences and contracts. The parties also committed to a behavioural remedy, agreeing to adopt measures to avoid undue information exchange between the joint venture partners.

SM/All Chemistry

In March 2019, the Administrative Tribunal ruled on the acquisition by SM Empreendimentos Farmacêuticos Ltd (SM) of All Chemistry do Brasil Ltd.[26] The main discussion in the case was related to the fact that SM's expansion strategy would include the acquisition of companies whose economic groups did not meet the revenue notification thresholds.

In this context, after a complaint was presented by a third party, CADE became aware of the transaction and required its notification, even though the turnover filing thresholds were not met. It understood that SM's dominance would cause a bottleneck effect in the pharmaceutical compounding market, raising barriers to access of final consumers to medicines to fit the unique needs of a patient; thus, approval of the transaction was conditioned on a set of behavioural remedies.[27]

GSK/Pfizer

In July 2019, a joint venture between GSK and Pfizer Inc (Pfizer)[28] (combining the companies' healthcare divisions) was approved by the Administrative Tribunal after the parties committed to structural remedies. CADE understood that there were concerns related to the simple antacids (A2A1) market. GSK would be the market leader, and there would be few other relevant players in the market (only GSK, Hypermarcas and Pfizer held market shares higher than 5 per cent).

To address those concerns, the transaction's approval was conditioned on a structural remedy – the divestiture of Pfizer's Magnésia Bisurada business. The divestiture was combined with behavioural remedies to guarantee its effectiveness (i.e., related to the independence of the divestiture, transitional agreements and personnel availability).

Hypera/Boehringer

In August 2020, Hypera's acquisition of Boehringer's Buscopan and Buscofem businesses in Brazil was approved by the Administrative Tribunal after the parties agreed to a merger control settlement in which they committed to divest Hypera's Composed Neocopan business.[29]

The parties provided a 'fix-it-first' remedy according to which they entered into a binding divestiture agreement with a selected purchaser before CADE had completed its review of the main transaction. For that purpose, Hypera made a filing,[30] completing the divestment of the aforementioned business to União Química, and the transaction was approved in June 2020 (i.e., before CADE decided on the main transaction).

Considering that CADE had already approved the remedial merger before deciding on the main transaction, CADE's decision required entry into a settlement merger control agreement with behavioural remedies in the context of the main transaction, to guarantee that the divestment would be fully effective.

Hypera/Takeda

In January 2021, Hypera's acquisition of Takeda's portfolio of Eparema, Xantinon, Nenê-Dent, Albocresil, Venalot, Nebacetin, Neosaldina, Ad-Til, Alektos, Nesina, and Dramin, as well as other related tangible and intangible assets, was approved by the Administrative Tribunal after the parties agreed to a merger control settlement in which they committed to divest its Xantinon and Xantinon Complex's businesses.[31]

In line with the solution adopted in Hypera/Boehringer, the parties provided a fix-it-first remedy according to which the aforementioned businesses were divested to União Química.[32] This parallel transaction was approved in October 2020, before CADE's decision on the main transaction.

The Administrative Tribunal conditioned the approval of the transaction on the compliance of a merger control agreement with behavioural remedies to guarantee that the divestment would be fully effective.

Pague Menos/Extrafarma

In June 2022, the acquisition by Pague Menos of Extrafarma was approved by the Administrative Tribunal after the parties agreed to a merger control settlement in which they committed to divest pharmacies in eight municipalities in the states of Ceará, Maranhão and Rio Grande do Norte.[33]

The parties provided a fix-it-first remedy: the applicants appointed a designated buyer, who was approved by CADE's commissioner who was directly involved in the negotiation. The commissioner understood that the Bruno Farma chain – the designated buyer – would be able to rival the applicants in the municipalities in which the competitive environment would be harmed by the main transaction. The transaction was, therefore, approved, conditional on entry into a merger control agreement in which the applicants agreed to complete the divestment to the designated buyer and comply with other behavioural remedies that guaranteed that the divestment would be fully effective.

Blau Farmacêutica/Laboratório Químico Farmacêutico Bergamo

In May 2023, after approval from CADE,[34] Blau Farmacêutica completed the acquisition of Laboratório Bergamo from the Amgen group. With the conclusion of the transaction, Blau Farmacêutica now has one of the most complete portfolios in the onco-hemato segment, with one of the largest production capacities in Brazil and a total addressable market of approximately 10 billion reais. They also consolidate their leadership position in high-complexity drugs.

Although the transaction did not have the imposition of remedies by CADE or the participation of interested third parties, it undoubtedly represented a relevant concentration in the Brazilian pharmaceutical sector, especially in drugs related to infectology, oncology, hematology, and nephrology.

Janssen/Lafepe/Nortec Química

In January 2024, CADE approved this transaction related to the transfer of technology, held by Janssen, to Lafepe and Nortec, to enable the latter two to produce and market, exclusively in the Brazilian public market, the drug darunavir, in its synthetic tablet form, in the context of a Technical Cooperation Agreement for the Development, Transfer and Absorption of Technology.[35]The transaction also involved Nortec producing and supplying Lafepe with the API darunavir, so that Lafepe could produce the synthetic drug. Darunavir is an antiretroviral medication used to treat and prevent HIV/AIDS.

This precedent confirms the traditional methodology adopted by CADE to estimate and define relevant markets in the pharmaceutical industry (ATC classification and therapeutic indication). An interesting point about the case is that CADE highlighted the pro-competitive aspects of the transaction, insofar as it expands the list of suppliers of protease inhibitors and APIs related to the treatment of AIDS, by enabling Lafepe to enter the market of supply of darunavir to the MoH. It should be noted that the MoH is primarily responsible for supplying antiretroviral drugs for the treatment of AIDS and, for this reason, it encourages partnerships between public and private institutions to expand access to drugs and health products considered strategic for the SUS.

Anticompetitive behaviour

In relation to CADE's role regarding punitive measures, the authorities are responsible for investigating and curbing alleged anticompetitive behaviour across a range of markets, including the pharmaceutical sector.

According to the Competition Law, anticompetitive practices encompass any acts that are intended or otherwise purport to produce the following effects, even if those effects are not achieved, and irrespective of fault:

1. limitation or distortion of, or other damage to, free competition or freedom of enterprise;
2. domination of a relevant market for goods or services;
3. an arbitrary increase in profits; and
4. engagement in the abuse of a dominant position.

Within this context, the Competition Law provides for a non-exhaustive list of practices that may be considered anticompetitive, including collusion and abuse of dominance.

Sham litigation

The Competition Law was amended through the addition of the following to the list of anticompetitive practices: 'the exercise or exploitation of industrial or intellectual property rights, technology or brands in an abusive manner'. Even though this conduct was already subject to punishment under the original legislation, listing it as a specific example signals that this type of conduct was significantly under CADE's radar at the time the law was enacted. This movement reflects upon recent claims of sham litigation involving intellectual property rights in the pharmaceutical sector.

A paradigmatic case involving sham litigation in Brazil commenced after a complaint was made to CADE by the Brazilian Association of Generic Drug Manufacturers against Eli Lilly do Brasil Ltd and Eli Lilly and Company (the defendants). The investigation refers to proceedings[36] in which the defendants filed contradictory and misleading claims to obtain patent protection and exclusivity rights to commercialise the medicine Gemzar.

The patent requests were submitted to both the judiciary and the INPI. The improper acquisition of exclusivity by the defendants made it impossible for patients with severe health problems to acquire more affordable treatment using a similar or a generic drug and prevented competitors from entering the market; thus, consumers lacked alternatives to access potentially different treatments that could have been promoted by other pharmaceutical companies had innovation not been hindered by the defendants.

As a result, the companies were convicted for sham litigation under the new regime,[37] even though the conduct occurred under the original regime,[38] as CADE concluded that its terms were more beneficial to the defendants.

Still on the topic of sham litigation, after years of investigation, CADE decided to dismiss a case in which the practice was being assessed. According to the case files, Genzyme would have filed a series of judicial and administrative abusive measures to delay the entry of competitors in the market.

The investigation was dismissed as CADE concluded that the evidence related to the abusive practice was insufficient to lead to conviction. It also stated that sanctioning Genzyme would imply hindering the search for technological innovation, which could reduce the incentives for companies within the pharmaceutical sector to invest in research and development.[39]

Collusion

Merck SA was convicted in 2014 in an investigation relating to a collusive scheme to prevent the sales of generic drugs.[40] CADE found that Merck had colluded with the biggest pharmaceutical labs in Brazil to hinder the entrance of generic drugs into the country. It concluded that Merck's participation in a meeting with other competitors was enough to serve as evidence for the scheme and demonstrate the company's attempt to boycott the generics market.

According to the case files, Merck did not actively agree to the strategy being discussed in the meeting where the anticompetitive conduct allegedly took place. Supposedly, the meeting allowed the companies to discuss paying generic drug makers to keep their competing products off pharmacy shelves;[41] however, CADE concluded that the acceptance was implicit, and – even though the decision was not unanimous – ultimately decided to convict the company.

This precedent signals that CADE is concerned about the generics market in Brazil. Generics present a more affordable option for consumers, so it assists a significant portion of the population that does not have access to the originators' drugs. The entrance of generics in the market constitutes a pro-competitive measure, and, probably sensing the urgency of combating conduct that poses a risk to this market, the authorities decided to convict Merck, despite there being little evidence.

CADE has also convicted companies in the pharmaceutical industry for colluding in the context of public bids. In 2016,[42] CADE held two companies and four individuals responsible for cartel formation on the market of inputs for the development of antiretroviral medicines.

According to the case files, the investigated companies previously agreed on the outcome of the bidding process, by using mechanisms such as price-fixing, cover proposals and the suppression of proposals. As a result, the medicine produced by the public laboratories – targeted by the cartel – was overpriced as the inputs acquired at the bids were overpriced.

Other relevant investigations

More recently, CADE decided to initiate an administrative procedure[43] – which is ongoing as of the time of writing – to investigate whether disclosing tables on the price of hospitality materials and drugs to companies in the market (i.e., electronic publications by Brasíndice and Simpro) could constitute anticompetitive conduct. The tables were published in electronic magazines and, supposedly, could enable hospitals to impose those prices on health plans and entities that represent the companies in the healthcare sector to influence their associates to adopt the prices displayed in the tables.

In the context of the covid-19 pandemic, CADE initiated an investigation[44] against companies related to the hospitality and pharmaceutical industries to evaluate whether there was an arbitrary and abusive increase in prices because of the high demand for medical and pharmaceutical products. CADE issued requests for companies that produce masks, alcohol-based hand rub products, and medicines that treat covid-19 symptoms, etc., to instruct the analysis. In May 2022, the investigation was dismissed owing to insufficient evidence that an antitrust violation had occurred.

Notwithstanding CADE's intention to restrain competitive conduct during the pandemic, the authorities have also indicated that they worked towards facilitating – on an exceptional basis – cooperation between competitors to mitigate the harmful effects of the pandemic. There is a record of CADE having facilitated cooperation between (non-pharmaceutical) competitors in the retail sector.[45]

CADE has also entered a cooperation agreement with ANVISA to exchange information so that CADE can use ANVISA's knowledge of the pharmaceutical industry while analysing

mergers and investigating anticompetitive behaviour to decide on those matters more precisely and technically. The agreement was created in 2013 and was renewed in 2019.

CADE has also initiated an investigation against Gilead Sciences[46] regarding an alleged abusive increase in the prices of Sofosbuvir – a medicine used in the treatment of hepatitis C – after receiving a complaint filed by 10 different entities. The case was dismissed due to the lack of evidence of an infringement of the economic order. The investigation showed that the price limits imposed by sector regulations for the sale of Sofosbuvir were observed, as well as the gradual and recurring reduction in the average price of the drug, especially when purchased in large volumes by the MoH.

In addition, an unprecedented investigation was recently started at CADE involving the duration of drug patents.[47] Apsen Pharmaceuticals alleged that the company Astellas Pharma acts to illegally extend the patent on the substance mirabegrone – used in treatments for overactive bladder/urinary incontinence. Apsen Pharmaceuticals claimed that the competitor has held the patent for at least 24 years. The case is considered the first to reach the authority after the Federal Supreme Court denied the request of pharmaceutical companies that would extend patents for more than 20 years in cases of delay by the INPI.

Apsen Pharmaceuticals told CADE that there would be anticompetitive conduct in the drug market, due to the creation of difficulties by Astellas Farma Brasil for other companies to produce generic or similar drugs. According to the accusation, there would be sham litigation.

Astellas said in the process that the complaint is an attempt by Apsen to extend to the competitive field judicial disputes over its patents. According to the company, Apsen had imported mirabegrone and then applied for registration of generic and similar drugs at ANVISA.

On 24 July 2023, CADE's General Superintendence shelved the preliminary investigation, understanding that the facts would concern private relations between the parties, and remarking that the competition defence agencies do not have the mandate to intervene on commercial disagreements of a private nature. This understanding was confirmed by the Administrative Tribunal.

Finally, since 2021[48] CADE has been investigating potential occurrences of cartel practices between 1990 and 2019 within the pharmaceutical industry in the manufacture and commercialisation chain of antispasmodic drugs (Scopolamine-n-Butyl Bromide). In September 2023, CADE signed a Cease-and-Desist Agreement (TCC) with the pharmaceutical company Boehringer Ingelheim and one individual. Under the TCC, Boehringer Ingelheim, who confessed its participation in the cartel, had to pay more than 23 million reais. Later, in October 2023, TransoPharm Handels GmbH and two individuals have also signed a TCC with CADE, and committed to pay 356,346.6 reais. The celebration of such agreements suspends the investigation in relation to these companies and individuals until the final judgment of the case by the Administrative Tribunal, when compliance with the obligations set out in the agreements will be assessed. The investigation is still underway regarding the other companies and individuals who did not reach agreements with CADE.

Outlook and conclusions

Cases involving the pharmaceutical industry may attract great exposure as a result of the essential nature of the market affected. If mergers and anticompetitive conduct concerning drugs and other medical equipment pass unnoticed, the harm to consumers could be immeasurable. For this reason, cases within this industry usually receive in-depth analysis by CADE.

Regarding merger control, apart from conducting a cautious analysis of transactions submitted for its approval and imposing merger remedies in more complex cases, CADE has also been monitoring transactions that are not notifiable but that may pose risks to consumers. That notwithstanding, an excess of regulation may also hinder innovation incentives, which is an important consideration in a market that heavily relies on those incentives to grow and provide access to more efficient health treatments.

CADE's approach to anticompetitive conduct in the pharmaceutical industry is also cautious as it recognises the urgent need to combat anticompetitive practices that affect the industry.

Finally, as the pharmaceutical industry is one of the most regulated sectors in Brazil, it may be viewed as a challenging market; however, we have seen some movement by the government to increase access to pharmaceutical products through public policies. For example, it has incorporated risk-sharing agreements as a possibility for the development of highly innovative pharmaceutical products and public purchases. It has also established specific regulations concerning pharmaceuticals for rare, negligent and emerging diseases, and the relaxation of ANVISA's regulations in extraordinary situations, such as the covid-19 pandemic.

Acknowledgements

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Endnotes

1 Brazilian Heath Regulatory Agency (ANVISA) Resolution RDC No. 576 of 2021. Back to section

2 Among others listed under Normative Ruling No. 106/2021. Back to section

3 ANVISA Resolution RDC No. 497 of 2021. Back to section

4 ANVISA Resolution RDC No. 625 of 2022. Back to section

5 See ANVISA Resolution RDC No. 16 of 2014 and regulations issued by state or municipal authorities. Back to section

6 Sole paragraph on Article 40 of the Industrial Property Law No. 9,279 of 1996. Back to section

7 Law No. 6,360 of 1976. Back to section

8 ANVISA Resolution RDC No. 753 of 2022. Back to section

9 Law No. 13,411 of 2016. Back to section

10 ANVISA Resolution RDC No. 204 of 2017. Back to section

11 Law No. 13,411 of 2016. Back to section

12 ANVISA Resolution No. 205 of 2017. Back to section

13 ANVISA Resolution No. 857 of 2024. Back to section

14 ANVISA Resolutions RDC No. 55 of 2010. Back to section

15 ANVISA Resolution RDC No. 875/2024. Back to section

16 ANVISA Resolution RDC No. 55 of 2010. Back to section

17 Resolution CADE No. 17/2016 determines that 'associative agreement' stands for any agreement with a duration equal to or above two years that sets out a joint enterprise to pursue an economic activity, provided that, cumulatively: (1) the agreement provides for sharing of the corresponding risks and results of the economic activity that formed its object; and (2) the parties, by way of a contract, are competitors in the relevant market object of the agreement. Back to section

18 To calculate the groups' revenues, the general definition of 'economic group' takes into consideration companies under common control and companies in which any member of the group holds at least 20 per cent interest. Specific rules are applied to investment funds. Back to section

19 Merger No. 08700.001206/2019-90 (GSK/Pfizer); Merger No. 08700.001339/2020-08 (GSK/Stada); Merger No. 08700.001255/2020-66 (Hypera/Boehringer); Merger No. 08700.003553/2020-91 (Hypera/Takeda); Merger No. 08700.003276/2021-05 (Bayer/União Química); Merger No. 08700.002430/2022-02 (Fresenius Kabi Aktiengesellschaft/Insud Pharma, SL/INVIM Corporativo SL); Merger No. 08700.005071/2022-37 (Grünenthal Gmbh/Bayer aktiengesellschaft); and Merger No. 08700.001692/2022-41 (Mercury Pharma Group Limited/Janssen Pharmaceutica NV). Back to section

20 GSK/Pfizer, GSK/Stada, Hypera/Takeda, Bayer/União Química and Fresenius Kabi Aktiengesellschaft/Insud Pharma, SL/INVIM Corporativo SL. Back to section

21 GSK/Pfizer, GSK/Stada and Hypera/Takeda. Back to section

22 GSK/Pfizer, GSK/Stada, Merger No. 08700.005093/2016-59 (Sanofi/Boehringer-), Merger No. 08700.006159/2016-28 (Pfizer/AstraZeneca), Merger No. 08700.003725/2015-69 (Pfizer/Perkins/Hospira), Merger No. 08700.009834/2014-09 (União Química/Novartis), Hypera/Boehringer, Hypera/Takeda, Bayer/ União Química and Fresenius Kabi Aktiengesellschaft/Insud Pharma, SL/INVIM Corporativo SL. Back to section

23 See footnote 18. Back to section

24 Hypera/Takeda and Bayer/União Química. Back to section

25 Merger No. 08700.008607/2014-66. Back to section

26 Merger No. 08700.005972/2018-42. Back to section

27 The behavioural remedies included prohibition from participating in mergers and acquisitions of competitors for the next two years, submission for CADE's approval of any transaction of the same nature in the following two years and submission for CADE's approval of any transactions in the markets horizontally or vertically related to the analysed market for the next four years. Back to section

28 GSK/Pfizer. Back to section

29 Merger No. 08700.001226/2020-02. Back to section

30 Merger No. 08700.002536/2020-36. Back to section

31 Hypera/Takeda. Back to section

32 Merger No. 08700.004735/2020-89. Back to section

33 Merger No. 08700.005053/2021-74. Back to section

34 Merger No. 08700.000599/2023-09. Back to section

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36 Administrative Proceeding No. 08012.011508/2007-91. Back to section

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41 Competition Policy International, 'Brazil: Merck fined for pay-for-delay deal' (12 August 2014). Back to section

42 Administrative Proceeding No. 08012.008821/2008-22. Back to section

43 Administrative Procedure No. 08700.001180/2015-56. Back to section

44 Preparatory Procedure No. 08700.001354/2020-48. Back to section

45 Petition No. 08700.002395/2020-51. Back to section

46 Preparatory Procedure No. 08700.005149/2019-18. Back to section

47 Preparatory Procedure No. 08700.009881/2022-62. Back to section

48 Administrative Procedure No. 08700.004235/2021-28. Back to section

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Summary

Introduction

This chapter is a summary of China's laws and practices in the pharmaceutical sector. It includes a brief introduction on how drugs get approvals, how the originators and the generics may settle a pre-market patent infringement dispute, and how competition and mergers and acquisitions in this area could be reviewed by administrative and judicial authorities.

Legislative and regulatory framework

Introduction

Affairs concerning pharmaceuticals and medicines generally fall under the responsibilities of three government agencies. The National Medical Products Administration (NMPA) handles pre-market affairs, such as drugs' market authorisation and approval. The National Healthcare Security Administration (NHSA) focuses on ensuring reasonable pricing for drugs, especially pricings for public purchase. The State Administration for Market Regulation (SAMR) oversees competition-related issues, such as anticompetitive practices.

As for the applied law, the NMPA handles its affairs mostly pursuant to the Drug Administration Law of the People's Republic of China, amended in 2019 (the Drug Administration Law). The Drug Administration Law includes provisions on drug research and development (R&D), approval procedures, approval holders' obligations, requirements for manufacture and marketing, responsibilities of medical institutions, market supervision, pricing and advertising guidelines, and so on. In its last amendment in 2019, it is further approved, among other things, that NMPA approval holders and their management should be fully responsible for the drug's quality and its marketing activities, and that any drug with quality issues should be recalled.

The NHSA enforces the Social Security Law of the People's Republic of China (amended in 2018) and the Basic Medical Care and Health Promotion Law of the People's Republic of China (promulgated in 2019).

The SAMR regulates anticompetitive practices such as forming monopolistic agreements and abusing a dominant market position pursuant to the Antitrust Law of the People's Republic of China, amended in 2022 (the Antitrust Law), and supervises anticompetitive behaviours such as trade secret misappropriation, commercial bribery and false advertising according to the Anti-Unfair Competition Law of the People's Republic of China, amended in 2019 (the Anti-Unfair Competition Law).

Innovation encouragement

A fast track for getting NMPA approval, aimed at encouraging cutting-edge findings in this field, is established by the NMPA's regulations. The fast track applies to pharmaceuticals under certain categories (e.g., breakthrough therapy drugs) and accelerates their approval

process.[1] This path of 'accelerated approvals for drugs registration' will be coverd in more detail later.

Innovation by drug companies may also be promoted by legal mechanisms covered by other sectors of law. One example is the patent system.

A patent law system has been established in China by the Patent Law of the People's Republic of China (the Patent Law) since 1984. This system enables a patent rights holder to prohibit competitors from manufacturing and selling the same products, including drugs.

Under the current Patent Law, once granted by the China National Intellectual Property Administration (CNIPA), an invention patent will have a term of up to 20 years from its filing date.[2] In addition, the patent term may be further extended under certain circumstances.-[3] Considering the market exclusivity it provides and the generous profits it further implies, the patent law system is a major incentive for innovation within the drug industry.

New drugs and biologics – approval, incentives and rights

Drugs

Key regulatory authority for new drugs and biologics

The NMPA (also known as China FDA) is the main regulatory authority regulating pharmaceutical products, including new drugs and biologics in China.

The NMPA's Drug Evaluation Centre (CDE) is responsible for the review of clinical trial applications (IND), new drug applications (NDA) and marketing authorisation applications (MAA) for pharmaceutical products, including those manufactured overseas.

Definition and classification of new drugs

In general, the NMPA provides three registration categories: chemical drugs (small molecule drugs), biological products and traditional Chinese medicines.

In 2016, the NMPA introduced a new classification system for chemical drugs, which redefines 'innovative drugs' and 'generics'. 'Innovative drugs' or 'new drugs' now refer to drugs that have never been marketed anywhere in the world. Drugs never marketed in China but marketed overseas would be classified as 'generic'.

For details of the reformed registration classification for chemical drugs, see the table below.[4]

Classification	Definition/scope
Class 1	Innovative drugs that contain new chemical entities with clinical value and

New drugs never marketed worldwide	have never been marketed anywhere in the world.
Class 2 Improved new drugs never marketed worldwide	• Innovative drugs that contain known active ingredients which are isomers produced by splitting or synthesising, or the acetylating or salifying of known active ingredients (including salts containing named or coordinated bonds), or the modification of the acid radical, base or metallic element of known salt - forming active ingredients, or the formation of other non - covalent derivative compounds (such as chelates, integrates or inclusion compounds), which have significant clinical advantages. • Innovative drugs containing known active ingredients in new dosage forms (including new delivery systems), with new prescription processes, or new routes of administration, which have significant clinical advantages. • New compound formulations containing known active ingredients, which have significant clinical advantages. • Formulations containing known active ingredients for new indications or therapeutic uses.
Class 3 Generic marketed overseas but not in China	Active pharmaceutical ingredients and their formulations that have the identical active ingredients, dosage form, specifications, indications, route of administration, and posology as referencing originator drugs.
Class 4 Generic already marketed in China	Active pharmaceutical ingredients and their formulations that have the identical active ingredients, dosage form, specifications, indications, route of administration, and posology as referencing originator drugs.
Class 5	5.1 originator's drugs

Imported drugs marketed overseas	5.2 non - originator's drugs

Regulatory approval pathways for new drugs

To market a pharmaceutical product in China, pharmaceutical companies need to file and obtain the NMPA's approval for investigational new drug (IND) application or new drug application (NDA). The NMPA will grant a market authorisation approval based on its evaluation of the safety, efficacy and quality of new drugs and biologics.

IND application

The NMPA currently encourages clinical development of 'truly' innovative drugs based on clinical value. New drug research and development for registration purposes in China include Phase I–Phase IV studies and a bioequivalence (BE) study.[5]

An applicant may submit their IND application to the CDE along with the proposed study protocol, CMC, non-clinical data and existing clinical data, etc. IND approval will be issued by default within 60 working days unless the CDE notifies the applicant that the IND application is subject to clinical hold.[6]

Clinical trial exemption

Local clinical trials are generally required for new drug registration unless an exemption is granted. For foreign-manufactured drugs, a clinical trial exemption would be granted typically when (1) there are adequate overseas clinical data to support drug registration in China; and (2) the concerned drugs are in urgent clinical need. Acceptance of overseas clinical data largely depends on the CDE's evaluation of data quality, efficacy and safety of the drug product, and ethnic factors.

NDA application procedure

After completing the pre-clinical studies and clinical studies supporting the drug registration as well as the validation of the manufacturing process of commercial batches, the NDA applicant may file the application with the CDE for technical review.

The CDE may initiate regulatory on-site inspections with consideration of the risk level and innovation of the applied drugs and the credentials of the clinical sites. The NMPA may extend its inspections to vendors and suppliers of the NDA or biologic licence application (BLA) applicants.

Accelerated approval process for new drugs

The NMPA provides the following green channels to accelerate the regulatory approval of new drugs, including:

1. breakthrough procedure;
2. priority review;

3. conditional approval; and
4. special approval.

Breakthrough procedure

The NMPA allows sponsors to file the breakthrough designation procedure during the clinical trials for innovative drugs treating life-threatening diseases, and for which there are no effective alternative therapies or there is sufficient evidence of clear clinical advantages compared with existing treatments.[7]

For breakthrough therapies, sponsors may communicate with the CDE at clinical milestones and may submit the regulatory dossiers to the CDE for review on a rolling basis.[8]

Priority review

NDA applicants may apply for priority review upon the NDA when the concerned drug shows apparent clinical value, including:

1. drugs in shortage with urgent clinical need;
2. innovative and improved new drugs for preventing or treating serious infectious diseases and rare diseases;
3. innovative paediatric drugs with new formulation, dosage forms or strength;
4. vaccines in urgent need for disease prevention and control and innovative vaccines;
5. breakthrough therapies;
6. drugs entitled to conditional approval; or
7. other circumstances deemed appropriate by the NMPA.[9]

Conditional approval

Sponsors may apply for conditional approval during clinical trials when the investigational drugs are:

1. for the treatment of serious life-threatening diseases for which there is no effective treatment, whose efficacy during clinical trials has been confirmed by data and clinical value can be predicted;
2. in urgent public health need, whose efficacy during clinical trials has been confirmed by data and clinical value can be predicted; or
3. vaccines that are urgently needed in response to major public health emergencies or vaccines with urgent clinical need as designated by the National Health Commission (NHC).

Market authorisation holders (MAHs, i.e., NMPA approval holders) of the drugs approved with conditions need to conduct post-approval studies as required upon the approval and take appropriate risk-control measures. The NMPA may cancel the MA approvals if MAHs fail to complete the required post-approval studies within the designated timeline or the studies show that the risks outweigh the benefits.[10]

Special approval

In the event of the threat of a public health emergency and after the occurrence of a public health emergency, the NMPA has the authority to grant special approval for drugs in urgent clinical need for addressing the public health crisis. The drugs under special approval would be marketed and used within the limited period and scope as approved by the NMPA.[11]

Statutory timeline for NMPA regulatory review

In practice, the typical timeline for the NDA or BLA approval process would range from one to three years, while the accelerated approval process could shorten the review process to six to 18 months. The statutory timelines fir drug applications under the different regulatory pathways are as follows:

1. Regular process for NDA or BLA review: 200 working days;
2. NDA under priority review: 130 working days; and
3. NDA for orphan drugs marketed overseas in urgent clinical needs: 70 working days.-[12]

Generic and follow-on pharmaceuticals

Regulatory requirements for generic drugs and pharmaceuticals marketed overseas

'Generic drugs' refers to drugs that are the same as the original brand-name drugs in dosage, safety and efficacy, quality, mode of action, and indications. Generic drugs will be approved if their quality and efficacy are proven to be equivalent to the originator products. The NMPA encourages development of generics of a high quality with proven therapeutic benefits, and where there is a clinical need.

Usually generic drug applicants will file MAA with the CDE after completion of bioequivalent studies and any other studies that may be required by the CDE. The MAA process for generic drugs is similar to the NDA or BLA review process.

Special clinical requirement for imported drugs marketed overseas

Imported originator drugs marketed overseas are classified as Class 5.1 and treated as generics in China. For imported originator drugs marketed overseas, whether a local clinical trial is required largely depends on the clinical needs of Chinese patients, the quality of the overseas clinical data and ethnic factors (see the table below for more detail).[13]

Local clinical requirements	Evaluation results
Exemption from local clinical trials	After assessment, the drug has been found to be safe and effective and without any racial sensitivity.
Local bridging clinical trials	After evaluation, it has been determined that the concerned drug is safe and effective, but there is a lack of ethnic sensitivity data or the existing data indicating ethnic sensitivity.
Necessary local exploratory and confirmatory clinical trials	Insufficient data on safety and efficacy.
Local clinical trials are not advised	Clinical data shows ineffectiveness or safety concerns.

For imported non-originator drugs marketed overseas, whether a local clinical trial is required largely depends on the clinical evaluation results and formulation (see the table below for more detail).[14]

Consideration of clinical evaluation results	For non - originator drugs, drug applicants may not be able to conduct sufficient clinical evaluation of the originator drugs as it is difficult for the non - originator drug applicants to access the complete clinical trial data of the originator drug. Therefore, it is usually necessary to conduct local clinical trials to support the safety and efficacy evaluation of the non - originator drugs for Chinese patients.
Formulation	A reference drug should be determined for the non - originator drugs. Usually an originator product with sufficient efficacy and safety data approved by the European Medicines Agency (EMA), the US Food and Drug Administration (FDA), and the Japanese Pharmaceuticals and Medical Devices Agency (PMDA) should be selected as the reference drug. The quality and efficacy consistency between the non - originator products and the originator product should be demonstrated through studies based on the pharmaceutical and biopharmaceutical characteristics.

Biologics and biosimilars

Biologics

'Biological products' refers to preparations made from starting materials such as microorganisms, cells, animal or human tissues and fluids using biological technology, which are used for the prevention, treatment and diagnosis of human diseases.

Biological products are classified into prophylactic biological products, therapeutic biological products, and certain in vitro diagnostic reagents that are regulated as biological products.

To market a biological product in China, pharmaceutical companies need to file and obtain the NMPA's approval for IND application and BLA. The NMPA will grant a market authorisation approval based on its evaluation of the safety, efficacy and quality of the biologic.

The IND application and BLA procedures for biologics are similar to those applicable to new drugs mentioned above. Biologics are also entitled to the same accelerated regulatory pathways as mentioned above for new drugs.

Biosimilars

Biosimilars are therapeutic biologics that are similar in quality, safety and efficacy to those approved reference biologics. In principle, the amino acid sequence of a biosimilar candidate drug should be the same as that of the reference drug. If a different host cell or expression system is used in the development process than the reference drug, sufficient research should be conducted.[15]

Notably, in consideration of the potential high risk of biologics, unlike generic chemical drugs, biosimilars follow the regulatory pathway for innovation drugs, given that biological products have more complex structures and more complicated manufacturing processes.

Overview of NMPA drug registration fees

The registration fees of drugs manufactured overseas will also apply to drugs that are manufactured in Taiwan, Macau and Hong Kong.[16]

Applications		For locally manufactured drugs	For drugs manufactured overseas
New drug registration fees	IND applications	192,000 yuan	376,000 yuan
NDA or BLA	432,000 yuan	593,900 yuan	
Generic drug registration fees	MAA without clinical trials	183,600 yuan	367,600 yuan
MAA with clinical trials	318,000 yuan	502,000 yuan	
Supplementary application registration fee	No technical review required	9,600 yuan	9,600 yuan
Technical review required	99,600 yuan	283,600 yuan	
Registration renewal fee (once every five years)		Varies among provincial MPAs	227,200 yuan

Patent linkage

Legal framework

The Patent Law was recently amended in 2020, allowing a party to request a declaratory judgment from the court or the CNIPA on whether a generic product seeking NMPA approval infringes the brand-name drug's patent.[17] In response to the amendment, the CNIPA, together with the Supreme Court, issued several implementation regulations.[18]

These laws and rules jointly established a new patent linkage mechanism in China, which is in some degree similar to the Hatch-Waxman Amendments in the United States.

The new mechanism

The new mechanism launched a Patent Information Registration Platform for Drugs Marketed in China (the Platform), where an NMPA approval holder must, within 30 days of obtaining NMPA approval, register the patent information of the drug.[19]

Afterwards, when a generic applicant applies for NMPA approval, the applicant is required to submit certification regarding the relationship between its generic product and the patents held by the brand-name drug's sponsor, wherein a Category IV Certification indicates that the applicant believes these patents to be invalid, or that they will not be infringed by the generic product.[20] The generic applicant should also notify the brand-name drug's sponsor of its certification and reasons.[21]

The owner of the brand-name drug patent or its licensee may, within 45 days of the NMPA publishing the Category IV Certification, file a complaint and request a declaratory judgment from the court or the CNIPA.[22] Once the NMPA is notified that a complaint has been filed, the approval process of the generic product in question will be subject to a nine-month non-extendable stay.

Under the Chinese patent linkage mechanism, the declaratory judgment will only determine whether the generic product falls within the scope of the drug patent, without any deliberation on the patent's validity. However, the validity issue can be resolved simultaneously through a patent invalidation procedure before the CNIPA.

If, within the nine-month stay, a declaratory judgment is issued and holds that the generic product infringes the patent, the NMPA will suspend the processing of the generic product's approval until the expiry of the patent.[23] Otherwise, the generic application will be processed as usual.

The new mechanism also grants the generic applicant 12 months' market exclusivity on a 'first-challenge-and-first-successful' basis.[24] Within the exclusivity period, other generics of the same kind will not be approved. However, at the time of writing, none of generic drugs or applicants have actually obtained this exclusivity.

As for biosimilars, under the new mechanism, applicants for biosimilars are required to file the same certifications, and the brand-name drug company may thereby file a complaint, but the rules on stay period and market exclusivity do not apply.[25]

Statistics

By the authors' count and analysis of published case documents, as of May 2023, which is less than two years after the patent linkage mechanism had completely launched, 14 declaratory judgment requests had been brought up in court, and 54 with the CNIPA.

Out of the 54 cases filed with the CNIPA, 20 cases (37 per cent) were voluntarily withdrawn by the brand-name companies, implying that a settlement may had been reached or a concession by either party been made; five cases (9 per cent) were dismissed because the underlying patent had been wholly invalidated before the ruling; and one case (2 per cent) was dismissed due to procedural issues.

Among the 28 cases (52 per cent) on which the CNIPA issued its opinions, the brand-name companies won 17 (61 per cent of the opined cases) of them, while generic applicants won 11 (39 per cent of the opined cases).

As for the deliberation time, the CNIPA on average took about 6.5 months to decide the case, with the longest being 7.4 months (225 days), and the shortest being 5.7 months (175 days).

Competition enforcers

Authorities and jurisdictions

Anticompetitive and antitrust behaviours can either be reported to and investigated by the SAMR, or be sued in court.

Between 2012 and 2022, the SAMR and its local branches initiated 159 investigations concerning antitrust behaviours in the pharmaceutical industry, and more than 1.7 billion yuan was forfeited.[26]

The SAMR and its local branches may also initiate investigations and impose administrative penalties for 'anticompetitive' behaviours, such as trade secrets misappropriation, commercial bribery and false advertising.

In addition, individuals harmed by anticompetitive and antitrust behaviours have the right to file lawsuits in court as well.[27] The cause of actions in these lawsuits are the same as those in the administrative procedures. In general, the court will order the successful plaintiff to be compensated for its suffered losses. However, claims for punitive damages in such cases have no legal basis and would not be supported.

Law enforcement emphasis

The SAMR and its corresponding branches in local governments are the primary authorities supervising competition and antitrust matters.

From the perspective of the underlying act, monopolistic agreements are a common concern. In 2021, the SAMR and its local branches initiated 30 cases and proceedings related to horizontal and vertical monopoly agreements, resulting in 11 administrative penalty decisions, totalling 1.673 billion yuan in fines.[28]

However, the abuse of a dominant market position may lead to harsher penalties. These abusive behaviours include unfair high prices, refusal to deal, restrictions on transactions, bundle sales, imposition of unreasonable transaction conditions, and discriminatory treatment.[29] In 2021, the SAMR and its local branches issued 11 administrative penalty decisions under these scenarios, with fines totalling 21.847 billion yuan.[30]

As for the targeted industry, the SAMR has stressed repeatedly that the pharmaceutical industry, especially the active pharmaceutical ingredient (API) industry, has been, and continues to be, its antitrust law enforcement emphasis.[31] In 2021, the SAMR promulgated the Guidelines on Anti-Monopoly in the Active Pharmaceutical Ingredient Industry (the API Guidelines), providing interpretations on antitrust enforcement matters for API-related companies.

Promise made, and promise kept. In a typical case involving Yangtze River Pharmaceutical Group Ltd (Yangtze River), which manufactures and sells many kinds of drugs, the SAMR found that between 2015 and 2019, Yangtze River reached and performed price fixation and lowest price restriction agreements with distributors and retailers on many levels, thereby constituting vertical monopolistic agreements. In 2021, Yangtze River was fined by the SAMR approximately 764 million yuan, which accounted for 4 per cent of its revenue in 2018.[32]

Another noteworthy trend is antitrust behaviours utilising intellectual property, which have gained more attention from the authority than ever before.

In 2019, the SAMR issued Guidelines on Anti-Monopoly for Intellectual Property (the IP Guidelines). The IP Guidelines provide that, in certain circumstances, IP-related agreements concerning joint R&D, cross-licensing, licensing back, no-challenge clauses, or standard setting may be deemed anticompetitive.[33] The IP Guidelines also specify what acts can be found as abuses of a dominant market position.[34]

In 2020, the SAMR published a draft of special regulations on the same issues and solicited comments from the public, which further consolidates many of the rules in the IP Guidelines.[35]

Although there have not been many to date, more IP-related antitrust cases instituted by the SAMR could emerge in the near future.

Merger control

Legal framework

Mergers and acquisitions, with respect to antitrust issues, are governed by the Antitrust Law and the SAMR's Provisions on the Review of Concentrations of Undertakings (the

Merger Control Review Provisions, promulgated in 2023). Since 2019, the SAMR has had sole administrative jurisdiction on this subject matter.[36]

The Antitrust Law provides that no merger shall be implemented if the threshold of declaration is met, unless it has been declared to and reviewed by the Antitrust Law enforcement agency.[37]

When reviewing a declared merger plan, the SAMR exercises its discretion with the following factors taken into consideration:[38]

1. market shares of the merging parties and their control over the market;
2. degree of concentration in the relevant market;
3. potential impact on market access and progress of technology;
4. potential impact on consumers and other market participants;
5. potential impact on the development of the national economy; and
6. other factors having an impact on market competition that shall be taken into account.

The SAMR suggests that the impact on technology progress may be evaluated based on how the merger would affect the incentives and capacity for innovations, and the utilisation and integration of technologies. Further, the SAMR assesses the impact on consumers by examining the quantity, price, quality and diversification of products or services provided to the market.[39]

Evidently, merging parties should also consider legal requirements imposed by other authorities. For example, in the case of a foreign investment, it should be considered whether the merger entails any national security risks. If so, a foreign investment security review by the National Development and Reform Commission is required.[40] When the merger involves the import or export of technology, a technology import/export licence should be obtained from the Ministry of Commerce or its branches in local government.[41] Foreign investors should also be aware that foreign-controlled institutions are forbidden from collecting and preserving human genetic resources within the territory of China.[42]

Merging parties' arguments

Merging parties may consider raising one or more of the following defences during the SAMR's merger control review process:

1. the merger would benefit the economic efficiency;[43]
2. the merger would be in favour of the public interests;[44]
3. at least one of the merging parties is on verge of bankruptcy;[45] or
4. the buyer has countervailing bargaining power.[46]

Other than all of the above defences, merging parties may also propose their intention to obey certain restrictive conditions on the transaction or their business, in order to obtain

the SAMR's approval of other parts of the merger plan.[47] The proposed conditions will be assessed by the SAMR and can be further negotiated.

Case review

In 2018, Zhejiang Garden Biopharmaceutical Co, Ltd (Garden Biopharm), a Chinese company, declared to the SAMR that it intended to establish a new company in China with DSM Nutritional Products Nederland BV (DSM), a Dutch company. The new company would manufacture 7-Dehydrocholesterol (DHC) and would be jointly controlled by both shareholders. The total transaction amount was around 80 million yuan.

After review, the SAMR found that Garden Biopharm and DSM had horizontal business overlap in veterinary and human vitamin D3 markets, and a vertical business relationship in the NF grade cholesterol market. Therefore, the SAMR identified the global and China market as the relevant market.

The SAMR concluded that the merger may be anticompetitive, because the transaction could enhance both parties' control over the market, and further increase the market concentration degree and their price-fixing incentive and capability. The SAMR believed the transaction may also lead to a blockage on the supply of raw materials and clientele.

The SAMR and the merging parties engaged in multiple rounds of negotiation. Seeking the SAMR's approval, the merging parties proposed and committed to adhere to certain restrictive conditions after the transaction.[48]

In October 2019, the SAMR issued a decision that the establishment of new company was approved subject to the following requirements being observed for five years: (1) keeping all merging parties (including the new company) and their business independent; (2) restricting the new company from conducting business other than DHC manufacture; and (3) withholding the relevant prices in confidence.[49]

Anticompetitive behaviour

Pay-for-delay

Even though specific regulations have been promulgated earlier, cases concerning anticompetitive acts on IP are numbered, whether they are brought before the court or the administrative supervising agency. Most cases in this area relate to the exercise and license of standard essential patent rights.

The term 'pay-for-delay' normally refers to a scenario where the generic drug's applicant quits challenging the patent of the brand-name drug, after the brand-name company and patentee agrees to indemnify the applicant, usually with monetary means.

The SAMR has not inspected or investigated any 'pay-for-delay' agreement under the Antitrust Law, but the issue was judicially reviewed for the first time in 2022 in a patent infringement case, namely AstraZeneca v. Aosaikang Pharm (docket number (2021) Zui Gao Fa Zhi Min Zhong No. 388). The Supreme Court found that a submitted infringement

settlement agreement may be identified as a 'reverse-payment agreement' and then determined to review the legality of the agreement under the Antitrust Law ex officio.

The Supreme Court held that when determining whether a 'pay-for-delay' agreement lessened competition in the relevant market and thus should be regarded as anticompetitive under the Antitrust Law, the court should evaluate the possibility of the underlying patent being invalidated if the generic drug's applicant were to advance its invalidation petition with the CNIPA, and should further evaluate its impact on the competition.

For the likelihood of patent invalidity, the Supreme Court commented that an unreasonably high payment within such an agreement could imply that the underlying patent is more likely invalid.

For competitive harms, the Supreme Court held that such harm can be assessed based on whether the agreement substantially prolonged the patentee's market exclusivity, and whether it substantially delayed or precluded market entry of other generic applicants, in fact or in theory.

China is not a case law country, but the rules established by the Supreme Court in this case could easily be applied in the administrative or judicial antitrust review of other 'pay-for-delay' agreements in the future.

Sham litigation

Sham litigation generally refers to situations where the patentee asserts their patent rights against others even though they have noticed that the underlying patent is invalid.

The SAMR has not investigated such acts in the name of anti-competition and reviewed them under the Antitrust Law. But the Supreme Court has issued a judicial interpretation, recognising that the party harmed by sham litigation may request compensation for incurred expenses (e.g., attorney fees) from the bad-faith patentee.[50]

Product hopping and authorised generics

Product hopping refers to a situation where the brand-name drug's company launches another product with the same API just before the original patent is to expire. The new product may or may not have improvements in its formulation and dosage.

Authorised generics refer to when a brand-name drug's company or its licensee markets the approved drug without the brand name on label. The authorised generics normally are sold at a lower price than the brand-name drug, in order to keep other generics out of the market.

These scenarios have not been administratively or judicially reviewed under the Antitrust Law in China to date.

Outlook and conclusions

China has been underscoring the significance of intellectual property across all government levels and sectors, with the pharmaceutical sector being a recent example of legislating for more rigorous rights protection. On the other hand, under this administration's policy of 'making people have a sense of gain', it should be no surprise to see more scrutiny of antitrust behaviours in the drug industry in the coming years.

These two trends proceed simultaneously and intertwine with each other in certain scenarios. And we are expecting to witness more legislative, judicial and administrative progress being made in both trends in the near future.

Endnotes

1 Article 13 and Articles 59 to 81 of the Measures for the Administration of Drug Registration. Back to section

2 Article 42(1) of the Patent Law, as amended. However, the term is 10 years for a utility model patent and 15 years for a design patent. Back to section

3 Article 42(2) and 42(3) of the Patent Law, as amended (providing that the 20-year invention patent term can be further extended if: (1) the CNIPA unreasonably delays a patent application's prosecution; or (2) an invention patent related to the new drug for which a marketing approval is obtained from the NMPA will be allowed the extension of the patent term at the request of the patentee). Back to section

4 See the NMPA's Notice on Chemical Drugs Registration Classification and Application Requirements (2020). Back to section

5 Article 21 of the Measures for the Administration of Drug Registration. Back to section

6 Article 29 of the Measures for the Administration of Drug Registration. Back to section

7 Article 59 of the Measures for the Administration of Drug Registration. Back to section

8 Article 62 of the Measures for the Administration of Drug Registration. Back to section

9 Article 68 of the Measures for the Administration of Drug Registration. Back to section

10 Article 63 of the Measures for the Administration of Drug Registration. Back to section

11 Articles 72–74 of the Measures for the Administration of Drug Registration. Back to section

12 Article 96 of the Measures for the Administration of Drug Registration. Back to section

13 See NMPA's Technical Guidelines on Clinical Requirements for Drugs Marketed Overseas But Not In China (2020). Back to section

14 See NMPA's Technical Guidelines on Clinical Requirements for Drugs Marketed Overseas But Not In China (2020). Back to section

15 See NMPA's Technical Guidelines on Development and Evaluation of Biosimilar (2015). Back to section

16 See NMPA's Notice on Updated Drug Registration Fee Standards (2020). Back to section

17 Article 76(1) of the Patent Law, as amended. Back to section

18 The regulations include Implementing Measures for the Early Resolution Mechanism for Drug Patent Disputes (2021), Provisions of Supreme People's Court on Several Issues Concerning the Application of Law in the Hearing of Civil Cases Involving Disputes over Patent Rights Relating to Drugs under Application for Registration (2021), and Administrative Ruling Measures on the Early Resolution Mechanism for Drug Patent Disputes (2021). Back to section

19 Article 4 of the Drug Patent Dispute Resolution Measures. Back to section

20 Article 6 of the Drug Patent Dispute Resolution Measures. Back to section

21 Article 6 of the Drug Patent Dispute Resolution Measures. Back to section

22 Article 7 of the Drug Patent Dispute Resolution Measures. Back to section

23 Article 9 of the Drug Patent Dispute Resolution Measures. Back to section

24 Article 11 of the Drug Patent Dispute Resolution Measures (providing that 12 months' market exclusivity will be awarded to the first approved generic applicant, if the applicant submitted a Category IV Certification and successfully challenged the brand-name drug's patent in a patent invalidity procedure). Back to section

25 Article 13 of the Drug Patent Dispute Resolution Measures. Back to section

26 See SAMR website: https://www.samr.gov.cn/fldys/sjdt/gzdt/art/2023/art_590fd65c74ba44079d84f86e1e07b6a8.html. Last visited 29 May 2023. Back to section

27 Respectively, Article 17 of the Anti-Unfair Competition Law, and Article 60 of the Antitrust Law, as amended. Back to section

28 See SAMR, China Antitrust Law Enforcement Annual Report (2021). Back to section

29 Article 22, the Antitrust Law, as amended. Back to section

30 See SAMR, China Antitrust Law Enforcement Annual Report (2021). Back to section

31 See SAMR website: https://www.samr.gov.cn/xw/mtjj/art/2023/art_15f5f47c555c41b1a11cd9cf5591a668.html. Back to section

32 In the Matter of Yangtze River Pharmaceutical Group Ltd (2021). Back to section

33 Article 7 to 11, Guidelines on Anti-Monopoly for Intellectual Property. Back to section

34 Article 14 to 19, Guidelines on Anti-Monopoly for Intellectual Property. Back to section

35 Provisions on the Prohibition of Abuse of Intellectual Property Rights to Exclude or Restrict Competition. Back to section

36 Decision of the First Session of the Thirteenth National People's Congress on the Institutional Reform Program of the State Council. Back to section

37 Article 26, the Antitrust Law, as amended. Back to section

38 Article 31, Provisions on the Review of Concentrations of Undertakings. Back to section

39 Article 35, Provisions on the Review of Concentrations of Undertakings. Back to section

40 Article 2, Measures for the Security Review of Foreign Investments (promulgated in 2020). Back to section

41 Article 2, Administrative Regulations of the People's Republic of China on Import and Export of Technologies (amended in 2020). Back to section

42 Article 7, Administrative Regulations on Human Genetic Resources of the People's Republic of China (promulgated in 2019). Back to section

43 See Article 36, Provisions on the Review of Concentrations of Undertakings (providing that the merger's impact on economic efficiency should be taken into account in the merger control review process). Back to section

44 See Article 37, Provisions on the Review of Concentrations of Undertakings (providing that the merger's impact on public interests should be taken into account in the merger control review process). Back to section

45 See Article 37, Provisions on the Review of Concentrations of Undertakings (providing that the merger control review should consider whether any merging party is on the verge of bankruptcy). Back to section

46 See Article 12, Interim Provisions on Assessment of Impact of Concentration of Undertakings on Competition (providing that the merger control review should consider the existence of any countervailing buyer power). The Interim Provisions were abolished by the SAMR's predecessor in 2021, because corresponding responsibilities shifted to the SAMR after the 2018 government reformation, but they are still instructive. Back to section

47 Article 39, Provisions on the Review of Concentrations of Undertakings. Back to section

48 The proposed restrictive conditions were scrutinised by the SAMR pursuant to the Rules for Imposing Restrictive Conditions on the Concentration of Undertakings. Even though the Rules were abolished by the SAMR's predecessor in 2021, because corresponding responsibilities shifted to the SAMR after the 2018 government reformation, the abolished Rules are still instructive. Back to section

49 In the Matter of Forming New Company between Zhejiang Garden Biopharmaceutical Co, Ltd and DSM Nutritional Products Nederland BV. Back to section

50 Reply of the Supreme People's Court on the Defendant's Request for Reasonable Expenses in Intellectual Property Infringement Litigation on the Ground of Plaintiff's Abuse of Rights (promulgated in 2021). Back to section

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Summary

Introduction

In this chapter, we aim to provide an overview of the general principles and recent developments in the area of intellectual property and competition law in Germany in relation to the pharmaceutical sector. Although Germany is home to some of the oldest and best-known pharmaceutical companies in the world, a lot of manufacturing has moved abroad, and the market is highly regulated because of, what is essentially, compulsory universal health insurance.

The covid-19 pandemic, general price increases, lack of competition between health insurance companies and rising costs of healthcare are prone to put pressure on the new federal government, which has been in office since the end of 2021, to rein in costs sooner or later; however, the focus of the government is to combat supply bottlenecks of innovative medicines and vaccines and to bring the production of medicines, including the production of active ingredients and excipients, back to Germany or the European Union.

To this end, bureaucracy for production facilities will be reduced and – one could say in typical continental European fashion – subsidies for those production facilities will be granted.

In the area of patent law, there are several striking developments: on the one hand, the Patent Act has been reformed in 2022, adding more ideas on proportionality to what has been called the 'automatic injunction'; on the other hand, the Unified Patent Court (UPC) successfully launched on 1 June 2023. For patents that have not been 'opted-out' of this new system, this increases the risk for both patentees and potential infringer, and all that under a fairly speedy system, too – a rare opportunity to shape a new system. So far, pharmaceutical companies have been reluctant to use the UPC and have let SMEs and electronic companies file the first actions. While there was some early movement in the space of medical devices, pure pharmaceutical cases are only now beginning. The inherent opportunities and risks of the systems remain the same, while some of the uncertainty of any new system is diminishing. We would therefore expect that the uptake of the UPC amongst pharmaceutical companies will increase and that, thus, the use of protective letters in the new system will increase as well.

Concerning legislation in the area of competition law, the (11th) amendment of the Act against Restraints of Competition (ARC) has entered into force which implements new rules with respect to (1) measures after a sector inquiry; (2) the disgorgement of benefits by the competent competition authority; and (3) the enforcement of the Digital Markets Act in Germany, which may also be applied in the pharmaceutical sector. A consultation for the planned 12th amendment to the ACR has taken place. With respect to the enforcement of competition law in the pharmaceutical sector, the FCO deals with mergers on a regular basis; however, concerning anticompetitive behaviour, pharmaceutical companies do not seem to have been in the focus of the FCO in the past year, which is not surprising given the regularly supra-national effect of such anticompetitive behaviour.

Legislative and regulatory framework

General framework of pharmaceutical law

As can be gathered from the parallel chapters on other EU Member States, German law is highly harmonised with EU law in this area. The core of German pharmaceutical law is the Medicinal Products Act of 1976 (MPA), as published on 12 December 2005 and last updated on 20 December 2022.

The MPA requires a marketing authorisation procedure (Section 21 et seq. MPA) to be followed to prove the quality, efficacy and safety of the medicinal product. Special strict liability in the event of damage to medicinal products is also included in the law.

Homoeopathic remedies, provided they do not specify an area of application, are exempt from the proof of efficacy. While the current federal health secretary is a friend of evidence-based medicine, the current draft of a reform of the German Health Public System does not change the status of homeopathic remedies. Otherwise the draft reform will have little to no effect on pharmaceutical law as such.

In the broader sense, the Pharmacy Act and the Narcotics Act are relevant, as is the Therapeutic Products Advertising Act governing the advertising of medicinal products and products that are advertised as having effects on health.

In addition to those laws, there are a number of ordinances and administrative regulations, such as the Ordinance for the Manufacture of Medicinal Products and Active Pharmaceutical Ingredients. Authorisation requirements are specified in the Medicines Evaluation Guidelines, which transpose Annex I of Directive 2001/83/EC into German law. For the dispensing of medicinal products, the Medicinal Products Prescription Ordinance is to be consulted, and for narcotics that can be prescribed, the Narcotics Prescription Ordinance. Details on clinical trials are set out in the Good Clinical Practice Ordinance, which makes good clinical practice mandatory.

Patents, their duration and their extension

Patent law is governed by a handful of laws, mainly the Patent Act, the European Patent Convention, the Agreement on a Unified Patent Court and the respective treaties. Patents, irrespective of whether they are granted by the European Patent Office or the German Patent and Trademark Office, have a duration of 20 years from their filing date, if the annual fees are paid and they are not retroactively nullified.

Additionally, as in other European jurisdictions, supplementary protection certificates (SPCs) may be granted in accordance with Regulation (EC) No. 469/2009.

Pricing and public purchasing

Germany spends more than €30 billion per year on medicinal products, and there is a plethora of measures that try to keep prices in check. Generally, manufacturers are free to set the prices as they wish. Further, all drugs must be sold through pharmacies, which apply an additional surcharge to the one already applied by wholesalers.

Prescription drugs are paid for by health insurance companies, while patients only need to pay a nominal fee of a few euros. Health insurance companies generally negotiate rebate agreements with drug manufacturers, using their bigger purchasing power to negotiate.

After patent expiry, prices can be fixed to a maximum amount. If the price in the pharmacy is higher than the fixed amount, patients must pay the difference, providing a strong incentive for patients to choose cheaper products (often generics) to save money. The fixed prices are reviewed at least once per year and are often decreased. Since 2004, it is also possible to set fixed prices for patent-protected products under quite limited circumstances.

The respective rules are stipulated in Sections 35 to 36 of the Fifth Book of the Social Code. It can be expected that owing to cost pressure, the number of products with fixed (maximum) prices will increase.

Encouraging innovation

As legislation is harmonised in the European Union, and as competition law at the European level provides for a uniform approach, innovation is encouraged mostly at the EU level (e.g., the Pharmaceutical Strategy for Europe[1] from 2020).

The German Federal Ministry for Education and Research has multiple programmes for direct subsidies to help innovation in specific areas, such as target drug delivery and computational life sciences.[2]

New drugs and biologics – approval, incentives and rights

Drugs

The EU centralised procedure (CP),[3] through the European Medicines Agency (EMA) in Amsterdam, the Netherlands, is the most important procedure for new drug applications in Germany. The mutual recognition procedure (MRP) and the decentralised procedure (DCP) are the applicable methods for obtaining approval of new drug applications:

1. In the MRP, the application is made to the medicines agency of one country in a coordinated fashion with the agencies of other countries. Once approval is granted, it is recognised by all those countries.
2. In the DCP, identical applications are made to several local agencies, and one country's agency is chosen as the leading one.

Countries may still decline applications under these regimes on grounds of danger to public health, which can lead first to discussions in a coordination group and later to arbitration before the EMA. All these rules apply to veterinary products mutatis mutandis.

National applications are possible in Germany through the Federal Institute for Drugs and Medical Devices for drugs and the Paul Ehrlich Institute for vaccines.

During the covid-19 pandemic, it became publicly known that there is also a way to expedite approval through the EMA's rolling review. In this procedure, the data is submitted to and reviewed by the EMA as it becomes available.

Additionally, there are specific expedited procedures for seasonal influenza vaccines, as well as an accelerated assessment within 150 days instead of the usual 210 days if the drug is effective against an illness that could not be treated previously.

Market authorisations for orphan drugs that treat diseases afflicting fewer than five out of 10,000 persons in the European Union are only granted through the CP. Status as an orphan drug may then be granted by the European Commission upon recommendation by the EMA's Committee for Orphan Medicinal Products. Incentives include lower fees for the application and prolonged market exclusivity. Regulatory protection is provided in Article 14(11) of Regulation (EC) No. 726/2004. Newly authorised products benefit from eight years of protection of the approval data (regulatory data protection) and a 10-year period of market protection, which may be extended to 11 years if, during the first eight years at least, one new therapeutic indication is obtained that brings significant clinical benefit over existing therapies.

Parallel to that, patent protection for 20 years from the date of applying is available, followed by five years of protection under an SPC if the requirements for that are met.

Generic and follow-on pharmaceuticals

Simplified conditions for authorisation apply to generic versions of medicinal products with market authorisation. To successfully apply for a generic market authorisation, the manufacturing and pharmaceutical qualities must be documented, and the bioavailability and bioequivalence to the original medicinal product must be proven. For the remaining non-clinical and clinical data, the applicant can refer to the data on the reference medicinal product.

Regarding regulatory protection, generic market authorisations can be applied for after eight years have passed since the initial original market authorisation. The launch can then take place after a further two or three years.

Biologics and biosimilars

Where a biological medicinal product that is similar to a reference biological medicinal product does not meet the requirements of a generic medicinal product, in particular because the starting materials or the manufacturing process of the biological medicinal product differ from those of the reference biological medicinal product, the results of appropriate pre-clinical tests or clinical trials relating to those differences must be provided.

The type and number of additional documents must be submitted in accordance with the relevant criteria, according to the state of scientific knowledge; however, the results of other tests from the marketing authorisation dossier of the reference medicinal product shall not be submitted.

Recent Constitutional Court case

Recently, the German Constitutional Court had to decide a case in which the decentralised procedure and regulatory protection were the key points.[4]

A generic company had marketing authorisations for the veterinary medicinal product Enroxil, which is essentially identical in content to Baytril, in the Czech Republic, Hungary and Poland. With reference to the UK marketing authorisation for Baytril, the authority competent for marketing authorisation of medicinal products in the United Kingdom (the UK authority) granted a national marketing authorisation for Enroxil as a generic product in September 2005.

In 2006, a company commissioned by the generic company for this purpose applied for a national marketing authorisation for Enroxil before the German Federal Office in the MRP of the UK reference marketing authorisation. After the Federal Office objected to the lack of documents on environmental compatibility during the formal preliminary examination of the application for authorisation, the UK authority sent the assessment report prepared in 2004 on the extension of the British authorisation for Baytril, which was based on the data from the Ecotoxicology Database (ECOTOX) prepared by the legal predecessor of the first defendant. The Federal Office then granted the authorisation.

The licensee of the original manufacturer sued the German Federal Office for a national marketing authorisation on the grounds that the authorisation by the UK authority should not have been accepted unchecked and that the ECOTOX data was used unlawfully.

In the end, all courts up to the Federal Constitutional Court dismissed the action, finding that the German Federal Office only needs to assess whether there is any danger to public health or the environment. The questions of whether formally a generic application or a mutual recognition was the right pathway and whether the UK authority had a right to send the ECOTOX data to Germany are irrelevant to the German Federal Office; thus, the marketing authorisation was rightfully granted.

The decisions clearly show the focus of the authorisation procedures for quick and unbureaucratic grants of authorisations.

The Regional Court Munich issues anti-anti-suit injunction in life science patent litigation

Anti-anti-suit injunctions are rare in life sciences patent litigation. However, in a patent infringement proceeding before the Regional Court Munich, 10x Genomics recently requested an anti-anti-suit injunction against the US company NanoString and its German subsidiary. The Regional Court Munich issued the anti-anti-suit injunction.[5]

The background to this anti-anti-suit decision was that the Regional Court Munich ruled against NanoString for indirect infringement of the German part of EP 2 794 928 B1. As a consequence, NanoString requested an anti-suit injunction and an anti-enforcement injunction at the US District Court Delaware. The anti-anti-suit decision of the Regional Court Munich therefore was the answer to NanoString's requests before the US District Court Delaware. Anti-anti-suit injunctions have become widely known in German patent litigation, particularly in the field of standard-essential patents. However, patent infringers are now less likely to request anti-suit-injunctions because they can no longer successfully assert their FRAND objection in German SEP disputes.[6] It therefore will be exciting to see whether anti-suit injunctions and anti-anti-suit injunctions make a comeback in the life

sciences sector. Overall, the global trend of different national courts interfering with each other by way of anti-suit injunctions and anti-anti-suit injunctions, and so on, does not bode well for the supposed global rules-based order.

The objection of disproportionality in German patent law

In 2022, the German legislator codified the disproportionality objection in the German Patent Act (PatG). This is a substantial change. Previously, Section 139 PatG stated that a patent infringer may be sued by the infringed person for injunction if there is a risk of repetition. The new version of Section 139 PatG now adds that the claim is excluded if it would lead to disproportionate hardship for the infringer or third parties not justified by the exclusive right due to the special circumstances of the individual case and the requirements of good faith.

According to the reasoning of the law, the objection of disproportionality and the compulsory licence under patent law are different legal instruments.[7] However, the Regional Court Düsseldorf did not follow this reasoning. The Court ruled on 7 July 2022 (Sofosbuvir),[8] that the objection of disproportionality is subsidiary to the compulsory licence action. It was decisive for the Court that the principles of the compulsory licence should not be evaded by the objection of disproportionality.

This decision has been partially criticised in literature. Subsidiarity of the objection of disproportionality would make it more difficult to consider and safeguard third party interests.[9] This, however, had been precisely one of the reasons for the introduction of the disproportionality objection. So far, the courts have been very reluctant to find that an injunction would be disproportional and injunctions have been granted as they have been before the mentions reform of the PatG.

Patent linkage

European patents can be challenged within nine months of their grant in an opposition procedure before the European Patent Office and after the opposition period before the competent national courts has lapsed. European patents can be challenged before the Unified Patent Court while an objection procedure is pending. German patents can be challenged within the same period at the German Patent and Trademark Office (DPMA).

After the end of either opposition period, the Federal Patent Court (FPC) is competent for nullity actions. While an opposition is pending, nullity proceedings are inadmissible. Decisions of the FPC can be appealed before the Federal Court of Justice (FCJ), Germany's highest civil court.

There is no link between opposition procedures or nullity actions on the one hand, and marketing authorisation procedures on the other. Neither is dependent nor formally linked to the other one.

Patents can be challenged based on lack of novelty, lack of inventive step, lack of disclosure, inadmissible extension and other, less relevant grounds. Anyone wanting to clear the way for market introduction would need to challenge the validity of the patent in one of those ways.

If the patent's validity is weak (e.g., if a novelty attack seems to have a high likelihood of success), the product may still be launched. If an infringement action is then started, a request may be made to stay the infringement action pending the outcome of the opposition or nullity action. The reason for this is the bifurcated German patent system, where specialised courts handle infringement matters, while the equally specialised FPC handles nullity matters; thus, the infringement courts cannot declare a patent void, but may stay a pending infringement action and wait for the FPC's decision.

Negative declaratory actions (e.g., to find a patent not infringed by a specific product) are available in principle but require a legal interest, which under these circumstances mostly requires that the patentee has threatened the new market entrant with a patent infringement action by way of a warning letter seeking a cease-and-desist declaration. Other reasons, such as the failure of the patentee to answer whether they consider their patent to be infringed by a specified product, unfortunately, do not give rise to such legal interest.

'Clearing the way' strategies, therefore, lack sure paths in Germany, while the case law on patent infringement is, in turn, highly developed, with the highest case load in Europe.

After many years of delays, the UPC launched on 1 June 2023. For the first time in history, it is possible to file for injunctive relief with effect across all 17 Member States party to the Agreement on a Unified Patent Court (UPCA) and to file a revocation action against a patent with the same effect. The risk was therefore raised for both patentees and potential infringer; however, legal certainty can be reached more quickly, with positive effects for the pharmaceutical market.

Something that still must be discussed is the role of supplementary protection certificates (SPCs) with the UPC. As of right now, there are close to no rules regarding SPCs and the UPC. Article 32 UPCA claims that the jurisdiction of the UPC extends to SPCs, however, further rules regarding SPCs can not be found in the provisions.

On 27 April 2023, the European Commission published several proposals for solutions regarding the treatment of SPCs before the UPC. Two of the four proposals refer to medicinal products.

The first proposal is based on the fact that the current purely national procedures lead to significant legal uncertainty.[10] The European Commission identifies a clear need to complement the unitary patent by a unitary SPC and proposes to grant the patentee the 'possibility of filing a 'combined' centralised SPC application in which he or she would request the grant of both a unitary SPC (for those Member States in which the basic patent has unitary effect) and national SPCs (for other Member States).'[11]

The second proposal aims to simplify the EU's SPC system, as well as to improve its transparency and efficiency.[12] The goal is supposed to be met by introducing a centralised procedure for granting SPCs for medicinal products.[13] The European Commission states that 'This would allow applicants to obtain SPCs in the respective designated Member States subject to marketing authorisations having been granted in/for each of them, by filing a single “centralised SPC application” that would undergo a single centralized examination procedure . . .'[14]

Competition enforcers

The major legal source in Germany concerning competition is the Act against Restraints of Competition (ARC). Under the ARC, there are several institutions when it comes to the protection of competition; however, the Federal Cartel Office (FCO) is the most relevant national institution, in particular with respect to the pharmaceutical sector.

The FCO is a higher federal authority within the scope of business of the Federal Ministry for Economic Affairs and Climate Action (FMEA). It is exclusively responsible for:

1. merger control based on national law (only under specific conditions, the FMEA may overrule the FCO) (Section 36 ARC);
2. antitrust consumer protection including sector inquiries in this regard (Section 32e (5) ARC);
3. the maintenance of the competition register in which certain economic offences by undertakings relevant for award procedures are listed (Section 1 Act on Competition Register);
4. the enforcement of the prohibition on cartels based on Article 101 Treaty of the Functioning of the European Union (TFEU) (Article 5 Regulation (EC) Nr. 1/2003; Section 50 ARC);
5. the enforcement of the prohibition on abusive practices by undertakings with a dominant market position based on Article 102 TFEU (Article 5 Regulation (EC) Nr. 1/2003; Section 50 ARC); and
6. the enforcement of the prohibition on abusive practices by undertakings with paramount significance for competition across markets (Section 19a ARC).

Besides the FCO, there are state cartel offices (SCOs). Depending on whether the anticompetitive behaviour exclusively affects a specific federal state (which is rarely the case) or has effects beyond the federal state, either the respective SCO or the FCO is responsible for:

1. the enforcement of the prohibition on cartels based on national law (Section 1, 48 (2) ARC);
2. the enforcement of the prohibition on abusive practices by undertakings with a dominant or strong market power based on national law (Section 18 et seq., 48 (2) ARC);
3. sector inquiries other that such concerning consumer protection (Section 32e ARC); and
4. the review of the awarding of public contracts by contracting authorities (Section 159 ARC).

Appeals against decisions of the FCO are exclusively handled by the Higher Regional Court of Düsseldorf. The Federal Court of Justice is competent for revisions.

Merger control

There are no specific provisions for merger control in the pharmaceutical sector under German law. Accordingly, the general provisions in Sections 35 et seq ARC apply.

The prerequisites for the FCO to conduct merger control are that (1) the thresholds in Section 35 ARC are fulfilled (turnover or transaction threshold);[15] (2) a merger as defined in Section 37 ARC shall take place; and (3) the merger does not have 'community dimension' as defined in Article 21 of the European Commission Merger Regulation (ECMR).

Merger control may be carried out over two phases (Section 40 ARC): (1) a preliminary investigation procedure; and (2) a main investigation procedure if further examination of the merger is required. Except in exceptional cases, the whole procedure shall take five months from notification of the planned merger being filed.[16]

The FCO may grant (1) clearance; (2) clearance under further conditions and obligations for the undertakings; or (3) prohibit the merger (Section 40 ARC). A merger will be prohibited if it significantly impedes effective competition, in particular if it is expected to create or strengthen a dominant position and no exception according to Section 36 ARC applies. Relevant questions to assess the effects on competition are (1) which behaviour is to be expected from the merged entity post-merger; (2) whether there would still be incentives for other companies to complete or if it is expected that they would align their commercial strategy and (3) whether access to suppliers or customers could be denied.[17]

he definition of the relevant market follows the 'demand-side-oriented market concept' ("Bedarfsmarktkonzept). The decisive question is whether the products are functionally substitutable from the point of view of the customer or person disposing of the product in question ('Verbrauchsdisponenten').[18] In the past, national courts and the FCO have defined the respective relevant markets in the pharmaceutical sector based on the following aspects:

1. The functional substitutability of products depends in particular on the therapeutic effect and the intended use of the product in question.[19] In this regard, the national courts and the FCO have referred to the Anatomical Therapeutic Chemical (ATC) classification of the European Pharmaceutical Marketing Research Association in the past, which categorises pharmaceuticals, inter alia, based on their therapeutic indication (ATC class 3) and their active substance (ATC class 4).[20]
2. Further criteria have been, for example, the manufacturing process,[21] prices and medical application[22] as well as side effects, toxicity and tolerance.[23]
3. With respect to prescription drugs, the physicians' point of view and their prescription habits have been identified to be decisive for the question of the functional exchangeability of products.[24] This is because consumers are limited in their choice by the prescribing habits of physicians.
4. Prescription drugs and OTC drugs have been found to form different markets due to differences in receipt (prescribed by a physician as opposed to autonomous purchase), in pricing (determination of pharmacy prices for prescription drugs by the state) and in payment (coverage of costs by the insurance company for prescription drugs).[25]

5. The hospital market and the wholesale have been found to form different markets because only hospital pharmacies can buy bulk packages for prices significantly below the prices the wholesalers must pay, are technically more competent than wholesalers, very price sensitive and regularly conduct annual contracts.[26]
6. The sales of prescription drugs by local pharmacies and mail-order pharmacies have been found to form one market due to the offer of a comparable assortment on similar terms and competitive conditions.[27]

Geographically, the markets are also defined based on the 'demand-side-oriented market concept'[28] and are national in the pharmaceutical sector.[29] This is because the markets still deviate in view of regulation, market authorisation and social law, IP law and the price level of the drugs.[30] The respective legal frameworks thus lead to different competitive conditions in the respective countries. In contrast, the market for active substances is at least EU-wide.[31]

In the past year, a few merger control cases have been published with the FCO, for example[32]:

1. On 27 May 2024, the FCO cleared the acquisition by Johnson & Johnson of all shares in Shockwave Medical which manufactures (1) medical devices used in the minimally invasive treatment of calcified arterial lesions (arteriosclerosis) including a new technology called intravascular lithotripsy (IVL) and (2) coronary sinus reducers used in the treatment of (refractory) angina pectoris.[33]
2. On 18 April 2024, the FCO cleared the acquisition by Novo Nordisc A/S of all shares in Cardior Pharmaceuticals GmbH which currently does not offer any approved substances but develops an active substance against cardiac insufficiency caused by heart attacks.[34]
3. On 17 April 2024, the FCO cleared the acquisition by Richter Gedeon Nyrt of the remaining shares and exclusive control over Richter-Helm BioLogics GmbH & Co. KG and Richter-Helm BioTech BioTech GmbH & Co. KG.[35]
4. On 17 April 2024, the FCO cleared the acquisition by Novartis AG of all shares in MorphoSys AG taking into account Novartis' Ruxolitinib against a special form of leukemia called myelofiboris and MorphoSys' new active substance Pelabresib close to being authorised and marketed in Europe.[36]

If a merger has 'community dimension', the ECMR applies. This is the case if the thresholds in Article 1 ECMR are fulfilled, and a merger as defined in Article 3 ECMR is at issue. Article 21(2) ECMR rules that the European Commission is exclusively competent for the application of the ECMR.[37]

Under certain conditions, the European Commission may refer a merger to a Member State to have it controlled under national law. Member States can also request that the Commission examine a merger that does not have a community dimension but affects trade between Member States (Article 22 ECMR). In 2021, the Commission published guidance on the application of this referral mechanism and in December 2022 further practical information in the form of a Q&A to motivate Member States to make more use of this mechanism. This is because a number of cross-border transactions, including in

the pharmaceutical sector, that could have an impact on the EU market escaped review by both the Commission and the Member States in the past since they did not meet the thresholds in the ECMR and the national competition laws.[38]The well known Illumina/Grail case was such a case. Illumina planned to acquire Grail. Neither the commission nor National Cartel Offices were notified about the planned merger since it did not meet the thresholds of the ECMR and the national competition laws due to Grail not generating any revenue at that time. The Commission informed the National Cartel Offices that the merger might fulfil the requirements set out in Article 22 (1) ECMR. National Cartel Offices then requested the investigation of the merger by the Commission which the Commission accepted. Illumina's and Grail's request for annulment of the Commission's decision to accept the referral was dismissed by the General Court. The appeal is currently pending before the ECJ. Advocate General Emiliou has handed down his opinion dismissing the arguments of the Commission and the General Court for the application of Article 22 EMCR in this case. The decision of the ECJ is eagerly awaited.[39]

Anticompetitive behaviour

As with merger control, there are no specific provisions under German law for the assessment of anticompetitive behaviour in the pharmaceutical sector. Therefore, the FCO applies Section 1, 2 and 18 et seq. ARC if the anticompetitive behaviour exclusively concerns the German market. If EU trade is affected, the FCO must also apply Articles 101 and 102 of the TFEU.[40] The Commission will generally investigate anticompetitive behaviour in the sense of Articles 101 and 102 TFEU if more than three Member States are substantially affected.[41]

Because of the harmonisation of the ARC with EU law, Sections 1 and 2 ARC concerning anticompetitive agreements substantially correspond to Article 101 TFEU. The provisions cover horizontal as well as vertical agreements. Section 2 ARC clarifies that the EU block exemption regulations apply. The most relevant regulations in the IP and pharmaceutical context are the Technology Transfer Block Exemption,[42] the Research and Development Block Exemption[43] and the Vertical Block Exemption[44] to which the Commission has also published guidelines.[45]

Also, with respect to the abuse of a dominant position, the harmonisation of the ARC with EU law has led to Section 19 ARC substantially corresponding to Article 102 TFEU. The requirement of market dominance is defined in Section 18 ARC.

The definition of the relevant market follows the principles set out with respect to merger control. However, the national courts and the FCO do not seem to explicitly refer to the ATC classification in the context of anticompetitive behaviour.[46]

If the FCO initiates proceedings, it may:

1. conduct sector inquiries;[47]
2. gather evidence by inspection and hearing witnesses and experts;
3. seize objects;
4. request information and documents;

5. inspect and examine business documents at the undertaking's premises during normal business hours; and
6. conduct dawn raids concerning business premises, homes, land and objects.

If the FCO concludes that there has been anticompetitive behaviour, it may:

1. request the (group of) undertakings to cease and desist from the anticompetitive behaviour;
2. impose fines on (groups of) undertakings of up to 10 per cent of the worldwide turnover in the preceding fiscal year;
3. impose fines on persons like directors or board members responsible for the anticompetitive behaviour of up to €1 million; or
4. disgorge the benefits achieved by the anticompetitive behaviour.

Competitors and other aggrieved market players may claim an injunction and rectification as well as damages (only the actual damages but no punitive damages).

Anticompetitive clauses in agreements are automatically invalid, and under certain circumstances, the whole agreement may be invalidated.

In the past, the FCO has dealt, inter alia, with the following constellations:

1. agreements on prices between drug manufacturers;[48]
2. agreements on prices and co-promotion for OTC drugs between pharmacies;[49]
3. coordination on prices in the supply of medical aids by the Working Group of Associations of Suppliers of Medical Aids ("ARGE") to the detriment of the statutory health insurance companies against the ARGE members;[50]
4. suggestions at speech events to refrain from price competition and to follow the recommended retail price;[51]
5. target agreements between drug manufacturers and pharmacies providing rebates for placing drugs as premium drugs for the recommended retail price;[52]
6. agreements on the return of clients of pharmacies and, therefore, profits and market shares from one to other pharmaceutical wholesalers;[53]
7. distribution agreements between a drug manufacturer and a distributor that oblige (1) the manufacturer to exclusively distribute its products with the distributor and (2) the distributor not to sell any other competitive products;[54]
8. stagger of rebates in the sense that distributors are only supplied if they achieve a certain profit with the products;[55] and
9. agreements between an association representing the interests of pharmacies and health insurance companies that the health insurance companies will not influence physicians and patients to purchase products from other providers but will indicate the possibility of purchasing the products in the pharmacies represented by the association.[56]

Finally, it is worth mentioning that the 11th amendment of the ACR, has entered into force on 7 November 2023 tightening German competition law.

First, the provisions on sector inquiries have been amended substantially (Sections 32e and 32f (3)-(9) ARC). Sector inquiries now have two phases: (1) in the first phase, a sector inquiry is conducted within 18 months which is completed with a report to be rendered by the FCO; (2) in the second phase, the FCO may (a) issue a decision determining that a significant and continuing malfunctioning of competition exists in at least one market which is at least national in scope, in several individual markets or across markets; and (b) behavioural or structural remedies necessary for eliminating or reducing the malfunctioning of competition irrespective of actual anticompetitive behaviour. Again, the FCO has 18 months to complete this phase. Since the term 'malfunctioning of competition' is indefinite, Section 32f (5) ARC provides examples and further criteria for the analysis to be conducted. The malfunctioning must have been present for the past three years and likely be present for at least two further years. If this is the case, the FCO can order remedies such as obliging the undertakings to conduct their business relations with each other in a certain way, to implement transparent, non-discriminatory and open norms and standards, or to separate organisation and accounting of business units. The sector inquiry can also effect merger control insofar as the FCO must be notified about mergers reaching the thresholds in Section 32f (2) ARC even if the thresholds in Section 35 ARC are not reached if the sector inquiry gives reason to believe that further mergers in the investigated sector would impede competition. Under certain conditions ('ultima ratio'), the FCO may even order market-dominant undertakings or those with paramount market-overarching importance to demerge.

Second, the FCO's measure of disgorging benefits achieved by anticompetitive behaviour (Section 34 ARC) has been strengthened by implementing a double statutory presumption: (1) first, it is assumed that the culpable anticompetitive behaviour has led to a benefit; (2) second, that the benefit amounts to at least 1 per cent of the national turnover achieved by the anticompetitive behaviour. The amount of the benefit may be estimated by the FCO. However, the disgorging is limited to 10 per cent of the total turnover of the (group of) undertakings in the preceding fiscal year. The statutory presumption is disprovable by showing that neither the (group of) undertakings nor the involved persons have achieved a benefit in the respective amount in the relevant time. In addition, the presumption does not apply if the achievement of benefits is excluded due to the specific nature of the anticompetitive behaviour.

Finally, the ARC now includes provisions on the Digital Markets Act (DMA) rendered on the EU level (Section 32g ARC). Although the European Commission is competent for the enforcement of the DMA, the FCO is now able to conduct investigations in cases of a potential violation of the DMA and then submit a report to the Commission.

Already one day before the 11th Amendment of the ARC entered into force, namely, 6 November 2023, the FMEA has already initiated a public consultation in preparation for the 12th Amendment of the ARC. On 23 February 2024, the FMEA published the received opinions. The consultation focused on the topics merger control, ministerial approval of mergers, sustainability, consumer protection and damages.

Outlook and conclusions

As in 2022/2023, the pharmaceutical sector does not seem to have played a major role in German competition law, in particular with respect to anticompetitive behaviour. The recently published Report 'Update on competition enforcement in the pharmaceutical sector (2018-2022)' of the European Commission also indicates that the FCO has not been engaged in investigations concerning anticompetitive behaviour.[57] Recent fines ordered by the Commission, for example against Alkaloids of Australia, Alkaloids Corporation, Boehringer, Linnea and Transo-Pharm for participating in a cartel concerning an important pharmaceutical ingredient show that such cases often have a supra-national character and are therefore dealt with by the Commission.[58] Accordingly, projects and decisions concerning the pharmaceutical sector will continue to mainly take place at the EU level.

Regarding patent infringement, the case law will continue to develop. In particular, the UPC has entered into operation. Although pharmaceutical companies have been reluctant in the past year to make use of this new court system, it is expected that they will do so in the future so that first decisions in the pharmaceutical context are eagerly expected.

Endnotes

1 Communication from the Commission to the European Parliament, the Council, the European Economic and Social Committee and the Committee of the Regions Pharmaceutical Strategy for Europe, COM/2020/761 final. Back to section

2 Federal Ministry of Education and Research, 'Förderung und Projekte'. Back to section

3 Regulation (EC) No. 726/2004 of 31 March 2004. Back to section

4 Federal Constitutional Court, decision of 27 April 2021 – 2 BvR 206/14. Back to section

5 Regional Court Munich, decisions of 17 May 2023 – 7 O 2693/22 and 7 O 5812/22. Back to section

6 cf. Kiefer/Walesch, Mitt. 2022, 97 et seq. Back to section

7 BT-DS 19/25821 P. 55. Back to section

8 Regional Court Düsseldorf, decision of 7 July 2023 – 4c O 18/21. Back to section

9 See also at Stief, PharmR 2023, 61, 64. Back to section

10 COM(2023)222, Proposal of the European Commission, 27 April 2023 p. 1. Back to section

11 COM(2023)222, Proposal of the European Commission, 27 April 2023 p. 2. Back to section

12 COM(2023)231, Proposal of the European Commission, 27 April 2023 p. 2. Back to section

13 ibid. Back to section

14 ibid. Back to section

15 The thresholds were increased with the 10th Amendment of the ARC, see FCO, 'Amendment of the German Act against Restraints of Competition' (19 January 2021).- Back to section

16 This deadline was added with the 10th Ammendment of the ARC. Back to section

17 The same applies for the European Commission, see Commission, 'Update on competition enforcement in the pharmaceutical sector (2018-2022)' (26 January 2024); 2.2.1. Back to section

18 KG, decision of 18 October 1995 – Kart 18/93 – Fresenius/Schiwa; FCO, decision of 13 August 2003, B3-11/03 – Novartis/Roche; for anticompetitive behaviour, see FCJ, decision of 3 July 1976 – KVR 4/75 – Vitamin B12; FCJ, decision of 16 December 1976 – KVR 2/96 – Valium; FCJ, decision of 12 February 1980 – KVR 3/79 – Valium II. Back to section

19 KG, decision of 18 October 1995 – Kart 18/93 – Fresenius/Schiwa; FCO, decision of 30 November 2000, B-24410-U-91/00; FCO, Activity Report 1981/82, p. 59 – Grindsted Products/BASF. Back to section

20 KG, decision of 18 October 1995 – Kart 18/93 – Fresenius/Schiwa; FCO, decision of 13 August 2003, B3-11/03 – Novartis/Roche. Back to section

21 FCO, Activity Report 1981/82, p. 59 – Grindsted Products/BASF. Back to section

22 KG, decision of 18 October 1995 – Kart 18/93 – Fresenius/Schiwa. Back to section

23 For anticompetitive behaviour, see FCJ, decision of 16 December 1976 – KVR 2/96 – Valium; FCJ, decision of 12 February 1980 – KVR 3/79 – Valium II. Back to section

24 KG, decision of 18 October 1995 – Kart 18/93 – Fresenius/Schiwa; for anticompetitive behaviour, see FCJ, decision of 16 December 1976 – KVR 2/96 – Valium. Back to section

25 FCO, decision of 30 July 2010 – B3 59/10 – Medco Health Solutions/Celesio. Back to section

26 For anticompetitive behaviour, see FCJ, decision of 12 February 1980 – KVR 3/79 – Valium II. Back to section

27 FCO, decision of 30 July 2010 – B3 59/10 – Medco Health Solutions/Celesio; FCO, decision of 2 July 2018, B3-89/18 – apo-rot/DocMorris. Back to section

28 KG, decision of 18 October 1995 – Kart 18/93 – Fresenius/Schiwa; for anticompetitive behaviour, see FCJ, decision of 13 July 2004 – KVR 2/03 – Sanacorp/ANZAG. Back to section

29 KG, decision of 18 October 1995 – Kart 18/93 – Fresenius/Schiwa; FCO, decision of 5 June 2009, B3-64/09 – GlaxoSmithKline/Pfizer. Back to section

30 KG, decision of 18 October 1995 – Kart 18/93 – Fresenius/Schiwa. Back to section

31 FCO, decision of 30 November 2000, B-24410-U-91/00. Back to section

32 A list of ongoing procedures concerning merger control can be found under https://www.bundeskartellamt.de/SiteGlobals/Forms/Suche/LaufendeVerfahren/LaufendeVerfahren_Formular.html?nn=49386 , a list of main investigation procedures under https://www.bundeskartellamt.de/DE/Aufgaben/Fusionen/Hauptpruefverfahren/hauptpruefverfahren_node.html (however, both only in German). Back to section

33 FCO, B3-57/24; 'Johnson & Johnson can acquire Shockwave Medical' (27 May 2024). Back to section

34 FCO, 'Novo Nordisk A/S can acquire Cardior Pharmaceuticals GmbH' (18 April 2024). Back to section

35 FCO, decision of 17 April 2024 - B3-51/24. Back to section

36 FCO, 'Novartis AG can acquire MorphoSys AG' (12 March 2024). Back to section

37 In the period 2018-2022, the Commission analysed more than 30 mergers in the pharmaceutical sector, of which five were problematic from a competition point of view. Four could be cleared, one was abandoned by the undertakings, see Commission 'Update on competition enforcement in the pharmaceutical sector' (2018-2022) (26 January 2024), 2.2.3. Back to section

38 Guidance on the application of the referral mechanism set out in Article 22 of the Merger Regulation to certain categories of cases, (2021/C 113/01), Introduction, No. 10; see also European Commission 'Practical information on implementation of the “Guidance on the application of the referral mechanism set out in Article 22 of the Merger Regulation to certain categories of cases – Frequently Asked Questions and Answers (Q&A)'. Back to section

39 General Court, decision of 13 July 2022 - T-227/21; Opinion of Advocate Deneral Emiliou, 21 March 2024 in the joined cases C-611/22 P and C-625/22 P; In the meantime, Illumina and Grail had conducted the merger (gun-jumping). In July 2023, the Commission fined Illumina and Grail for conducting the merger while the merger control was ongoing. In October 2023, the Commission ordered Illumina to reverse the acquisition of Grail.
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40 Article 3(1) of Council Regulation (EC) No. 1/2003 of 16 December 2002. The European Commission has started an initiative to evaluate the procedures following changes to the economic landscape, e.g., digitalisation, see https://ec.europa.eu/info/law/better-regulation/have-your-say/initiatives/13431-EU-antitrust-procedural-rules-evaluation_en. Back to section

41 Commission Notice on cooperation within the Network of Competition Authorities (2004/C 101/03), No. 14. Back to section

42 Commission Regulation (EU) No. 316/2014 of 21 March 2014. On 17 April 2023, the European Commission initiated a public consultation to get an impression of the functioning of the block exemption and the respective guidelines. The consultation's deadline was 24 July 2023. On 6 December 2023, DG Competition held an online workshop to gather more information on the functioning of the Technology Transfer Block Exemption Regulation (TTBER) and the accompanying Guidelines on technology transfer agreements (Guidelines) https://competition-policy.ec.europa.eu/public-consultations/2023-technology-transfer_en Back to section

43 Commission Regulation (EU) No. 2023/1066 of 1 June 2023. Back to section

44 Commission Regulation (EU) No. 2022/720 of 10 May 2022. Back to section

45 Guidelines on the applicability of Article 101 of the treaty on the Functioning of the European Union to horizontal co-operation agreements - 2023/C 259/01; Guidelines on vertical restraints - 2022/C 248/01; Guidelines on the application of Article 101 of the Treaty on the Functioning of the European Union to technology transfer agreements - 2014/C 89/03. Back to section

46 See, for example, FCJ, decision of 16 December 1976 – KVR 2/96 – Valium; FCJ, decision of 12 February 1980 – KVR 3/79 – Valium II. Back to section

47 To date, the FCO has not conducted a sector inquiry into the pharmaceutical sector but only into hospitals, see FCO 'Final report on the sector inquiry into hospitals: Merger control guarantees competition and quality' (2 September 2021). Back to section

48 FCO, B 3-144/08, 'Retraction of Price Agreement for Colistin Antibiotics'. Back to section

49 FCO, 'Bundeskartellamt imposes fines against pharmacists on account of price agreements for non-prescription medicines' (8 January 2008). Back to section

50 FCO, 'Provision of medical aids: Anticompetitive price coordination stopped following Bundeskartellamt proceeding' (6 November 2023). Back to section

51 FCO, decision of 21 December 2007, B3-6/05. Back to section

52 FCO, 'Bundeskartellamt imposes fine against Bayer Vital' (28 May 2008). Back to section

53 FCO, decision of 28 August 2006, B3-129/03 – FCO v. Andrae Noris Zahn/Sanacorp Pharmahandel, Phoenix Pharmahandel/Gehe Pharma Handel. Back to section

54 FCO, decision of 14 July 2009, B3-64/05 – FCO v. Merck/VWR. Back to section

55 FCO, decision of 19 May 2011, B3-139/10 – FCO v. Merck/VWR. Back to section

56 FCO, decision of 29 September 2014, B3-123/11 – FCO v. Apothekerverband Westfalen-Lippe eV. Back to section

57 Commission, 'Update on competition enforcement in the pharmaceutical sector (2018-2022)' (26 January 2024); In the period 2018-2022, National competition Authorities and the Commission rendered 26 decisions concerning pharmaceuticals for human use (see 2.1.4 of the Report). The list can be found under https://competition-policy.ec.europa.eu/document/download/552ebb75-e502-491a-9fbd-f0f9d61dac39_en?filename=2024_pharmaceuticals_report_antitrust_decisions_2018-2022.pdf. At the time of publication of the report, the National Competition Authorities and the Commission investigated more than 30 cases in the pharmaceutical sector. Back to section

58 Commission, 'Commission fines pharma companies €13.4 million in antitrust cartel settlement' (19 October 2023); mainly settled by Commission's settlement procedure. The decision is worth mentioning because it is the first time the Commission has ended a proceeding concerning anticompetitive behaviour with respect to an active ingredient with a fine. Back to section

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Summary

Introduction

This chapter provides an overview of India's legislative and regulatory framework for drug and biologic approvals, drug pricing mechanisms, and patent regulations as well as the processes addressing intellectual property disputes associated with generic and biosimilar products. We also outline the interplay between intellectual property and antitrust law in India and discuss how strategies involving pharmaceutical intellectual property may come under scrutiny from a competition angle. Overall, the Indian policy and systems are designed to strike a balance between the competing interests of fostering pharmaceutical innovations, ensuring public health, and promoting generic industries.

Year in review

This review offers an update on the landscape of pharmaceutical intellectual property and antitrust issues while focusing on India’s significant policy, regulatory, and judicial developments in the sector during the past year. A pivotal moment occurred in July 2023 when the Delhi High Court delivered a landmark judgment on the conflicting zone between patent and competition laws. In reconciling the two statutes, it held that the Competition Act deals with the anticompetitive agreements and abuse of dominant position generally and there is clear legislative intent that the Patents Act being special law would override the Competition Act as regards anticompetitive behaviour by a patentee. In particular, any anticompetitive practice of a pharmaceutical patent holder would be addressed exclusively by the statutory patent authority and IP courts. The ruling marks a tectonic shift in Indian jurisprudence prompting pharmaceutical innovators to recalibrate their IP strategy.

The recently constituted specialised IP courts continued to provide efficacious and expeditious resolution of patent litigations and appeals. The current review of decisions reflects the balanced approach adopted by Indian courts in the adjudication of pharmaceutical patent cases. On one hand, enforcement of patent rights remained intact, with owners of valid patents receiving interim injunctive and other forms of relief in the event of infringements. On the other hand, courts continued to be watchful to check any attempt at anticompetitive practices using evergreening, line extensions, or serial patenting strategies. In appropriate cases, courts have allowed the patent applicant to submit post-filing evidence to establish the patentability requirements. Biologics innovators obtained favourable orders against biosimilar manufacturers in cases of alleged non-compliance with drug regulations and guidelines. The defence of public health factors (affordability and accessibility to drugs) may be considered in infringement proceedings, nonetheless, it is not a complete exception to a legally valid patent, and interim relief may be granted.

Patents Amendment Rules, 2024 have been notified introducing several provisions aimed at simplifying the process of obtaining and managing patents. The procedure of pre-grant oppositions has been streamlined to curb fraudulent oppositions and simultaneously encourage genuine oppositions. The frequency of filing the statements of working of

patents has been reduced. On the policy front, the new National Pharmaceuticals Policy, 2023 has been drafted to simplify drug and licensing regulations.

Legislative and regulatory framework

Drug regulations

The Central Drugs Standard Control Organization (CDSCO) under the Directorate General of Health Services, Ministry of Health & Family Welfare (MoHFW), is designated as the National Regulatory Authority (NRA). The primary legislation and regulations for the Indian pharmaceutical sector comprise the Drugs and Cosmetics Act, 1940 (DCA) and the rules framed thereunder, viz., Drugs and Cosmetics Rules, 1945 (DCR) and the New Drugs & Clinical Trial Rules, 2019 (NDCT Rules).

The DCA, DCR, and NDCT Rules regulate new drug approval, import, manufacture, distribution and sale of drugs. Under DCA, CDSCO is responsible for the approval of drugs, conduct of clinical trials, laying down the standards for drugs, control over the quality of imported drugs in the country, and coordination of the activities of State Drug Control Organizations for uniform enforcement of DCA. While the central government issues marketing approval for new drugs, state governments grant licences to manufacture new drugs for sale or distribution. The NDCT Rules replaced the previous regime concerning clinical trials under Part XA and Schedule Y of the DCR. Since 2019, NDCT Rules have regulated all new drugs, investigational new drugs for human use, clinical trials, bioavailability, and bioequivalence (BA/ BE) studies.[1]

Further, DCR requires a drug manufacturer to furnish an undertaking that its proposed brand or trade name shall not lead to any confusion or deception in the market and that such or similar brand or trade name is not already in existence with respect to any drug in India based on search in the relevant databases.[2] Moreover, the Drugs and Magic Remedies (Objectionable Advertisements) Act, 1954 prohibits misleading advertisements of drugs and remedies alleged to possess magic qualities in certain cases.

Drug pricing

By exercising powers conferred by the Essential Commodities Act, 1955, the Indian government has notified the Drugs (Price Control) Order, 2013 (DPCO) to control or regulate the pricing of certain drugs and ensure equitable availability of life-saving drugs at a reasonable price. The National Pharmaceutical Pricing Authority (NPPA) is entrusted to implement and enforce the DPCO. Drug price regulation is based on the 'essentiality of drugs' as laid down in the National List of Essential Medicines (NLEM), a dynamic list declared by the MoHFW under the DPCO.

In 2013 DPCO employed a price control mechanism for scheduled drug formulations (all essential medicines included in the NLEM), whether branded or generic, and a price monitoring mechanism for non-scheduled formulations (all non-essential medicines).[3] A division bench of the Delhi High Court clarified that the government or NPPA has the power to fix and revise prices of scheduled formulations only and it can merely monitor

the change in MRP of non-scheduled formulations.[4] Thus, non-scheduled formulations are not under a price control regime. A manufacturer of a non-scheduled formulation may increase its maximum retail price by 10 per cent per year and not beyond this limit.[5] Moreover, in the public interest and extraordinary circumstances, the government may fix the price of any drug, even non-scheduled ones.[6]

Patent regulations

The grant and validity of patents and rights thereunder are governed by the Indian Patents Act, 1970 (IPA) and the Patents Rules, 2003. At the Indian Patent Office (IPO), the Controllers of Patents are trusted to decide on patent applications under IPA. The orders of the Controllers can be appealed to a High Court. India has a first-to-file system for granting patents. The term of every patent granted is 20 years. India does not allow the extension of patent terms.

Section 2 of IPA requires an invention to satisfy the fundamental patentability criteria of novelty, inventive step, and industrial applicability. Besides, pharmaceutical innovations must not be a subject matter as proscribed from patentability under Section 3 of IPA. The main provisions are:

1. Inventive step: the invention must involve a technical advance compared to the existing knowledge and not be obvious to a person skilled in the art.
2. Follow-on innovations: Section 3(d) of IPA bars the patentability of the mere discovery of a new form of a known pharmaceutical substance unless it significantly enhances the therapeutic efficacy of that substance. It also prohibits patenting the mere discovery of any new property or new use for a known pharmaceutical substance.
3. Synergism: as per Section 3(e) of IPA, a patent would not be granted to a combination of known pharmaceutical substances unless it exhibits a synergistic effect.

A patent enforcement action or infringement suit under Section 104 of IPA, can be initiated before a district court or higher. However, if a defendant in an infringement action counterclaims the patent's invalidity, the suit and the counterclaim are automatically transferred to the High Court for further adjudication. Moreover, Section 105 of IPA enables an applicant to seek a declaration of non-infringement.

Under Section 13(4) of IPA, the grant of a patent does not guarantee its validity. The IPA expressly enables a challenge to the validity of a patent at various stages:

1. Pre-grant opposition under Section 25(1) before the IPO;
2. Post-grant opposition under Section 25(2) before the IPO;
3. Revocation petition under Section 64(1) before the High Court; and
4. A counterclaim seeking revocation in a suit for infringement under Section 64(1) before the High Court.

Antitrust laws

In India, participants in the pharmaceutical sector are also subject to the competition law. The framework and key provisions of the Indian antitrust law are discussed in 'Competition enforcers'.

New drugs and biologics – approval, incentives and rights

New drugs

The drug manufacturer or importer must obtain marketing authorisations for new drugs from the Central Licensing Authority (CLA). The Drug Controller General of India (DCGI), the head of the CDSCO, is CLA. On the successful completion of a clinical trial in India, CLA grants marketing approval for new drugs. No new drug shall be manufactured for sale unless it is approved by CLA. A manufacturing licence for new drugs is granted by the State Licensing Authority (SLA). Based on the clinical trial, safety and efficacy data of the new drug must be submitted for the manufacturing licences to be granted.

As per Rule 2(w) of New Drugs & Clinical Trial Rules, 2019, a 'new drug' means:

1. a drug, including active pharmaceutical ingredient or phytopharmaceutical drug, which has not been used in the country to any significant extent, and has not been approved as safe and efficacious by the CLA with respect to its claims;
2. a drug approved by the CLA for certain claims and proposed to be marketed with modified or new claims including indication, route of administration, dosage and dosage form (known as the 'subsequent new drug');
3. a fixed-dose combination (FDC) of two or more drugs, approved separately for certain claims and proposed to be combined for the first time in a fixed ratio, or where the ratio of ingredients in an approved combination is proposed to be changed with certain claims including indication, route of administration, dosage and dosage form;
4. a modified or sustained release form of a drug or novel drug delivery system (NDDS) of any drug approved by the CLA; or
5. a vaccine, recombinant Deoxyribonucleic Acid (r-DNA) derived product, living modified organism, monoclonal anti-body, stem cell-derived product, gene therapeutic product or xenografts, intended to be used as a drug.

The drugs covered under (a), (b), and (c) shall be considered new drugs for four years from the date of their marketing approval by the CLA and the drugs referred to in (d) and (e) shall always be deemed new drugs.

Data exclusivity

India does not interpret Article 39.3 of the TRIPS as an obligatory provision offering explicit regulatory (data and market) exclusivity. Utilising policy space, India has no data exclusivity akin to those that prevailed in the United States and Europe. However, limited data exclusivity is ostensibly available in India. An approved new drug [(a), (b), and (c) above] of an innovator or originator ceases to be a new drug beyond four years from the date of its marketing approval by the CLA. Within this four-year window, any subsequent applicant (including a generic competitor) seeking fresh marketing approval for the same drug cannot rely upon the originator's clinical data and must submit independent clinical evidence to obtain the marketing approval. Even if a drug is not patentable, such form of data exclusivity is available as long as it continues to be a 'new drug' under drug regulations.

Patented new drugs

All manufacturers producing a 'new drug' patented under the IPA are exempted from price control for five years from the date of commencement of their commercial marketing in India.[7] Earlier, such an exemption was available to patented new drugs not produced elsewhere and developed through indigenous research and development. However, DPCO was amended in 2019 to remove the 'local' condition.[8] Thus, the existing exemption regarding new drugs covered by product patents would attract pharmaceutical multinational companies to launch their new drugs in India. However, if a new drug is covered by a process patent, the 'local' condition still applies to claim price control exemption.[9]

Orphan drugs

An 'orphan drug' means a drug intended to treat a condition that affects not more than five lakh persons in India.[10] The manufacturer or sponsor may apply to the CDSCO for the expedited review process if the new drug is an orphan drug.[11] CDSCO may also relax local Phase IV clinical trial requirements for an orphan drug.[12] Moreover, orphan drugs as decided by MoHFW are exempted from price control.[13]

Post-filing data for patent applications

Indian courts acknowledge the inherent complexities and protracted nature of the drug development process, and it may not be possible to provide all data (such as clinical trial data or empirical evidence of a drug's efficacy) at the time of filing the patent application.-[14] No specific time bar has been provided in the IPA that prevents an applicant from submitting post-filing data. However, post-filing data can only be taken into account to confirm the existence of the inventive step, or significant enhancement in therapeutic efficacy, which is found embedded in the specification and not to rely upon the same to establish such step or enhancement for the first time.[15]

Generic drugs

Generic drugs are not defined in the DCA and rules made thereunder. However, generic drugs are generally those that contain the same amount of the same active ingredient or ingredients in the same dosage form and are intended to be administered by the same route of administration as that of branded medicine.[16] Further, drugs manufactured in

India, whether generic or branded, are required to comply with the same standards as prescribed in the DCA, DCR, and NDCT Rules for their quality.[17]

However, a generic drug may undergo an abbreviated regulatory review upon referencing an already-approved drug. After the lapse of the four-year window from the date of marketing approval of an innovator's new drug, a generic drug manufacturer or importer is not required to conduct clinical trials and it can rely on clinical data generated by the innovator to obtain marketing approvals for its drug. Before April 2017, generic drug manufacturers were not obligated to prove their bioequivalence to their branded/innovator congeners. To ensure the efficacy of generic drugs, the DCR has been amended providing that the applicant including the generic manufacturer is required to submit the result of the bioequivalence to obtain a manufacturing licence from SLA for certain drugs (falling under Category II and Category IV of the Biopharmaceutical Classification System), even though they are not new drugs.[18] DCR has been further amended, making it mandatory for all drugs, that the applicant must submit evidence of stability, safety of excipients, etc. to SLA before granting a product manufacturing licence.[19]

Bolar exemption

Section 107A of the IPA carves out an exception for the use of the patented product or process during its term for research or regulatory approvals both in India and abroad. The Bolar exception facilitates timely entry of generic drugs by exempting certain activities such as research and development and obtaining regulatory approvals from patent infringement actions. The manufacturers of generic drugs would be able to commence their activities immediately upon the expiry of the patent in the public health interest.

Biologics and Similar Biologics

A biologic is derived from living organisms or their cells. Unlike traditional pharmaceutical drugs that are typically synthesised through chemical processes to create small-molecule drugs, biologics are produced using intricate biotechnological methods involving recombinant DNA technology, controlled gene expression, and antibody production. A similar biologic (biosimilar) product is defined as being 'similar' in terms of quality, safety, and efficacy to an approved reference or innovator biologic based on comparability.[20-] Under regulations, biologics including biosimilars continue to be a 'new drug' forever.[21] Therefore, the manufacturers of biosimilars must conduct clinical trials in India to obtain marketing approval.

The 'Guidelines on Similar Biologics' (2016) lay down the regulatory pathway for a similar biologic claiming to be similar to an already authorised reference biologic. The demonstration of bio-similarity depends upon detailed and comprehensive product characterisation, and preclinical and clinical studies carried out in comparison with an approved reference/ innovator biologic. The Biosimilar Guidelines thus underscore the balance between developing similar biologics within the framework of existing (reference) biologics and adhering to the stringent standards for maintaining the integrity and efficacy of these biosimilars. The authorities involved in the approval process of biosimilars include the Institutional Bio-Safety Committee (IBSC), the Review Committee on Genetic Manipulation (RCGM), the Genetic Engineering Appraisal Committee (GEAC), and CDSCO. A biosimilar can also go through an abbreviated review process and the extent of clinical trials required is to be considered by the concerned authorities.[22]

Since DCGI or CDSCO does not determine the rights of manufacturers of innovator drugs at the time of granting approvals to other new drug manufacturers, manufacturers of innovator drugs may file a civil suit challenging approvals to protect their rights in relation to their drugs.[23] For instance, in Roche v. DCGI & Ors., the court recorded the prima facie finding that the process of obtaining approval was flawed due to non-adherence to the statutory provisions of DCA, DCR, and the Biosimilar Guidelines.[24]

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Patent linkage

Patent linkage refers to linking the patent status of innovator drugs with the grant of marketing/ manufacturing approval for generic drugs. Patent linkage is not available in India as such linkage would delay the entry of generic medicines. In Bayer Corporation v. Union of India, the Delhi High Court clarified and confirmed the absence of patent linkage under the Indian legal system.[25] The drug regulator (DCGI) need not ensure the protection of a patent by refusing marketing approval to a generic manufacturer only because the drug in question is patented.[26] However, the patent holder is entitled to seek appropriate remedies under IPA to enforce and protect its patent from infringement.

Competition enforcers

Competition law in India aims to foster competition and protect Indian markets against anticompetitive practices by enterprises. The Competition Act, 2002 prohibits:

- anti-competitive horizontal agreements and anti-competitive vertical agreements – that cause an appreciable adverse effect on competition (AAEC) in India (Section 3);
- abuse of dominant position by enterprises ((Section 4); and
- regulates combinations (mergers, amalgamations, and acquisitions) to ensure that there is no AAEC in India. (Sections 5 and 6).

The Competition Commission of India (CCI), a statutory authority under the Competition Act, is the competition regulator in India. The CCI enforces antitrust rules in the pharmaceutical and healthcare sectors to ensure that effective competition is not undermined in these markets. The CCI looks into cases and investigates anticompetitive practices or attempts by the innovator pharmaceutical company to delay the generic drug's market entry or to foreclose the market. While determining whether an agreement has an AAEC under Section 3, CCI considers the following factors:

1. creation of barriers to new entrants in the market;
2. driving existing competitors out of the market;
3. foreclosure of competition by hindering entry into the market;
4. accrual of benefits to consumers;
5. improvements in the production or distribution of goods or services; and
6. promotion of technical, scientific, and economic development.

Section 26 of the Competition Act empowers the CCI to ascertain if there is a prima facie case of anticompetitive practice. If a prima facie case is found, CCI directs the Director General to investigate the matter. The orders of the CCI can be appealed to the National Company Law Appellate Tribunal (NCLAT).

So far, the CCI has received more than 55 cases from the pharmaceutical sector, pertaining mostly to the pharmaceutical distribution segment.

Anticompetitive behaviour

Patents and competition law

The allegations of anticompetitive practice by the patent holder are assessed under the provisions of the Indian Patents Act. IPA empowers the Controller of Patents to grant a compulsory licence if the reasonable requirements of the public are not satisfied, the patented invention is not available to the public at a reasonably affordable price, or the patented invention is not worked in India. In particular, Section 84(7) of IPA declares that the reasonable requirements of the public are not satisfied:

1. if the refusal of licence results in existing trade or industry, or development thereof, or establishment of a new trade or industry in India, or the trade or industry of any person or class of persons or manufacturing in India is prejudiced;
2. if refusal of licence results in the establishment or development of commercial activities in India being prejudiced;
3. if conditions imposed by the patentee result in the use of patented articles, or manufacture, use or sale of material not protected by the patent, or establishment or development of any trade or industry in India is prejudiced;
4. if conditions such as exclusive grant back, or prevention of challenges to the validity of patent, or coercive package licensing are imposed by the patentee; and
5. if working of the patented invention in India on a commercial scale is being prevented or hindered by importation of the patented article.

In Monsanto v. Competition Commission of India (2023), a division bench of the Delhi High Court explained the interplay between the IPA and the Competition Act and, resolved the perceived repugnancy between the two statutes.[27] The factors that the CCI considers when assessing an AAEC or abuse of dominant position under Sections 3 or 4 of the Competition Act are nearly identical to those that the Controller will consider while granting a compulsory licence in terms of Sections 84(6) and 84(7) under Chapter XVI of IPA. However, the Patents Act being the special statute must prevail over the Competition Act on the issue of anti-competitive agreements and abuse of dominant position by a patentee in exercise of its rights under IPA.[28] The CCI has no power to investigate in this respect. As concluded by the division bench, Chapter XVI of IPA is a 'complete code' in itself on all issues regarding unreasonable conditions in agreements of licensing of patents, abuse of status as a patentee, inquiry in respect thereof, and reliefs to be granted therefor.[29]

Evergreening or line extension

'Evergreening' is a term used to label practices wherein a trifling change is made to an existing product, and claimed as a new invention. The robust patentability

standards under IPA may be applied to curb evergreening and anti-competitive practices. According to Section 3(d) of IPA, follow-on drugs or derivative pharmaceutical innovations must demonstrate an additional therapeutic efficacy over and above the known substance. Section 3(d) thus acts as a second tier of qualifying standards for follow-on pharmaceutical products leaving the door open for genuine inventions, and simultaneously checking any attempt at repetitive patenting or extension of the patent term on spurious grounds.[30] This clause prevents the 'evergreening of patents' by prohibiting patents of incremental inventions involving only minor or slight improvements that extend the life of patents that are about to expire.[31] It, therefore, ensures generic competition by patenting only novel and genuine pharmaceutical inventions. Through this anti-evergreening clause, India strives to balance international patent obligations and its commitments to protect and promote public health.[32]

In the context of enforcement of patents concerning drugs, the courts are vigilant towards attempts by the patentee that aim at evergreening an invention that does not involve an inventive step, namely, a technical advance.[33] In an infringement case where the defendant set up a credible challenge to invalidity, the court refused the interim injunction to ensure generic competition for the production of follow-on drugs by reinforcing the doctrine of obviousness-type double patenting.[34]

If patents for the same inventive concept can be granted more than once, successively in time, it will prevent others from using the new product invented by the patentee until such time as the patentee successively keeps on obtaining such patents.[35] In certain cases of selection inventions, attempting to patent both the genus and species patent may amount to evergreening or layering of patent protection, which is impermissible under the Indian patent law. The second patent (species) for such a compound that was fully covered by the first patent (genus) would be vulnerable to invalidity due to lack of novelty and inventive step.[36]

Therefore, by filing multiple patents using the line extension or double patenting strategy a patentee may artificially extend the protection period beyond 20 years causing AAEC in the market, resulting in higher prices of drugs and denial of market access as no other competitor can enter the market.

Sham or vexatious litigation

From a competition perspective, litigation may be termed frivolous and vexatious when it is initiated by a dominant undertaking to cause anti-competitive harm through the inappropriate use of adjudicatory, government processes or legal rights. Usually, the objective behind such litigation is to either subdue a competitor by increasing operational costs or delay the entry of a competitor into the market.

As per CCI precedents, the following needs to be examined to determine whether litigation or legal recourse is an abusive conduct by a dominant player:

1. whether a case filed against an enterprise on an objective view is baseless and appears to be an instrument to harass the enterprise; and
2. whether the legal action appears to be conceived with an anti-competitive intent to eliminate or thwart competition in the market.

Therefore, the lawsuit in question must be objectively baseless so that no reasonable litigant could realistically expect success on its merits and, it is filed not to protect a legitimate right but to prevent a competitor.

In re Macleods Pharmaceuticals Limited v. Boehringer Ingelheim Pharma (2023) before the CCI, the filing of several patent infringement suits by innovators (patentees) against the generic competitors and giving notices to third parties such as medical practitioners to not engage with the competitors were not found to be a case of vexatious litigation or abuse of dominant position.

Refusal to deal

The CCI has held that firms may choose their trading partners as long as the exercise of such autonomy does not affect the fair functioning of the markets.[37] Depending upon the market power held by firms, their conduct on refusal to deal may lead to foreclosure of the market for other players. A refusal to deal, total or partial, could also have underlying valid justifications with commercial consideration.[38]

In re Swapan Dey v. Vifor International (2022), the CCI highlighted that the freedom to choose its trading partner is not absolute. However, not every company may seek access to the patent, unless it demonstrates that there is indeed a need for such access, based on the existing supply conditions of an essential product/facility as against its demand by the consumers, to affect the market adversely by non-dealing on the part of the entity (patentee) with significant market power. Any company requesting for grant of access to the patent should also demonstrate its ability to the patent holder, to satisfy the requirements specified for receipt of the grant of license.

Price discrimination

The CCI propounds that all price differentiations may not be discriminatory, more so when the same is based on reasonable classification of consumers to which they are offered.[39] The prices offered in government procurement may not be comparable with the products being sold on the open market on quantity criteria (bulk v. individual buying) as well as purpose criteria (public purpose or distribution free of cost v. private consumption).[40]

Special considerations

Public health interest

In Indian jurisprudence, the courts would look at the public interest in granting an injunction, as access to life-saving drugs and their pricing is an important facet of the Indian patent regime. The three general principles for granting or denial of an injunction are a prima facie case, the balance of convenience, and irreparable injury. In patent infringement suits concerning drugs, the fourth dimension of public health interest factors including affordability and accessibility to drugs has been added by Indian courts to the well-established triple test for interim reliefs.

In India, public health interest has been recognised both as a separate factor and as a tie-breaker factor for the balance of convenience. For instance, in AstraZeneca v. Intas Pharmaceuticals (2020), the court noted a big price differential (250 to 350 per cent) between the plaintiffs' patented antidiabetic drug and the defendants' generic drugs and held that the balance of convenience would tilt in favour of the defendants and, therefore, refused the interim injunction. A similar stand on significant price gap and affordability was reinforced recently in Boehringer Ingelheim Pharma v. Vee Excel Drugs (2023). However, in Merck Sharp and Dohme Corp. v. Glenmark Pharmaceuticals (2015), an interim injunction was granted by noting that the price differential (30 per cent) between the patentee's drug and the infringing products was not so startling as to compel the division bench to consider the public health interest dimension.

However, the defence of public health interest is not a complete exception to a legally valid patent and it is not interpreted too broadly as it would undermine the patentee's rights, and upholding the patent enforcement is also in the public interest.[41] Where a granted patent is prima facie found to be valid and infringed and is being exploited without a licence from the patent holder, the balance of convenience is always in favour of restraining further infringement even if the drug in question is needed for treating various serious ailments, including cancer.[42]

Clearing the way

As an equitable principle, while exercising discretion in granting injunctions the court may consider whether the infringer defendant has 'cleared the way' before exploiting the patent in question by filing any pre-grant or post-grant opposition or revocation petition or declaration of non-infringement.[43] Where litigation is bound to ensue if the defendants introduce their product, the defendants could have avoided the interim injunction if they had cleared the way first. In Eisai Co. Ltd. v Satish Reddy (2019), the balance of convenience for the grant of an interim injunction tilted in favour of the patentees as the defendants had not 'cleared the way' before obtaining marketing approval for the launch of the infringing drug.[44] The defendants were aware that there may be a possible challenge to their product, but they chose to seek the marketing approvals without first invoking revocation proceedings or attempting to obtain a licence.

Doctrine of equivalent (DOE)

In a few instances, the US-style doctrine of equivalent has been recognised by Indian courts.[45] DOE protects patent rights from being infringed by infringers using the colourable method of making some minor, insubstantial variations to escape the reach of the patent. In cases of non-literal infringement, the purposive construction or the 'triple identity' test (substantially the same function, in substantially the same way and to yield the same result) may be applied by courts.

Outlook and conclusions

The draft National Pharmaceuticals Policy, 2023 (NPP) envisages regulatory harmonisation of India's drug standards with international best practices, reducing

compliance burdens and simplifying the licensing system. The new NPP also envisions strengthening the Indian Patent Office and facilitating patent applications by fast-tracking the examination. The enforcement of pharmaceutical intellectual property continues to be strengthened and robust. India sternly prohibits infringement of a valid patent, and it may not be possible for competitors to argue public health interests to justify infringing drugs to circulate in the market. In recent years, the creation of the Intellectual Property Division in the High Courts has given further impetus to speedier adjudication of patent disputes. Patent rules have been amended recently to curb impostors and fraudulent pre-grant opposition.

Indeed, multiple patents can be filed for different aspects of a particular pharmaceutical drug, if patentability criteria are met. However, serial patenting to evergreen a particular monopoly is not permissible in India. Such anti-competitive attempts will be screened through patentability standards and validity challenges. The validity of patents is to be tested before the courts under the provisions of the Indian Patents Act. The question of the validity of patents is not looked into by the competition authority (CCI) for want of subject matter competence. Moreover, following the High Court's pronouncement last year, it is now settled that the Indian Patents Act per se provides adequate safeguards against anti-competitive licensing of patents and abuse of dominant status by a patentee, and the CCI's jurisdiction is completely ousted on that count. The tussle between intellectual property and competition law will be resolved conclusively when the Supreme Court issues its final judgment on the CCI's appeal against the ruling of the High Court.

Endnotes

1 Notification GSR 227(E) dated 19 March 2019 Back to section

2 Notification GSR 828(E) dated 6 November 2019 Back to section

3 DPCO 2013, paragraphs 13, 14, 20 Back to section

4 Union of India v. Bharat Serums & Vaccines Ltd (2023:DHC:8164-DB) Back to section

5 DPCO 2013, paragraph 20 Back to section

6 DPCO 2013, paragraph 19 Back to section

7 DPCO 2013, paragraph 32(i) (amended by SO 39(E) dated 3 January 2019) Back to section

8 Order SO 39(E) dated 3 January 2019 Back to section

9 DPCO 2013, paragraph 32(ii) Back to section

10 New Drugs & Clinical Trial Rules 2019, Rule 2(x) Back to section

11 New Drugs & Clinical Trial Rules 2019, Second Schedule Back to section

12 New Drugs & Clinical Trial Rules 2019, Rule 80(7) Back to section

13 DPCO 2013, paragraph 32(iv) (inserted by SO 39(E) dated 3 January 2019) Back to section

14 Ischemix LLC v. Controller Of Patents (2023:DHC:8496) Back to section

15 Id. Back to section

16 PIB Press Release ID 1705065 dated 16 March 2021 Back to section

17 Id. Back to section

18 Notification GSR 327(E) dated 3 April 2017 Back to section

19 Notification GSR 360(E) dated 10 April 2018 Back to section

20 Guidelines on Similar Biologics (2016) Back to section

21 New Drugs & Clinical Trial Rules 2019, Explanation of Rule 2(x) Back to section

22 Boehringer Ingelheim v. DCGI & Anr (2019:DHC:5391), Order dated 23 February 2024 in CS(COMM) 159/2024 Back to section

23 Roche v. DCGI & Ors, (2016:DHC:3153), See also F Hoffmann La Roche v. DCGI & Ors, (2023:DHC:6522) Back to section

24 Roche v. DCGI & Ors, (2016:DHC:3153) Back to section

25 Bayer Corporation v. Union of India & Ors (2010:DHC:771-DB) Back to section

26 Id. Back to section

27 Monsanto Holdings Pvt Ltd v. Competition Commission Of India (2023:DHC:4783-DB) Back to section

28 Id. Back to section

29 Id. Back to section

30 Novartis v. Union of India, [2013] 13 SCR 148 Back to section

31 Review of IPR Regime in India, Parliamentary Standing Committee Report (2021) Back to section

32 Id. Back to section

33 AstraZeneca v. Intas Pharmaceuticals Ltd (2020:DHC:3125) Back to section

34 Id. Back to section

35 AstraZeneca v. Intas Pharmaceuticals Ltd (2021:DHC:2116-DB) Back to section

36 Natco Pharma v. Novartis (2024:DHC:3198-DB) Back to section

37 Hiveloop Technology v. Britannia Industries, CCI order dated 16 June 2022 Back to section

38 Id. Back to section

39 Swapan Dey v. Vifor International, CCI order dated 25 October 2022 Back to section

40 Id. Back to section

41 Merck Sharp and Dohme Corp. v. Glenmark Pharmaceuticals (2015:DHC:2712-DB) Back to section

42 Pharmacyclics LLC v. Hetero Labs Limited (2023:DHC:9246) Back to section

43 Merck (2015:DHC:2712-DB) Back to section

44 Eisai Co Ltd v. Satish Reddy (2019:DHC:2476) Back to section

45 FMC Corporation v. Natco Pharma Limited (2022:DHC:5311-DB), See also 2024:DHC:1945 Back to section

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Summary

Introduction

This chapter provides an overview of Japan's pharmaceutical legislative and regulatory framework, how to bring drugs and biologics to market, and the use of and challenges in using patent and regulatory exclusivity for product launch of generics and biosimilars. We also provide an overview of the competition law environment in Japan, including a review of the rules on anticompetitive agreements and merger control.

Year in review

This article examines the most consequential features of the IP and competition law frameworks in relation to the pharmaceutical sector in Japan, with particular regard to recent developments.

Legislative and regulatory framework

Marketing authorisations for drugs and biologics

The primary legislation governing pharmaceutical products is the Act on Securing the Quality, Efficacy and Safety of Pharmaceuticals, Medical Devices, Regenerative and Cellular Therapy Products, Gene Therapy Products and Cosmetics (Act No. 145 of 1960) (the PMD Act). The competent regulatory authority of the PMD Act is the Ministry of Health, Labour and Welfare (MHLW), which has the authority to grant marketing approval for drugs and biologics. The Pharmaceuticals and Medical Devices Agency (PMDA) is a regulatory agency that is delegated regulatory work by the MHLW. The PMDA conducts scientific reviews of marketing approval applications for pharmaceuticals and monitors their post-marketing safety. The PMDA is also responsible for providing relief compensation for sufferers of adverse drug reactions and infections from pharmaceuticals or biologics. The PMD Act also provides a certain data exclusivity period for innovative drugs through a re-examination system depending on the type of pharmaceutical product.

NHI drug price

The Health Insurance Act (Act No. 70 of 1922) provides regulations on pricing of prescription drugs that are reimbursed under the National Health Insurance system. The Japanese government reimburses patients for drugs at prices listed in the Drug Price Standard published by the National Health Insurance programme. Entries of new drugs in the NHI price list are made four times a year (in February, May, August and November), after those drugs have been approved. Entries of generic drugs in the NHI price list are made twice a year (June and December). The NHI prices for listed drugs are reviewed and revised on the basis of their market prices, in principle, every year. Marketing approval holders are required to launch their products listed in the NHI price list within three months after the listing approval date. For generic drugs, the MHLW requires that generic manufacturers

maintain a stable supply of their generic drugs for at least five years after listing in the NHI price list.

Patent duration

In addition to incentives in the form of regulatory exclusivities, Japan's patent system grants exclusive rights to make, use, sell or import into Japan inventions for which a patent has been granted. The Patent Act (Act No. 121 of 1959) governs the Japan Patent Office (JPO) and the rights and remedies available under the patent system. The nominal term of a Japanese patent is 20 years from the patent application filing date. Since a patent application for a pharmaceutical must be filed before marketing approval is granted for the pharmaceutical product, the period in which the pharmaceutical product can be sold under its exclusive patent rights is shorter than the granted patent term. To address this gap, the Patent Act allows up to a five-year extension of the patent term to compensate for the time during which the patent could not be used because of the clinical trial period and regulatory filing process.

Competition law environment

The Act Concerning Prohibition of Private Monopolisation and Maintenance of Fair Trade (Act No. 54 of 1947) (the Antimonopoly Act or AMA) is the main competition law in Japan. The AMA aims to promote fair and free competition and mainly prohibits the following types of activities:

1. Unreasonable restraint of trade: business activities, by which any enterprise, by contract, agreement or any other means, in concert with other enterprises, mutually restricts or conducts business activities in such a manner so as to fix, maintain or increase prices, or to limit production, technology, products, facilities or counterparties, thereby causing, contrary to the public interest, a substantial restraint of competition in any particular field of trade,[1] which covers horizontal restraints, including cartels.
2. Private monopolisation: business activities, by which any enterprise, individually or by combination or in conspiracy with other enterprises, or by any other manner, excludes or controls the business activities of other enterprises, thereby causing, contrary to the public interest, a substantial restraint of competition in any particular field of trade.[2]
3. Unfair trade practices: acts designated by the AMA or the Japan Fair Trade Commission (JFTC) that may impede fair competition,[3] which mostly covers vertical restraints.

The AMA also provides merger regulations, which prohibit 'business combinations' (such as share acquisitions, mergers and business transfers) when competition in a market is substantially restrained, and requires prior notification for business combinations that satisfy certain thresholds.

New drugs and biologics – approval, incentives and rights

Drugs

Marketing approval

Standard review

To market a new drug in Japan, an applicant must submit a new drug application (NDA) to the PMDA for the agency's review and approval. The standard review period is 12 months.

Expedited programme

Priority review

The review period for priority review is nine months. The shorter review period is a great advantage for applicants and patients in terms of rapid access to products. The following criteria must be fulfilled for priority review designation:

1. severity of the target disease:
    - the symptoms are life-threatening;
    - the symptoms are irreversible and significantly hinder daily life; or
    - the symptoms are otherwise serious; and
2. clinical utility:
    - no existing treatments, prophylactic measures, or diagnostics; or
    - the product offers superior clinical advantages over existing treatments, prophylactic measures or diagnostics in terms of efficacy, safety and physical/psychological burden on patients.

Orphan drugs review

The review period for orphan drugs is nine months. In addition to a shorter review period than that of the standard review, an orphan drug applicant gets a refund from the government for research and development costs, as well as tax breaks, and the price of the product will be a special premium when it comes onto the market. These are incentives for orphan drugs. The following are the criteria for orphan drug designation:

1. severity of the target disease;

2. clinical utility;
3. the number of patients is fewer than 50,000 or the target disease is an 'intractable disease' in Japan; and
4. feasibility of product development.

SAKIGAKE designation system

'SAKIGAKE' is a Japanese word meaning 'pioneer' or 'forerunner' inspiring great innovation. The review period for SAKIGAKE products is six months. The purpose of SAKIGAKE is to enable practical use of innovative drugs and devices developed in Japan at the earliest possible time. The following are the designation criteria for SAKIGAKE:

1. the product should be innovative;
2. the product should target a serious disease;
3. the product should have expected prominent effectiveness or significant improvement of safety; and
4. the product should be developed, and an NDA should be submitted, in Japan first, or simultaneously with other countries.

Once a product has obtained SAKIGAKE designation, priority consultation is granted, and a PMDA staff member review partner helps the applicant smoothly communicate with the PMDA review team. The applicant can consult with the PMDA review team at any time, and there is also a prioritised review – a rolling review ahead of the NDA, which means that the applicant does not need to submit the entire application dossier at once.

Conditional early approval

The review period for conditional early approval is nine months. The purpose of conditional early approval is to facilitate faster patient access to products for which confirmatory clinical studies are especially difficult to conduct. The following are the criteria for conditional early approval:

1. severity of the target disease;
2. clinical utility;
3. confirmatory clinical studies seem impracticable to conduct, or if deemed feasible, are anticipated to require considerable time due to a small population of subjects; and
4. results of clinical studies other than confirmatory clinical studies suggest a certain level of efficacy and safety.

Once a product is designated as a conditional early approval product, the applicant submits an NDA with the results of the exploratory clinical trial. However, various conditions

are imposed upon approval (e.g., conducting post-marketing surveys or other studies to reconfirm efficacy and taking necessary measures for proper use of the product).

Exclusivity

Patent exclusivity

The patent term is, in principle, 20 years from the application filing date; however, if the patent cannot be implemented because of the need to obtain marketing approval under the PMD Act, the patent term can be extended for a maximum of five years. The extension compensates for the time during which the patented invention cannot be used, such as the period from the investigational new drug filing date or the date of patent registration, whichever is later, until the date on which marketing approval for the drug is granted. In order to be granted an extension of a patent term, it is necessary to apply for an extension of the registration with the JPO before the patent term expires and within three months of the date when marketing approval is granted.

Regulatory/data exclusivity (re-examination system)

In Japan, there is no legislation that expressly provides for data exclusivity or marketing exclusivity like that of the US or the EU. However, a re-examination system under the PMD Act functions in a manner similar to data exclusivity, although its primary purpose is to ensure the efficacy and safety of newly approved drugs.

The purpose of this re-examination system is to ensure the safety and efficacy of newly approved drugs by having the marketing approval holders collect clinical data during a certain period after marketing approval is granted so that the MHLW can re-examine the safety and efficacy of the drugs. The holder of marketing approval for a new drug must apply for re-examination by the MHLW within three months after expiry of a certain period of time based on the category of the drug.

Under the PMD Act, a marketing approval application for a new drug with new active pharmaceutical ingredients must contain extensive data. In contrast, a marketing approval application for a generic drug with the same active ingredients and quantities, dosage, administration and indications as an approved original drug requires less information. Due to these relaxed requirements, generic companies enjoy a reduction in time and costs for marketing approval applications, although only after expiry of the original drug's re-examination period.

A generic company may apply for marketing approval for a generic drug even during the original drug's re-examination period; in this case, however, the generic company must submit the same or more extensive data than was attached to the marketing approval application for the original drug. This is to ensure the safety and efficacy of the generic drug, whose active ingredients, quantities, dosages, administration and indications have not yet been re-examined after the marketing approval. Therefore, when a generic company applies for marketing approval for a generic drug during the original drug's re-examination period, it does not enjoy the reduction in time and costs; thus, in practice, the re-examination system thereby serves as a protection for innovators in a

manner similar to data exclusivity, which prevents generic companies from filing marketing approval applications for generic drugs.

The re-examination period for each category of drug is as follows, and each period starts on the date marketing approval is granted:

1. 10 years for orphan drugs;
2. 10 years for drugs requiring a pharmacoepidemiological evaluation;
3. eight years for drugs containing new active ingredients;
4. six years for new combination drugs;
5. six years for drugs with a new route of administration;
6. four years for drugs with new indications (provided that if an approved drug has indications solely for an orphan disease, the period is five years and 10 months); and
7. four years for drugs with new dosages or administration (excluding route of administration).

The MHLW can extend the re-examination period by up to 10 years after hearing the opinion of the Pharmaceutical Affairs and Food Sanitation Council (a consultative panel for the MHLW) and confirming that the extension is necessary to perform a proper re-examination of a new drug.

Generic and follow-on pharmaceuticals

Generic drugs are approved by the MHLW through the same regulatory pathway. An NDA filing for a generic drug must reference an approved pharmaceutical product and relies on the PMDA's findings of safety and efficacy, rather than providing independent evidence of safety and efficacy in the application. The standard review period for generic drugs is one year. New generic drugs are approved twice a year, in February and August.

NDA filings for generic drugs must contain the same active ingredients, conditions of use, routes of administration, dosage forms, strengths, and labelling as the original drugs upon which the applications rely and must demonstrate bioequivalence to such drugs.

In Japan, there are no statutory patent linkage provisions in the Patent Act or the PMD Act; however, the MHLW considers the existence of patents unofficially in the process of reviewing generic drug applications.

According to administrative notices issued by the MHLW, a generic drug will not be approved until the substance patent or the use patent of the original drug expires and production of the active ingredient becomes possible. If only some of the indications or the dosage and administration are patented, the generic drug application may be approved so long as it is marked with other indications or a different dosage and administration. Formulation patents and manufacturing process patents generally do not block approval of generic drugs.

An applicant cannot submit a generic drug application until the re-examination period for the original drug has expired. For generic drug applications, animal studies and clinical

studies are not required because the drugs' safety and efficacy are already established. Bioequivalence and quality studies are only necessary in the development of generic drugs. To begin the approval process, the generic applicant must certify that the patents of the original drug or other relevant patents are no longer enforceable or will not be infringed upon by the manufacture, use or sale of the generic product. This requirement is necessary to ensure a stable supply of generic drugs.

Biologics and biosimilars

Biological products are defined as products derived from living organisms. Biological products include various products, such as blood products and urine-derived products, as well as vaccines. There are also gene therapy products, including genetically engineered vectors, cell tissue-based products such as regenerative medicine under biotechnology-applied products utilising genetic modification technology or recombinant DNA technology. Much like small molecule drugs that are approved under the PMD Act, biologics are also approved under the PMD Act as pharmaceuticals or regenerative medicine.

Approval for a biosimilar is also based on a determination that the product is safe, pure and potent (the equivalent of safety and effectiveness for a drug) and that the facility in which the product is manufactured, processed, packed or held meets standards designed to assure such safety, purity and potency. Like drugs, biological products are also eligible for periods of exclusivity (re-examination period).

For biological products, it is difficult to prove the equivalence of active ingredients with those of existing drugs, unlike small molecule drugs; therefore, the MHLW issued guidelines in 2009 concerning the required documents and data for the filing of applications for marketing approval for biosimilar products.[4] Applicants for marketing approval for biosimilar products are required to establish their own manufacturing processes, clarify the quality attributes, and demonstrate a high similarity of those attributes to the reference products. In addition, the data of both clinical and non-clinical studies are required to demonstrate biosimilar comparability.

Patent linkage

Patent linkage is generally understood as a system that takes into account the valid patent rights of an original drug when the regulatory authority grants marketing approval for a generic drug. The purpose of this system is to ensure a stable supply of generic drugs to the market by resolving patent disputes between originators and manufacturers of generics and biosimilars prior to commercialisation of generic drugs. In Japan, there is no explicit legislation for patent linkage; however, the MHLW provides and operates a certain patent linkage system on the basis of the MHLW's notice dated 5 June 2009 by setting the following requirements for marketing approval application review of generic drugs:[5]

1. the active ingredient of the original drug is not protected by a valid patent on the expected approval date of the generic drug; and
2.

the indications, dosage and administration of the original drug are not protected by a valid patent on the expected approval date of the generic drug.

After obtaining marketing approval for a new drug, the originator is required to submit a 'drug patent information report form' to the PMDA before the end of the re-examination period to provide information on substance or use patents covering the active pharmaceutical ingredients of the original drug. However, the provision of patent information is voluntary and will not be disclosed to the public.

The MHLW uses the patent information (substance and/or use patents) submitted by the originator to ascertain the patent protection period of the original drug and will not approve a generic if the original drug's active pharmaceutical ingredient cannot be manufactured due to the existence of an innovator's valid patent on that active ingredient. Therefore, in the marketing approval application procedure for a generic product, the generic company is required to indicate whether there is a substance or use patent on the active pharmaceutical ingredient of the drug and, if so, to attach a document indicating that the drug can be marketed immediately after marketing approval.

To show that an innovator's patent is invalid, the generic company is required to attach documents such as a patent invalidation trial decision or a court decision. However, the JPO's decision may be overturned in an appeal, which may lead to patent infringement litigation and affect the stable supply of generic products, depending on the outcome of the subsequent court judgment. Marketing approval can also be granted by showing that the consent of the patentee or exclusive licensee has been obtained.

Even if there is a patent on some indications or the dosage and administration of the original drug, if the re-examination period has expired, an application for a basic indication excluding those indications or dosage and administration is allowed to be filed for the generic product. Depending on the particulars of the use patent, a generic product may be approved for some of the indications of the original drug.

Once a generic drug is approved, the NHI price listing process usually begins. Generic companies are required 'to coordinate in advance with the parties concerned about any patent-related concerns regarding the listing of a generic drug on the NHI price list and to only take the NHI price listing process for products for which a stable supply is thought to be possible.' If a generic company wishes to list on the NHI price list a product for which there is a possibility of patent disputes, it is required to make prior arrangements with the patent holder manufacturer of the original drug and to take NHI price listing procedures only for products for which a stable supply is possible (e.g., where there is written consent from the patentee).

Since patents of substance and patents of use will have already been confirmed at the time of approval of a generic product, what is at issue at this stage are formulation patents, manufacturing process patents, and other peripheral patents. Generic companies develop generic products separately, and their formulation technologies and manufacturing methods vary. Therefore, even among generic companies entering the market at the same time, there are cases where patent rights may or may not be infringed, depending on the specifications of the product.

Under the current system in Japan, the originator has no way of knowing the details of a generic application until it is approved. Even if there is a difference of opinion between the

parties regarding an original drug patent, it is difficult to resolve the issue through prior coordination procedures within a few months after approval until the drug is listed on the NHI price list. If prior coordination is not successful with respect to formulation or process patents, the original company may file a patent infringement suit immediately before or after the generic product is listed on the NHI price list.

In Japan, patent linkage was introduced in 1994, and since the 2000s, the number of patent infringement lawsuits against generic companies has slowed to about three active pharmaceutical ingredients per year, which is not very frequent. This trend suggests that patent linkage in Japan may be effective in deterring patent disputes after the launch of generic products. However, due to the recent expansion of the generic market and fragmentation of patent expiry in Japan, patent disputes involving issues that are difficult to address have recently arisen.

For example, in 2017, a patent infringement suit was filed against trastuzumab BS (a biosimilar of Herceptin), the first such case for a biosimilar. The patent at issue was a regimen patent, which relates to an invention characterised by dosage and administration. As a result, to avoid infringement, the manufacturer of the biosimilar did not apply for approval for 'breast cancer', whose dosage and administration conflicted with the regimen patent, but for a partial indication of 'gastric cancer' only, which was approved. In particular, since many anticancer drugs have multiple combination therapies for each indication, an increase in the number of regimen patents in the future may encourage the filing of basic indication applications, in which generic drugs are filed for only some indications, as was the case with trastuzumab BS.

Also in 2017, for the first time, the IP High Court ruled on the scope of effect of an extended patent right, holding that the effect of an extended patent right extends to the scope of 'substantially identical' pharmaceutical products, not just 'the thing that was the subject of the marketing approval' as identified in the approved specifications of the original product (the Oxaliplatin case[6]). Although the patent right at issue was a formulation patent relating to a pharmaceutically stable preparation, this concept also applies to substance patents and use patents. For substance patents and use patents, the timing of patent expiry is confirmed by patent linkage, but for extended original patents, based on this concept, it is necessary to confirm whether the patents are 'substantially identical' in each extension period.

As patent expiry in Japan becomes more fragmented and the timing of market entry of generic products becomes more complex and more difficult to determine, it is expected that conflicts between the views of original and generic companies on the time of patent expiration will increase. It is necessary to carefully monitor future developments with regard to the MHLW's operation of the current patent linkage mechanism.

Competition enforcers

The primary regulator responsible for competition policy in Japan is the Japan Fair Trade Commission (JFTC).

In cases of unreasonable restraints of trade (such as cartels) and private monopolisation, if the JFTC files a criminal accusation with the Prosecutor General, the Public Prosecutors

Office will handle the case through criminal proceedings. However, the JFTC's policy is to limit criminal accusations to malicious and serious violations, such as price cartels, supply limit cartels, market split agreements, bid rigging, joint boycotts and private monopolisation, which may also have a broad impact on daily lives.[7] In practice, criminal accusations are filed only once every few years.

In addition, enforcement of the AMA is supplemented by civil litigation by persons who suffer private damages due to violations of the AMA, which is not as active as in some other jurisdictions, though. A person who has committed an act in violation of the AMA may be liable for damages based on tort. If the JFTC issues a cease and desist order and it becomes final and binding, such a person will be strictly liable for damages.[8] Also, victims whose interests are likely to be harmed by unfair trade practices have the right to demand an injunction.[9]

Merger control

The merger regulations under the AMA apply to business combinations in the pharmaceutical field, and prohibit them if they substantially restrict competition in a market. In addition, major business combinations, such as share acquisitions, mergers and business transfers, that meet certain thresholds (such as domestic sales) are subject to a prior notification requirement and cannot be implemented for 30 days after filing a notification, which essentially means it is necessary to obtain clearance from the JFTC prior to the close of the transactions. In practice, the parties usually consult with the JFTC in advance to start the review and make a formal filing at a stage where the JFTC is expected to give clearance within 30 days. In addition, even for business combinations that are not subject to the prior filing requirement, since many of them are still subject to merger regulations, the parties often voluntarily consult with the JFTC to seek clearance when the business combinations may raise a competition issue. Also, in order to appropriately regulate acquisitions of start-up companies, whose domestic sales are small but that may affect domestic competition, the JFTC reviews acquisitions where a large amount of consideration is expected and that may have a significant impact on domestic customers. In particular, the JFTC recommends voluntary consultation for acquisitions having a total consideration exceeding ¥40 billion and a potential impact on domestic customers or business.[10] Therefore, for acquisitions of start-up companies in the pharmaceutical field, it is necessary to consider voluntarily consulting with the JFTC even if they do not meet the notification thresholds.

If the JFTC finds that a business combination substantially restrains competition, it may issue a cease and desist order requiring that the parties take the measures necessary to eliminate the violation. In practice, however, problematic business combinations tend to be remedied by the parties themselves with consent from the JFTC in the course of its review or are voluntarily abandoned by the parties.

While a list of cases filed with the JFTC is publicly available, the details of the review results are published for only approximately 10 cases each year. The recent published pharmaceutical sector cases are as follows:

1. integration of Bristol-Myers Squibb Company and Celgene Corporation;[11]

2. acquisition by Takeda Pharmaceutical Co, Ltd of shares in Shire plc;[12]
3. business swap between the Sanofi Group and Boehringer Ingelheim Group;[13] and
4. acquisition of business from GlaxoSmithKline Co, Ltd by Novartis AG.[14]

In these cases, the JFTC took the view that it is appropriate to define the scope of the product market for each drug that has the same functions and benefits from the viewpoint of doctors and medical institutions. The JFTC usually identifies competing products and defines the scope of products based on the third level of the ATC classification system established by the European Pharmaceutical Market Research Association and then considers and defines the product market based on the fourth level and further classifications if the functions and benefits of drugs with the same ATC code in the third level are not the same from the viewpoint of medical institutions and are not used alternatively in practice. In addition, in the JFTC's review, if the parties engage in research and development of products competing with each other, the impact on competition will be determined by considering the actual state of such research and development as well. In the pharmaceutical field, not only products that have already been sold in the market but also pipeline products are considered during the review depending on the probability of their being launched in the market.

Anticompetitive behaviour

The AMA prohibits anticompetitive unilateral conduct such as private monopolisation or unfair trade practices. The types of conduct constituting private monopolisation and unfair trade practices are largely overlapping, but the JFTC seeks enforcement of private monopolisation only for cases where the market share of a product supplied by a party exceeds approximately 50 per cent and the conduct is deemed to have a serious impact on daily lives. The types of conduct falling under unfair trade practices are so broad that most unilateral conducts generally having the potential of a restrictive effect on competition are covered. Among them, resale price restriction and transactions on restrictive terms tend to be an issue in the pharmaceutical field. Unfair trade practices are subject to cease and desist orders by the JFTC. However, since the introduction in 2018 of commitment procedures (procedures for promptly resolving suspected violations based on agreements between the JFTC and a party), many cases that may fall under unfair trade practices are handled through the commitment procedures rather than cease and desist orders. The major unfair trade practice topics in the pharmaceutical area in recent years are as follows.[15]

Intellectual property law and the AMA

The AMA provides that it does not apply to acts found to constitute an exercise of rights under intellectual property laws, including the Patent Act.[16] However, in the case where an act is ostensibly regarded as an exercise of a right but cannot be substantively regarded as such based on the purpose of the intellectual property system in terms of fair and free competition, the provisions of the AMA will still apply. The JFTC's Intellectual Property Guidelines[17] comprehensively set forth its approach to the application of the

AMA to restraints related to the use of technology. For example, the guidelines state that 'in the case where technology provides the basis for business activities in a particular product market and a number of entrepreneurs, accepting licenses for the technology from the right holder, engage in business activities in the product market, the conduct of discriminatorily refusing to license a particular entrepreneur without reasonable grounds is found to deviate from or run counter to the intent and objectives of the intellectual property system.'[18]

Resale price restrictions

The restriction of a distributor's sales price (resale price) by a manufacturer in principle falls under unfair trade practices and is illegal.[19]

In a published consultation case, the JFTC argues that it is problematic under the AMA for a pharmaceutical manufacturer to sell its pharmaceutical products to a wholesaler at its suggested wholesale price and then revise its invoice price afterwards in accordance with the wholesaler's actual wholesale price because it has restrictive effects on the wholesaler's wholesale price.[20]

On the other hand, in the case where a pharmaceutical manufacturer and a medical institution agree through negotiation on the wholesale price for the medical institution, and the wholesaler only assumes responsibility for logistics and collection of proceeds without risk of inventory, and only sells the products at that wholesale price to receive fees for delivery thereof, the JFTC found that it is the pharmaceutical manufacturer who virtually sells the products to the medical institution, and thus determination of the wholesale price is not problematic under the AMA.[21]

Restriction on sales method

The JFTC takes the position that restrictions on retailers' sales methods (excluding those relating to sales prices, sales territories and sales destinations) do not themselves pose a problem under the AMA as far as there are reasonable grounds for appropriate sales of the products, such as ensuring safety, maintaining quality, and maintaining the reputation of trademarks, and the same conditions are imposed on other retailers. However, in cases where a manufacturer virtually imposes restrictions on a retailer's sales prices, trade of competing products, sales territories and customers by restraints on the retailer's sales methods, the legality of those restrictions is examined in terms of resale price restriction, exclusive transactions and transactions on restrictive terms.

In a recent case, the JFTC suspected that Alcon Japan Ltd was engaging in unfair trade practices (transactions on restrictive terms) by requesting that retailers not display sales prices in advertisements and not sell their contact lenses via the internet.[22]

In addition, the JFTC suspected that Nihon Medi-Physics Co, Ltd (NMP) was engaging in unfair trade practices (interference with a competitors' transactions) by (1) informing wholesalers, when Fujifilm RI Pharma Co, Ltd (FRI) entered into the market for a certain drug, that NMP would suspend the sale of its drug if the wholesalers transacted with FRI; (2) explaining to medical institutions that the automated drug administration device developed by FRI could not handle NMP's drug without sufficient grounds; and (3) refusing

to provide same-day delivery of its drug to medical institutions that purchased the same drug from FRI.[23]

Prescription drug distribution

The JFTC published a report and made recommendations on the distribution of prescription drugs in 2006 from the perspective of competition policies, including the following:[24]

1. Interference with generic transactions by originators would be problematic under the AMA (interference with competitors' transactions), and originators must not provide medical institutions with inappropriate information on generics.
2. Restrictions on wholesalers' sales prices based on information obtained from wholesalers constitute a problem under the AMA (resale price restriction). The JFTC will continue to pay close attention to prevent such conduct.

Special considerations

In the 2024 Special 301 Report issued by the United States Trade Representative, stakeholders expressed concerns about the current pharmaceutical regulatory system in Japan, such as the pricing of innovative drugs and the lack of transparency and predictability in annual NHI price revisions,
patent term extension registration for pharmaceuticals, patent linkage, and regulatory exclusivity. No particular amendments to the legislation for those pharmaceutical regulatory systems are being discussed; however, it should be further monitored whether the Japanese government will take the points raised in the report seriously and proceed with specific reviews to revise each system.

Outlook and conclusions

In Japan, there have yet to be specific decisions on competition law issues related to pay-for-delay by the JFTC or the courts. One reason for this is that, as in Europe, there is no system in Japan for granting an exclusive sales period to the first applicant of a generic drug, and there are few pay-for-delay cases. In addition, while in Europe and the US there is direct price competition between brand-name drugs and generics, in Japan the NHI price (the official price of prescription drugs) for a generic is in principle set at 50 per cent of the brand-name drug, and the patient co-payment ratio for prescription drugs is set at 10–30 per cent. Therefore, compared to the US and Europe, the entry of generic drugs is less likely to cause a significant price decline for original drugs or a sharp decrease in sales or market share of original drugs. This might be one of the reasons why there have not been many pay-for-delay cases in Japan. However, to reduce medical costs, the Japanese government set in a cabinet decision in June 2017 a target use rate of 80 per cent for generics by September 2020 to promote the use of generic drugs, and the competitive environment between brand-name drugs and generics has been changing. If

price competition with originators intensifies in Japan in the future, there is a possibility that incentives for pay-for-delay will increase among originators of innovative drugs.

In addition, although there are only a limited number of published cases in which the JFTC has actually conducted investigations, the JFTC has constantly paid close attention to the pharmaceutical sector, as pharmaceuticals are important for national welfare, there are long-standing issues in the drug distribution system, and oligopolies have been forming. The JFTC also keeps a close eye on global competition law enforcement trends, with increasing attention being paid to competition issues in the pharmaceutical sector worldwide. The JFTC's future enforcement activities should be closely monitored.

Endnotes

1 Article 2, paragraph 6 of the AMA. Back to section

2 Article 2, paragraph 5 of the AMA. Back to section

3 Article 2, paragraph 9 of the AMA. Back to section

4 'Guidelines for the Quality, Safety and Efficacy Assurance of Follow-on Biologics' (the MHLW's notification No. 0304007 dated 4 March 2009, as amended on the MHLW's notification No. 0204001 dated 4 February 2020) and 'Re: Marketing Approval Applications for Follow-on Biologics' (the MHLW's notification No. 0304004 dated 4 March 2009). Back to section

5 'Re: Handling of drug patents in relation to the review of marketing approval and NHI price listing of generic drugs under the PMD Act' (the MHLW's notification No. 0605001/0605014, 5 June 2009). Back to section

6 20 January 2017, case No. 2916 (ne) 10046. Back to section

7 The JFTC's 'Policy on Criminal Accusations and Investigation of Criminal Cases in Violation of the Antimonopoly Act' (7 October 2005). Back to section

8 Articles 25 and 26 of the AMA. Back to section

9 Article 24 of the AMA. Back to section

10 The JFTC's 'Policies Concerning Procedures for Review of Business Combinations' (established on 31 May 2004, as amended on 17 December 2019), Section 6(2). Back to section

11 JFTC Major Business Combination Cases for FY 2019, Case 1, published on 22 July 2020. Back to section

12 JFTC Major Business Combination Cases for FY 2018, Case 3, published on 19 June 2019. Back to section

13 JFTC Major Business Combination Cases for FY 2016, Case 4, published on 14 June 2017. Back to section

14 JFTC Major Business Combination Cases for FY 2014, Case 4, published on 10 June 2015. Back to section

15 The JFTC's 'Guidelines for Exclusionary Private Monopolisation under the Antimonopoly Act' (established on 28 October 2009, as amended on 25 December 2020), Part 1. Back to section

16 Article 21 of the AMA. Back to section

17 The JFTC's 'Guidelines for the Use of Intellectual Property under the Antimonopoly Act' (established on 28 September 2007, as amended on 21 January 2016). Back to section

18 Intellectual Property Guidelines Part 4, 2(3). Back to section

19 Article 2, paragraph 9, item 4 of the AMA. Back to section

20 JFTC Consultation Case for FY 2000, Case 4. Back to section

21 JFTC Consultation Case for FY 2001, Case 2. Back to section

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Summary

Introduction

In Portugal, there is a fundamental right to health protection specifically set out in the Chapter dedicated to fundamental rights in the Constitution of the Portuguese Republic. The right to health protection must be guaranteed: (1) by means of a universal and general national health service, which, with particular regard to the economic and social conditions of the citizens who use it, tends to be free of charge; and (2) by creating economic, social, cultural, and environmental conditions that particularly guarantee the protection of children, the young, and the elderly; systematically improving living and working conditions, promoting physical fitness and sport at schools and among the general population; and developing the public's health and hygiene education, and healthy living practices.[1]

As a result of this, the health sector, which includes the pharmaceutical industry, is a prominent, fast-evolving sector in Portugal, which has experienced a remarkable evolution over the past couple of decades.[2] This trend has naturally been reinforced by the covid-19 pandemic, which forced states to adapt to a global public health crisis, rethink the organisation of healthcare, and promote the adoption of measures to improve existing health systems.

Portugal is known for having a sound, trustworthy, and competent workforce in the life sciences sector. Employees in this sector are trained in current scientific developments and market tendencies by universities, and the government is strategically committed to strengthening the country's scientific resources. Collaboration projects between multinational pharmaceutical corporations, Portuguese biotech firms, and reputed universities have produced some of the most advanced research and therapies developed for worldwide application.

Established in 2008, the Health Cluster Portugal (the Health Cluster) includes R&D pharmaceutical companies, hospitals, universities and government bodies. It is a platform located in Porto, which aims to turn Portugal into a competitive player in the research, invention, development, manufacture and commercialisation of products and services of high added value related to health that can compete in a framework of excellence in the international market. It currently has approximately 233 members, embracing the country's entire spectrum of life sciences.[3]

Public and private healthcare providers are trying to integrate the services that they offer intending to attract more medical tourism to Portugal. The Health Cluster and relevant government bodies are working with these players to establish a consolidated Portuguese presence in this area.

Two of the most significant events in the life sciences domain in Portugal in the past decade have been the official opening of the Champalimaud Centre for the Unknown in October 2010, and the placement in US pharmacies of the first medicine protected by a Portuguese patent.

The Champalimaud Centre was made possible by the €500 million donation by the Portuguese entrepreneur António Champalimaud. It is a medical research centre that puts Lisbon at the forefront of advances against cancer and the development of neuroscience.

The company BIAL[4] developed the first medicine patented and researched in Portugal to be placed in US pharmacies in April 2014 by Sunovion Pharmaceuticals Inc, a licensee of BIAL. The trade name in the United States for the innovative anti-epileptic drug, Aptiom, was approved by the US Food and Drug Administration in November 2013.

In 2014, BIAL developed a new medicine for Parkinson's disease, Ongentys (opicapone), reinforcing the sustainability and success of its R&D projects. The medicine was granted marketing authorisation (MA) by the European Medicines Agency (EMEA) in July 2016, and its commercialisation in China was announced in 2018.

More recently, two Portuguese universities have initiated new groundbreaking projects in the field of biomedical and health solutions [5] and in 2024 the Portuguese government created a Health Research Incentive Programme aimed at promoting health research in public institutions providing health services and care, enhancing the value and training of health professionals, and providing qualifications in the exercise of health promotion and disease prevention activities.[6]

Year in review

According to the latest available data, in 2022, the investment by companies, in Portugal, in research and development (R&D) amounted to an expenditure of €2.572 million, representing 1.73 per cent of the GDP, out of a total annual expenditure in R&D, in Portugal, of €4.134 million.[7]

In 2018, pharmaceutical and biotechnology products accounted for €1.291 billion in exports. This sector represented an annual turnover of around €27 billion, and investment in health reached €462 million in 2017, representing 10.5 per cent of total business investment in R&D in Portugal. More recently, in 2023, Portuguese healthcare product exports broke all records. The latest figures from the Portuguese Agency for Investment and Foreign Trade (AICEP), based on data from the National Statistics Institute (INE), have shown that sales in the sector totalled €3.3 million in 2023. This is an increase of approximately 36 per cent compared to €2.460 million in 2022.[8]

One public policy priority has been to enhance human resources training and qualifications, together with workforce placements in healthcare institutions and measures to attract foreign talent to Portugal.[9] Between 2012 and 2023, the share of human resources in science and technology in the working population in Portugal increased from 28.7 per cent to 41.5 per cent.[10] In line with this, in 2022, there were 243 hospitals in Portugal, three more than in the previous year and 14 more than in 2012.

Portugal represents about 2 per cent of the EU pharmaceutical market. In 2022, there were 2,921 pharmacies and 197 mobile pharmaceutical units in Portugal, 28 for every 100,000 inhabitants.[11] In 2023, the Portuguese pharmaceutical market was valued at €5.292 million.[12]

Generic drugs in Portugal achieved a market share of 51.9 per cent in 2024.[13] In 2021, there were 9,050 generic drugs with MAs granted by the Portuguese Regulatory Medicines Agency (Infarmed).[14] In addition, pharmaceutical products and raw materials imports amounted to nearly €3.759 million in 2023, while exports amounted to €2.811 million.[15] There were 523 active clinical trials in Portugal in 2023.[16]

As in other EU countries, the covid-19 pandemic greatly affected the Portuguese healthcare system. In addition to any long-term consequences resulting from such an event, in 2023 Portugal underwent a year of political instability, which, inevitably, impeded certain structural reforms that may have been planned for the national healthcare system. Therefore, although the market has shown a great disposition to invest in R&D and exports in the health sector keep growing, it remains to be seen how the status of public and private health systems will evolve.

Legislative and regulatory framework

Decree-Law 176/2006, of 30 August 2006 (the Medicines Act), was approved amid an extensive in-depth review of the Portuguese pharmaceutical legislation carried out in 2006, which implemented several EU directives and reviewed the national legislation in force. The main purpose of the Medicines Act, as amended, is to regulate the manufacture, quality control, safety, efficacy, entry on the market, and advertisement of medicinal products for human use.

The rules regulating prescription drug pricing were subject to significant changes in 2015 and are now set out in Decree-Law 97/2015 of 1 June 2015, as amended by Decree-Law 115/2017 of 7 September 2017 (Decree-Law 97/2015). The establishment of the sales price for consumers (PVP) of the pharmaceutical products in question depends on the pricing framework used in the 'reference countries' for pricing purposes (according to Ruling 280/2021 of 3 December 2021).[17] The PVP must be determined by calculating the maximum price at the level of production or importation in Portugal (the sale price to wholesalers), which cannot exceed the limits imposed by Article 6 of Ruling 195-C/2015 of 30 June 2015, as amended.

Decree-Law 97/2015 also sets out the rules governing the reimbursement of prescription pharmaceutical products. In this regard, Infarmed is the competent authority that analyses any applications filed by the MA holder for the reimbursement of a prescription pharmaceutical product by the National Health System. Infarmed then presents the reimbursement proposal to the Ministry of Health for the latter's final decision, which depends on verifying two cumulative requirements: a technical-scientific demonstration of the therapeutic innovation or its therapeutic equivalence for the claimed therapeutic indication; and a demonstration of its economic advantage.

In addition to the two requirements described above, reimbursement is also subject to, among other things, one of the following:

1. an innovative pharmaceutical product that will overcome any given therapeutic shortcoming, defined by greater efficiency, effectiveness or safety by reference to the existing alternative treatments;
2. a new pharmaceutical form, a new dosage or a significantly different package size of a pharmaceutical product already reimbursed, with an identical qualitative composition to the extent that the existence of a therapeutic need and an economic advantage are demonstrated or acknowledged; and
3.

new pharmaceutical products that are not a significant therapeutic innovation, if they present economic advantages in relation to medicinal products already reimbursed, are used with the same therapeutic objectives, and possess proven identical action mechanisms.

The main Portuguese legal framework for patents is found in Articles 50 to 125 of the Industrial Property Code, as approved by Decree-Law 110/2018 of 10 December 2018, as amended (CPI). Pursuant to Article 100 of the CPI, patents are valid for 20 years from the date of filing, which may be extended by means of supplementary protection certificates.

On the other hand, the main body for the enforcement of competition rules in Portugal is the Portuguese Competition Authority (AdC), which ensures respect for the rules that promote and defend competition and holds sanctioning, supervisory and regulatory powers. The AdC has extensive practice in matters concerning the pharmaceutical industry, within merger control and restrictive practice proceedings.

The main legal framework regulating competition law matters is the Portuguese Competition Act (the Competition Act), Law 19/2012, of 8 May, amended in 2022 by Law No. 17/2022. This last amendment of the Competition Act resulted from the transposition of the ECN+ Directive.[18] The AdC led the transposition of the ECN+ Directive into Portuguese law and took advantage of this opportunity to propose adjustments to the existing Portuguese competition law framework, exceeding the scope of the ECN+ Directive. This led to an increase in the AdC's investigative powers and access to evidence, but also provided new guarantees to whistle-blowers (such as anonymity for whistle-blowers who request it).[19]

In 2018, the Portuguese private enforcement regime was established by Law No. 23/2018,[20] following the Private Enforcement Directive.[21] This Law marks the adoption of the first specific set of rules in force in Portugal concerning actions for damages resulting from a breach of competition rules.

There are no specific statutes, regulations, or guidelines directly regulating the interaction between pharmaceutical intellectual property and competition issues in Portugal, or acquisitions and infringements within the pharmaceutical sector; however, there are inevitably points that cross over between the two concepts, and pharmaceutical intellectual property-related actions may fall under the general competition law prohibitions.

Under Portuguese legislation, and in accordance with European law, holders of intellectual property rights (IPRs) are not exempt from the competition law rules; therefore, the AdC is competent when, in the context of the use of IPRs, an undertaking infringes any prohibition of practices restricting competition, under Articles 9 and 11 of the Competition Act (respectively corresponding to Articles 101 and 102 of the Treaty on the Functioning of the European Union (TFEU)). The AdC is also competent to assess merger transactions that meet the notification thresholds, including when they involve assets related to IPRs.

New drugs and biologics – approval, incentives and rights

Drugs

As Portugal is an EU Member State, the approval of drugs for placement on the national market is governed by the rules and procedures of the European regulatory system applicable to this area. It, therefore, comprises four possible procedures: the centralised procedure, the mutual recognition procedure, the decentralised procedure and the national procedure. The drug approval process in Portugal is governed by the Medicines Act.

Under the national procedure, to obtain an MA for a specific medicine, an applicant must provide the following information, in accordance with Article 15 of the Medicines Act:

1. name or corporate name, permanent address of the applicant and (where applicable) the manufacturer's name;
2. VAT number, unless the applicant has its registered office or establishment in another EU Member State; and
3. number of dossiers that form the application.

The application must be submitted together with the following information, in Portuguese or English, or both:

1. a pharmaceutical form, and qualitative and quantitative particulars of all the constituents of the medicinal product, including but not limited to the active substances and excipients, in their usual terms, and, if applicable, the reference to its international non-proprietary name, or in the absence of this, its chemical name;
2. the therapeutic indications, contra-indications and adverse reactions;
3. the dosage, method and way of administration;
4. reasons to adopt any preventive or security measures to store the drug, its administration or the disposal of its waste, together with an indication of potential environmental risks resulting from the drug;
5. one or more copies of the summary of the product characteristics (SPC),[22] a sample of the outer packaging and the container and, if applicable, the results of the evaluations carried out with the target groups of patients;
6. a copy of the manufacturing licence valid in Portugal, or when the drug is not manufactured in Portugal, a certificate of the manufacturing licence granted to the respective manufacturer;
7. information regarding the manufacturing of the medicinal product, including a description of the manufacturing method;
8. a description of the control methods undertaken by the manufacturer;
9. a written declaration from the medicine manufacturer, supported by audit reports, attesting that the manufacturer of the active substance of the medicine has complied with the principles and guidelines of good manufacturing practices. The statement should include the date of the last audit report and indicate that the result

of the audit report confirms that the manufacturing process follows those principles and guidelines;

10. the results of the pharmaceutical tests and preclinical and clinical trials;[23]
11. a detailed description of the pharmacovigilance system, together with evidence of the existence of a person responsible for it and of the means required to notify any adverse reaction detected and, if applicable, of the risk management system to be used by the applicant;
12. an environmental risk valuation report, including, if applicable, an indication of the measures proposed to limit such risk;
13. a statement evidencing that the clinical trials carried out outside the European Community have complied with the ethical requirements set out under the clinical trials legislation;
14. a copy of MAs issued in other EU countries, as well as any decision rejecting the granting of the authorisation, the grounds for rejection and a summary of the information in relation to safety, including, when applicable, information related to the periodic safety and adverse reactions;
15. a copy of the MAs issued by the authorities responsible in other countries, as well as any decision refusing to grant the authorisation, if any, and the grounds for such refusal;
16. a list of Member States in which an application for an MA has been submitted, with copies of the SPC and the package leaflets proposed or authorised therein;
17. if applicable, a copy of the qualification of the drug as an orphan drug, with a copy of the opinion of the EMEA;
18. a document evidencing the payment of the fees due; and
19. other elements detailed in Annex I of the Medicines Act.

In addition to the standard procedures, there are three abridged or expedited applications: the abridged application for generic drugs, the authorisation for special use (ASU), and the early-access programme.

The ASU, as established under Article 92 of the Medicines Act and Infarmed's Regulation 1546/2015 of 6 August 2015, as amended by Regulation 1079/2021 of 21 October, allows Infarmed to authorise the use of medicines for which no MA has been granted if:

1. those medicines are considered indispensable (by means of a clinical report) for the treatment and diagnosis of certain pathologies;
2. they are necessary to prevent an actual or potential spread of pathogenic agents, toxins, chemical agents or nuclear radiation likely to have harmful effects; or
3. they are acquired by a pharmacy and to be used by a particular patient (only in exceptional cases).

Both hospitals and existing MA holders can apply for an ASU. If the applicant is a hospital, the following criteria must be met: there is no other medicine in Portugal that presents an identical qualitative and quantitative composition of active substances and

pharmaceutical form, with a valid MA or, if it exists, it is not currently being commercialised; and the medicine must be considered as essential for the prevention, diagnosis or treatment of certain pathologies, with no proven therapeutic alternative in existence. It is also necessary to demonstrate that the medicine has a well-known clinical benefit or presents preliminary evidence of a clinical benefit.

If the applicant is an existing MA holder, the application must be shown to be in the interest of patients and necessary to guarantee access to a certain drug during market disruption, and where there is no proven therapeutic alternative.

The ASU is exceptional and temporary; therefore:

1. in the case of medicinal products with a well-known clinical benefit, the ASU expires on the last day of the year for which it was granted;
2. in the case of medicinal products with preliminary evidence of clinical benefit, the authorisation is valid at the end of the treatment for which it was requested, with a maximum limit of one year; and
3. the ASU expires when the medicines have been distributed to the patients who meet the described exceptional requirements.

In addition, it is also possible for an ASU to be granted to a hospital under an early-access programme, under the conditions established in Infarmed's Resolution 80/CD/2017.

Under Articles 27 and 28 of the Medicines Act, if an MA is granted, it is valid for five years but is renewable for an indefinite period following its first renewal. In addition, Article 19 of the Medicines Act provides exclusivity periods for medicinal products as follows:

1. after the granting of the MA for a medicinal product, the originator company's preclinical and clinical data cannot be used in a generic marketing authorisation application for eight years;
2. the generic medicine can only be marketed after 10 years have elapsed from the initial granting of the MA to the originator company; and
3. one additional year of marketing exclusivity is available if a new therapeutic purpose is registered, within eight years of the granting of the reference product's MA, which is considered to be of significant clinical benefit compared to existing therapies.

Generic and follow-on pharmaceuticals

Under Article 3(1) of the Medicines Act, generic drugs are defined as those with the same qualitative and quantitative composition in active substances, under the same pharmaceutical form, and for which respective bioequivalence with the reference drug has been demonstrated, based on appropriate bioavailability studies.

As such, the procedure for their approval follows the same steps as those described in 'Drugs', with some differences established in Paragraphs 3 and 5 of Article 19 of the Medicines Act:

1.

it is not necessary to present reports on preclinical tests and clinical trials, except when:

- it is not demonstrated that the medicine meets the bioavailability requirements defined in Infarmed's directives or the Community area;
- the bioequivalence may not be demonstrated using bioavailability studies; or
- the medicine has, in relation to the reference medicine, differences in the active substances or its therapeutic indications, in its dosage, its pharmaceutical form or method of administration; and

2. the marketing of generic drugs must respect the data and market exclusivity granted to the MA holder of a reference drug, which means that those drugs can only be marketed 10 years after the initial authorisation is granted to the reference medicine at a national or EU-level or 11 years after the initial authorisation is granted to the reference medicine, if within the initial eight years the MA holder of the reference medicine has obtained an authorisation to one or more new therapeutic indications, which, upon a scientific evaluation prior to its authorisation, are considered to bring a significant clinical benefit in relation to the existing therapeutics.

A significant modification introduced by the Medicines Act and Law 62/2011 of 12 December 2011 (Law 62/2011) is that the issuing of a generic drug MA is not considered an infringement of the rights granted by patents or supplementary protection certificates.

Biologics and biosimilars

Portuguese law does not define 'interchangeability' or 'substitutability'. The Medicines Act defines an 'essentially similar medicine'[24] as a medicine that has the same qualitative and quantitative composition of active substance or substances, has the same dosage form and is bioequivalent to a reference product. Generic medicines are considered to be essentially similar medicines.

According to the Medicines Act, medicines that are identified as generics on a list of medicines published on the Infarmed website are considered interchangeable and may be substituted for prescribed medicines at the pharmacist's discretion, unless a medicine is prescribed by a product (trade) name and substitution is prohibited.

In addition to this, Portuguese law does not establish any specificity for the approval process of biologic drugs. Further, and in relation to biosimilar medicines, if they do not fall within the definition of generic drugs, owing to, in particular, differences relating to raw materials or differences in manufacturing processes of the biological medicinal product and the reference biological medicinal product, they may not benefit from the simplified procedure of generic drugs. As a consequence, under Article 19(6) of the Medicines Act, the approval of an MA by Infarmed of such a biosimilar drug requires the presentation of appropriate preclinical tests or clinical trials.

Infarmed issued specific guidance on biosimilar substitution in February 2018.[25]

Patent linkage

Law 62/2011 established, among other important changes to the Medicines Act, a compulsory arbitration regime for disputes emerging from industrial property rights, whenever reference drugs and generic drugs are at issue. This new regime intended to avoid the excessive use of patent litigation in the administrative courts in Portugal, as has been the case in recent years, where the validity of administrative acts that might violate industrial property rights was disputed.[26]

With the enforcement of this law, arbitration was mandatory to resolve disputes emerging from industrial property rights related to reference drugs and generic drugs, regardless of whether the dispute related to process, product or utility patents, or whether supplementary protection certificates were at issue.

This law was amended by Decree-Law 110/2018 of 10 December 2018. It now establishes that the disputes emerging from industrial property rights concerning reference and generic drugs, including precautionary proceedings, are subject to voluntary (rather than compulsory) arbitration (institutionalised or not institutionalised) if all parties agree. Proceedings must be initiated within 30 days of the publication of an MA request for a generic drug on Infarmed's website. Any party intending to invoke its industrial property rights (which is usually the owner of the reference drug) may do so at the institutionalised arbitral court or request to submit the case to non-institutionalised arbitration.

After notification from the arbitral tribunal, the applicant for the MA must present a defence within 30 days. Failure to do so means that the applicant cannot commence the industrial or commercial exploitation of the drug (which is usually the generic drug) as long as the industrial property rights invoked by the owner of the reference drug remain in force.

In the arbitration proceedings, it is possible to invoke and recognise the invalidity of a patent with an inter partes effect. Moreover, in the arbitration proceedings, the documentary evidence must be filed together with the pleadings. The hearing for the production of evidence, which must be presented orally, must take place within 60 days of the filing of the defence.

From the decision rendered by the arbitral tribunal, it is possible to file an appeal with the Court of Appeal; however, this pending appeal does not stay the arbitral proceedings, which means that it does not suspend the decision of the arbitral tribunal.

Resolving disputes through arbitration helps to reach a decision more rapidly, thereby shortening the period of legal uncertainty over the generic drug. The concern regarding efficiency leads to the imposition of tight deadlines and preclusions: failure to respond to the initial pleading will forbid the defendant from marketing the generic medicine until the industrial property right has expired.

Competition enforcers

The main body for the enforcement of competition rules in Portugal is the AdC, which is an independent administrative body in charge of the public enforcement of competition law in Portugal, without exceptions in all sectors of the economy in Portugal.

In this context, the AdC is competent to investigate and sanction anticompetitive practices – such as anticompetitive agreements and concerted practices (Article 9 of the Competition Act) and abuse of a dominant position (Article 11 of the Competition Act) – and to assess merger transactions when they meet the notification thresholds. The AdC has significant experience in the pharmaceutical sector, comprising the full spectrum of AdC enforcement.

Judicial appeals against the decisions and proceedings carried out by the AdC fall under the jurisdiction of the Portuguese Competition, Regulation and Supervision Court (the Competition Court) and the Lisbon Court of Appeals.

In cases of mere acts of unfair competition matters involving IPRs or patent infringement or conflicts, the AdC and the Competition Court have no jurisdiction, as these come under the jurisdiction of the Intellectual Property Court.

Merger control

The AdC is competent to assess merger transactions that meet the relevant notification thresholds. In this context, the AdC has noteworthy experience in merger cases in the pharmaceutical and healthcare sectors. The most recent examples include the acquisitions of: Advanz Pharma;[27] Udifar II;[28] the Laboratório de São Lázaro by the Unilabs group;[29] the Raxone business by the Italian company Chiesi Farmaceutici;[30] the MedicalMedia II assets by Stemlab, SA;[31] Logifarma – Logística Farmacêutica SA by Alliance Healthcare and Iberfar;[32] the Priadel assets by Essential Pharma limited;[33] Udifar II by Plural - Cooperativa Farmacêutica CRL;[34] and Cresbard Invest by ArchiMed.[35]

In the context of pharmaceutical intellectual property, the acquisition of IPRs occurs frequently. Under Portuguese competition law, the mere acquisition of IPRs may constitute a merger, provided that it leads to a lasting 'change of control in the whole or parts of one or more undertakings' and that the assets constitute an activity resulting in a presence in a market to which a turnover arises.[36]

A recent example is the Raxone case, whereby Chiesi Farmaceutici acquired the rights of representation, distribution and development of the Raxone business, it being the only drug approved on the market for the symptomatic treatment of Leber hereditary optic neuropathy.

Additionally, there is the case of the acquisition of sole control over the assets necessary for the production and marketing of the orphan medicine Cystagon in every country, excluding the United States, Australia, and Japan.[37] Cystagon's assets include the assets necessary for the production and marketing of the Cystagon orphan drug, including IPRs, such as trademarks; relevant marketing authorisations and business files related to customers and suppliers; and the rights and know-how necessary for the manufacture of Cystagon.

In this case, the AdC authorised the transaction and considered that it did not present any anticompetitive practices based on three main grounds:

1. the operation consisted of the mere vertical integration of the Cystagon assets with its current exclusive distributor, Orphan Europe (having no impact on the structure of the offer of this medicine in Portugal);
2. Cystagon was no longer protected by patent rights, which could prevent similar products from entering the Portuguese market; and
3. there was one medicine that could represent a potential competitor to Cystagon in Portugal: Procysbi – despite not being marketed in Portugal, Procysbi has held an MA at the European level since 2013 and, therefore, could potentially enter the Portuguese market.

In the case of the acquisition of Astellas Pharma's dermatological business by LEO Pharma, the target assets included trademarks, domain names, patents, MAs, cosmetic quality records, safety data, technology, and marketing know-how and rights resulting from manufacturing contracts, supply and distribution contracts, in-licensing and out-licensing contracts. Each one of those assets was related to four prescription medicines – Protopic, Pimafucort, Locoid, and Zineryt – and a cosmetic product, Locobase Repair.[38]

In another case, the AdC assessed the acquisition of the assets related to the medicine Vesanoid, made up of trademarks, registrations, inventories, and agreements relating to the production and marketing of Vesanoid in Portugal.[39] Vesanoid, as an orphan drug with no generic version available, and the only existing treatment for acute promyelocytic leukaemia, had a market share of 100 per cent in Portugal; however, the AdC approved the transaction, considering it to involve a mere transfer of market share without impacting the competitive structure of the relevant market.

More recently, in November 2023, the AdC scrutinised the acquisition by the Insud Pharma Group, through Insud Pharma S.L. and Chemo Project S.A., of exclusive control over the Viatris Group's Women's Healthcare Business, which included a set of assets and marketing rights for Viatris' Women Healthcare Business products on a global scale.[40-] In particular, the business acquired is dedicated to the development, manufacture and marketing of (1) prolactin inhibitors (G2D); (2) hormonal contraceptives for systemic use (G3A); (3) oestrogens in combination with non-hormonal substances (G3C); (4) selective oestrogen receptor modulators (G3J); and (5) anti-Parkinson's medicines (N4A). The AdC approved the transaction, given the absence of or limited horizontal overlap between the activities of the parties involved in the transaction.

In 2024, the AdC has also assessed a transaction in the Pharma sector, involving the acquisition by Esteve Healthcare, S.L. of part of Perrigo's business.[41] Perrigo is a Spanish pharmaceutical group, which operates in Portugal through its subsidiary HRA Pharma Iberia S.L. The acquired business comprises three drugs for the treatment of orphan endocrinal and oncological diseases: Lysodren (a drug used to treat symptoms of advanced adrenocortical carcinoma), Metopirone, and Ketoconazole (both used to diagnose and treat Cushing's Syndrome). The AdC cleared the transaction as it merely resulted in a transfer of market shares from the Perrigo business to the Acquirer's group, with no change in the structure of the relevant markets.

Anticompetitive behaviour

Portuguese law, both in the area of IPRs and competition, is largely based on European law.

The AdC is competent when, within the context of IPRs, an undertaking infringes the prohibition of bilateral or unilateral restrictive practices, respectively established in Articles 9 and 11 of the Competition Act, which mirror Articles 101 and 102 of the TFEU; therefore, under Portuguese law, anticompetitive restraints related to intellectual property in the pharmaceutical sector may fall under either the prohibition of agreements and concerted practices (Article 9), or the prohibition of abuse of dominant position (Article 11).

Anticompetitive practices in breach of Articles 9 and 11 are sanctioned with fines up to a maximum of 10 per cent of the offending undertaking's turnover in the year preceding the decision.[42] The Competition Act also provides for ancillary penalties, which include a prohibition of up to two years on the right to take part in public tenders, as well as the publication of the infringement decision in the Portuguese Official Gazette and in national, regional or local newspapers.

Additionally, members of the board of directors of the infringing undertakings, as well as any individuals responsible for the management or supervision, may be sanctioned with fines that cannot exceed 10 per cent of the individual's annual income deriving from the exercise of their functions in the undertaking concerned. Undertakings may also be subject to the payment of damages, as provided by the private enforcement rules.[43]

Under its supervisory function, the AdC may issue guidance addressed to specific undertakings or sectors. For example, in the pharmaceutical sector, in May 2020 it issued guidance regarding a proposal of the National Association of Pharmacies (ANF) on the maximum margin to apply in the sale of personal protective equipment against the covid-19 pandemic – which would later be subject to legislative intervention – recalling, in general terms, that the limitation of the freedom of its members through the imposition of commercial (and other) conditions constitutes an infringement of the competition rules, punishable under the Competition Act.[44]

In September 2018, the AdC and the Infarmed signed a memorandum of understanding agreeing to a regular exchange of information on the supervision and monitoring of the sale and consumption of medical products for human use, medical devices and cosmetics, aiming at detecting market failures and competitive distortions in timely manner. Both authorities wish to closely monitor the evolution of prices, patent periods, the introduction of generic medicines, the development of biosimilars, and shortages of medicines in the market to be able to assess the extent to which anomalous situations may be related to the existence of anticompetitive practices.

In this context, the AdC sanctioned Natus Medical Incorporated (Natus) for alleged restriction of competition in the distribution of essential medical devices in the Portuguese market; thus, Natus was fined €100,000, further to a settlement with the AdC whereby it acknowledged that it engaged in vertical conduct that would have prevented its distributors from selling to customers located outside the geographical areas allocated to them and following unsolicited orders, and further defined the portfolio of products that could be resold by the distributors to specific customers from 2018 until December 2020.[45]

Under this framework, agreements made between undertakings that aim to prevent the access of substitutes to the market, such as pay-for-delay, are prohibited (Article 9 of the Competition Act).

In 2014, in the AstraZeneca case, the AdC assessed for the first time a potential pay-for-delay infringement.[46] At issue was an agreement that was concluded between Teva and its subsidiary Ratiopharm with the company AstraZeneca, through which Teva and Ratiopharm agreed to withdraw the product Rosuvastatin Ratiopharm, distributed by Ratiopharm, from the Portuguese market.

In Portugal, AstraZeneca commercialises the medicines Crestor and Visacor, which are composed of the active substance rosuvastatin. Crestor was protected by a patent until 2012 and by a supplementary protection certificate until 2017 (valid at that time); however, Rosuvastatin Ratiopharm, a competing product, entered the market without any verification of the IPRs at stake. In this context, AstraZeneca filed patent infringement proceedings, and the parties settled the conflict through an agreement that covered the withdrawal of Rosuvastatin Ratiopharm from the Portuguese market.

In the same case, the AdC pointed out that intellectual property dispute settlement agreements may be found to be anticompetitive under Article 9 of the Competition Act. To this end, it has clarified that agreements between companies to settle patent litigation are, like any other agreement between undertakings, subject to scrutiny of the competition rules. This means that although companies have the right to settle their patent disputes, they must do so while respecting the competition rules; the fact that these agreements are based on a patent dispute and a consequent arbitration decision does not exempt them from complying with the competition rules.[47]

The first time the AdC took interest in what concerns restrictive practices in the pharmaceutical sector was in 2005. The AdC fined five pharmaceutical companies (Abbott, Bayer, Johnson & Johnson, Menarini and Roche) in the first sanctioned cartel case in Portugal.

The case involved the alleged concertation of these five pharmaceutical companies in several public tenders for the supply of reagent strips of various Portuguese hospitals, and a total fine of around €19 million was imposed on these companies. Some of the sanctioned undertakings appealed the AdC's decisions and, because of procedural irregularities, the Commercial Court of Lisbon (competent for competition cases before the Competition Court was established) partially annulled the AdC's decisions and required the AdC to repeat some procedural acts.

Subsequently, in 2008, the AdC restated its first assessment of the case, confirming that the involved undertakings concerted on numerous occasions, from 2001 to 2004, to fix the prices to be submitted in bids for reagent strips in hospital tenders, aiming to raise their prices; thus, having corrected the procedural errors, the AdC again imposed an overall fine of €13.5 million on the appellant companies, which was, at the time, a record.[48]

In 2015, in the ANF case, ANF, the largest association of pharmacies operating in Portugal, and three other undertakings of the same group[49] had allegedly abused their dominant position through margin squeezing in the market of commercial data of pharmacies, and in the markets of pharmaceutical market studies based on this data.[50] In short, ANF made access to IMS Health Lda pharmacy data difficult.

IMS Health Lda provides market studies in the health sector and is an undertaking competing with HMR (a company created within the ANF Group to operate in the market for the production and sale of market research based on commercial pharmacy data). The AdC considered that the ANF Group's practice was abusive and had led to upstream and downstream markets foreclosure. It imposed an overall fine of €10.3 million.

The Competition Court upheld the AdC's decision while reducing the amount of the fine to €6.89 million because of the nature and size of the affected market.[51] ANF appealed this decision, and in June 2017 the fine was reduced for a second time by the Lisbon Court of Appeal because the requirements to establish Farminveste's parental liability were not met, resulting in the revocation of the fine of €6.08 million specifically imposed on Farminveste.[52]

Earlier, in 2012, the AdC found that Roche Farmacêutica Química Lda had abused its dominant position (in relation to certain medicines) in the context of tender proposals in hospitals by providing mixed bundles and loyalty discounts in its medicine tender proposals. The AdC imposed a fine of €900,000.[53]

In 2021, the AdC sanctioned AOC Health GmbH with a fine of €35,000 for gun jumping, characterised by the failure to notify, under the merger control regime, the acquisition of Stemlab. Stemlab is the company that controls the Crioestaminal and BebéCord brands.-[54]

In November 2022, the AdC sanctioned, with a fine of €1.25 million, Farmodiética - Cosmética, Dietética e Produtos Farmacêuticos, S.A. (a supplier of food supplements and healthy food products, for fixing and imposing retail prices to distributors). According to the AdC, between 2015 and 2022, Farmodietica imposed on its distributors the retail price at which its products should be sold to final consumers by sending them retail price tables and setting the maximum applicable discounts on the retail price of its products. According to the AdC's decision, Farmodiética operated a monitorisation system allegedly to ensure that its distributors implemented the resale prices and maximum discounts imposed and created an incentive system, thereby threatening or reducing the commercial conditions of its distributors, as well as limiting, restocking, or even cutting supplies in case of non-compliance. The case came to an early conclusion due to Farmodietica's use of the settlement mechanism, whereby the company admitted liability and agreed to settle the case, ending the infringement.[55]

Special considerations

Further to the health and financial crisis arising from the covid-19 pandemic, specific attention is being paid to the pharmaceutical sector. In the context of the pandemic, the AdC has spent time evaluating options to strengthen competition regimes, with a special focus on innovation. It drew attention to the importance of promoting innovation towards a better and more sustainable economic recovery.

Making protection and incentives for innovation one of its priorities for 2021, and again in 2022, the AdC considers that the removal of structural and legislative barriers that impede innovation, efficiency, and growth contribute to greater competitiveness between companies.[56] This increasing attention over innovation concerns is leading to more

sophisticated, substantive assessments in merger control proceedings, especially for more importance to be given to the merger's impact in terms of reducing choice and harming innovation.

Outlook and conclusions

Portuguese law does not provide specific provisions regarding the relationship between pharmaceutical intellectual property and competition law, and relies on general competition prohibitions to assess the validity of intellectual property-related practices. The regulation of the crossover between both areas is largely similar in substance to the applicable EU rules because the main legal developments affecting pharmaceutical intellectual property and competition law have occurred at the European level; many issues are yet to be addressed at the national level.

One of the first alleged cartels sanctioned by the AdC involved the supply of pharmaceutical products to Portuguese hospitals. There were also investigations concerning abuse of a dominant position in the pharmaceutical sector, which evidences the relevance of the monitoring activity of the AdC in this sector.

The AdC's decision practice demonstrates a certain concern towards mitigating the eventual anticompetitive effect of practices, including those related to IPRs, in the pharmaceutical sector, which allows for some expected developments at the national level in this area.

Further developments can undoubtedly be expected shortly, and undertakings must remain vigilant for new rules and, especially, new enforcement approaches.

Endnotes

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16 Of which 116 were pharmaceutical companies affiliated with Apifarma. See footnotes 6 and 8. Back to section

17 Spain, France, Italy and Slovenia are referred to as the 'reference countries' for 2022. Back to section

18 Directive (EU) 2019/1 of the European Parliament and of the Council of 11 December 2018 to empower the competition authorities of the Member States to be more effective enforcers and to ensure the proper functioning of the internal market ("ECN+ Directive"). Back to section

19 For further information on the transposition of the ECN+ Directive into Portuguese law, see: Nuno Salazar Casanova, Tânia Luísa Faria, Duarte Peres and Margot Lopes Martins, 'A fish out of water – critical analysis of the AdC's draft proposal for the transposition of the ECN+ Directive into Portuguese law', Competition and Regulation Journal, No. 42–43, available at https://www.concorrencia.pt/sites/default/files/imported-magazines/Revista_CR_42-43.pdf. Back to section

20 Law No. 23/2018 of 5 June 2018. Back to section

21 Directive 2014/104/EU of the European Parliament and of the Council of 26 November 2014 on certain rules governing actions for damages under national law for infringements of the competition law provisions of the Member States and of the European Union, OJ L 349, 5.12.2014, pp. 1–19. Back to section

22 Which, under Article 18 of the Medicines Act must include the following information: (1) name of the medicinal product; (2) qualitative and quantitative composition; (3) pharmaceutical form; (4) clinical data (therapeutic indications, dosage and way of administration, side effects, warnings and special precautions, pregnancy, effects on drivers, adverse reactions and overdoses); (5) pharmacological properties (pharmacodynamic properties, pharmacokinetic properties and preclinical safety data); (6) pharmaceutical data (a list of excipients, incompatibility, shelf life, special storage precautions, type of outer packaging, instructions for using and handling); (7) marketing authorisation (MA) holder; (8) MA number; (9) first authorisation and renewal date; and (10) latest update. Back to section

23 Under this requirement, Infarmed may request the entity responsible for the placement of the drug to submit samples of it to a third-party laboratory. Back to section

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Summary

Introduction

The market size of Korea's pharmaceutical industry accounts for approximately 3 per cent of the global pharmaceutical market and is growing every year. While Korean pharmaceutical companies have mostly been generic companies, the number of companies focusing on research and development (R&D) is also increasing. In this regard, the government has used subsidies, tax breaks, reimbursement policies and intellectual property (IP) laws to promote R&D investment in Korea by both domestic and multinational firms.

The Patent Act provides exclusive patent rights to originators, and the Pharmaceutical Affairs Act (PAA) protects data through a re-examination (post-marketing surveillance (PMS)) system to promote R&D investment in Korea.

The Korea–United States Free Trade Agreement (KORUS FTA), entered into force on 15 March 2012 and contains provisions on facilitating high-quality healthcare and improving access to safe and effective innovative and generic pharmaceutical products. KORUS FTA requires the United States and Korea to ensure fair, reasonable and non-discriminatory treatment and to provide predictability and transparency in the pricing and reimbursement process for pharmaceutical products. Importantly, it also strengthens patent protection by introducing the patent approval linkage system. The PAA provides more detailed provisions on the patent approval linkage system, such as generic notice or generic stay.

While IP essentially aims to be pro-competitive as it ensures the protection of R&D results, it can be anticompetitive if IP is unduly protected to grant exclusivity over non-differentiating features. In the pharmaceutical industry, 'pay-for-delay' patent settlements are a representative example of where IP rights can be abused. In pay-for-delay arrangements, generic manufacturers agree to delay the launch of new products into a market in return for some form of payment by pharmaceutical patent holders. As such, in pay-for-delay cases, patent rights are abused because patent holders enjoy exclusivity regardless of the expiry or invalidation of their patent rights, thereby depriving the market of fair competition among products.

The Korean Fair Trade Commission (KFTC) and the Korean courts regulate these abusive activities and other unfair activities, such as undue solicitation and unfair collusion, between originators and generic companies.

Year in review

In terms of completion update, in May 2024, the KFTC initiated a market study on medical device companies to investigate whether medical device companies unfairly supported their affiliates by distributing their products through such affiliates, and using these affiliates as a conduit for providing rebates. The KFTC is currently also investigating whether there are unfair trade practices, such as excessive price reduction, pass-on of logistical cost or requiring disadvantageous settlement conditions in the medical device field. The outcome of this market study is expected by the end of 2024.

As for drug pricing, Korea's Supreme Court ruled that generic companies are not liable for damages incurred by original companies in the event of systematic drug price cuts occurring due to generic drug entry even in cases where such generic is ultimately ruled to infringe on the original company's patent.

Legislative and regulatory framework

The PAA and its attendant regulations govern the authorisation of pharmaceuticals. The National Health Insurance Act and its attendant regulations provide regulations on drug pricing.

According to the Patent Act, patent duration is 20 years from the patent application date (the term of the patent begins on the patent registration date and lasts up to 20 years from the filing date).[1] Because a drug patent application must be filed before marketing approval is obtained for the drug, the period in which the drug product can be sold under its exclusive patent rights is shorter than the patent term granted by law.

To resolve this gap, the law allows up to a five-year extension of the patent term with regard to the period during which the patent could not be exercised because of the clinical trial period and regulatory approval process.

In addition to patent protection, data exclusivity is also protected for innovative drugs during the PMS period. PMS periods vary depending on the type of medicinal product, as follows:

1. six years for a new drug, a new combination drug and a drug that has a different route of administration;
2. four years for a drug that has a new indication; and
3. 10 years for orphan drugs (11 years for children's orphan drugs).

Once the PMS period expires, a third party can apply for generic authorisation, referring to safety and efficacy data submitted by the applicant of the referenced drug.

Korea does not have a system of public purchasing of drugs by the government or public medical institutions; however, according to the Infectious Disease Prevention Act, vaccines used to prevent infectious diseases may be purchased by the government and administered to the public.

The National Health Insurance System has a drug price reimbursement system, and the National Health Insurance Service negotiates drug prices with pharmaceutical companies to ensure that the drugs are supplied at an appropriate price. The National Health Insurance Act provides a system in which incentives are given or drug price adjustments are made to preserve the costs of drugs that are needed to treat patients and that pharmaceutical companies tend to avoid producing or importing because of economic inefficiency.

If the supply of certain drugs, including orphan drugs and essential drugs designated by the World Health Organization, is suspended, the reason for the suspension must be reported to the Ministry of Food and Drug Safety (MFDS) at least 60 days before the date of suspension pursuant to the PAA and its attendant regulations.

Aside from this, the Korea Orphan and Essential Drug Centre, which was established according to the PAA, carries out the task of building a stable supply of orphan drugs and national essential drugs.

Under the Fostering and Support of Pharmaceutical Industry Special Act, the Ministry of Health and Welfare (MOHW) certifies the following companies as innovative pharmaceutical companies: a pharmaceutical company that invests a certain amount or more in the R&D of new drugs (e.g., for pharmaceutical companies with a revenue of 100 billion won or more in annual drug sales, an investment of 5 per cent or more of its annual sales; and in the case of pharmaceutical companies whose drug manufacturing and quality control standards have been determined to be suitable by the government or public institutions of the United States or the European Union, an investment of 3 per cent or more of its annual sales); and a foreign pharmaceutical company that is conducting new drug R&D or has invested a certain amount into new drug R&D investment in Korea.

The above-mentioned innovative pharmaceutical companies have priority in participating in national R&D projects, benefit from a certain amount of tax deduction and receive preferential treatment in drug pricing.

The PAA contains provisions governing anticompetitive activity and unfair solicitation of customers, while the Monopoly Regulation and Fair Trade Act (MRFTA) is the general competition law. Both laws are applicable with respect to pharmaceutical issues, as are their sub-regulations and the guidelines issued by the KFTC.

New drugs and biologics – approval, incentives and rights

Drugs

To obtain marketing approval for pharmaceuticals, the applicant must submit to the MFDS, among other things, documents or data showing the quality, safety and efficacy of the product; a good manufacturing practice certificate; and a leaflet that includes information for patients.

It generally takes 25 to 120 business days to obtain a marketing authorisation for pharmaceuticals, depending on factors such as whether a review of safety and efficacy data is necessary. The MFDS's review may take longer if it finds it necessary to review additional materials and orders the applicant to supplement those materials.

The fee for obtaining marketing authorisation for pharmaceuticals is between about US$2,200 and US$6,800, depending on whether the drug is a new drug, an orphan drug or any other type of drug, or other factors such as whether a review of safety and efficacy data is necessary. This fee is discounted by about 10 per cent for electronic filings.

Marketing authorisation for pharmaceuticals is valid for five years. The marketing authorisation holder must file a renewal application with the MFDS six months before expiry. Registration of medicinal substance and export authorisation for pharmaceuticals

does not require renewal. A renewal application must include information on safety and quality control and sales during the authorisation period.

In Korea, data exclusivity is protected during the PMS period. Once the PMS period expires, a third party can apply for generic authorisation, referring to safety and efficacy data submitted by the applicant of the referenced drug.

An applicant for a new drug application (NDA) can request an expedited review of its NDA if the drug was designated as an orphan drug and is expected to have therapeutic effects on life-threatening or incurable diseases. If the expedited review is granted, the NDA applicant may be allowed to delay the submission of certain parts of the required materials for authorisation until sometime after launch. Further, the extent and amount of safety or efficacy data, or both, can be reduced.

The MFDS may also prioritise the NDA for an orphan drug; however, in practice, an expedited review does not significantly shorten the review time compared with a standard review.

Generic and follow-on pharmaceuticals

After both the patent period and the PMS period (data exclusivity period) expire, generic companies may apply for authorisation of generic drugs. Generic companies can receive authorisation after submitting bioequivalence test data that compares the generic drug to the original drug. The bioequivalence test data refers to the results of a test performed to prove that two drugs containing the same active ingredient and using the same administration method are statistically equivalent in bioavailability. In the case of injections and eye drops, the results of the physicochemical equivalence test can be substituted for the bioequivalence test results.

Generic exclusivity may be recognised as the first generic drug to successfully challenge the patent rights of an original drug. A detailed explanation will be provided in 'Patent linkage'.

In 2021, the MFDS introduced a bundled approval system for generic drugs to increase the quality of generic drugs and the efficiency of the drug review process. The bundled approval system is a system in which speedy approval can be made if generic products from multiple companies are being manufactured in a single manufacturing site, by uniformly applying established approval criteria, such as consistent data requirements. This system is based on the reasoning that although the product names are different, the manufacturing site, raw materials, manufacturing method, biodata and quality of the products are the same.

Biologics and biosimilars

The approval system for biologics is no different from the approval system for new drugs in general; however, the MFDS does not think it is appropriate to apply the established evaluation method for generic chemical drugs when reviewing biosimilars and sees a need for demonstration of the equivalence of quality, safety and effectiveness. This means that the review should be based on scientific evaluation, as is the case for other biologics, using

data regarding quality and data from non-clinical and clinical trials, as well as additional bioequivalent data compared with reference biologics.

The same system applies to both biologics and general drug products with regard to the patent linkage approval system.

Patent linkage

Pursuant to the KORUS FTA, which was first signed on 30 June 2007 and entered into force on 15 March 2012, Korea has introduced a drug approval-patent linkage system, which is the Korean version of the US Hatch-Waxman system.

Under this system, originators list their patents covering a drug on the patent list called the Korean Green List, and the latecomer pharmaceutical companies that are applying to market their generic products must provide notification to the respective party that registered the patent information on the Korean Green List and the patent owner. The Korean Green List covers not only traditional pharmaceutical products but also biological products.

For the above notification, the following items must be included: the marketing authorisation application date, the market authorisation application details, and justification for patent invalidity or non-infringement of the registered patent.

This notification must be provided within 20 days of the date of the application for marketing authorisation; however, if the patent term has expired, an applicant wishes to sell its drugs after the patent expiry date, or the party that registered the patent information on the Korean Green List and the patent owner agree not to notify, notification of its marketing authorisation application is not required.

The patent owner of the registered drugs may file a patent lawsuit against the applicant within 45 days of the date of receiving notification and apply for a sales stay against the concerned generic drug to the MFDS.

Under the patent linkage approval system, there are two possible outcomes: a stay of the generic sales or generic exclusivity to the first generic that meets certain criteria.

The patent owner of the registered patents may apply for a sales stay by submitting a statement that provides that:

1. the patent has been registered lawfully;
2. litigation to seek an injunction for, or prevention of infringement, or a petition trial to confirm the scope of patent rights has been filed in good faith;
3. a prospect of winning the case exists; and
4. the case shall not be delayed unreasonably.

When the application for sales stay is approved, the period of sales stay is nine months from the date of receiving the notification; however, if the court determines that the registered patent is invalid or the generic drug does not infringe the patent, sales of the generic will not be stayed. Generic exclusivity can be granted to the first applicant to

file a petition for trial to challenge the relevant patent together with any multiple generic applicants that are deemed to share the status of this first applicant. In the case of the first applicant, generic exclusivity will be granted if the applicant has received a trial ruling or ruling that the registered patent is invalid, the registration for extension of the registered patent is invalid, or the relevant drug does not fall within the scope of the registered patent before nine months have passed from the date of receipt of notice.

In the case of the other applicants, generic exclusivity will be granted if the applicant has filed the above petition for trial within 14 days of the filing date of the first trial, or has received the trial ruling or ruling, before any other applicant (including the first applicant).

When generic exclusivity is granted, sales of other generic drugs may be stayed for nine months from the date when the sale of drugs with generic exclusivity is first possible.

Meanwhile, due to Korea's drug pricing system, when a generic drug is approved and begins selling, the original drug price is subject to immediate mandatory reduction. Even if the price of the original drug is lowered and the generic drug is ultimately ruled to infringe on the original company's patent and generic sales become difficult, the price of the original drug will not recover. Additionally, Korea's Supreme Court ruled that generic companies are not liable for damages incurred by original companies due to such drug price cuts.

Competition enforcers

The KFTC is the authority that enforces the competition and consumer laws of Korea. It is a ministerial-level central administrative organisation under the authority of the prime minister and also functions as a quasi-judiciary body.

The KFTC is divided into the Commission and the Secretariat. The Commission is in charge of making KFTC decisions, while in the Secretariat, each division of bureaus under the secretary general investigates a case and submits its examination reports to the Commission. The Commission comprises nine commissioners, including the chair and the vice chair. Among them, four commissioners are non-standing members of the KFTC.

The main legislation governing competition laws in Korea is the MRFTA. The MRFTA regulates anticompetitive agreements, abuse of dominance, mergers and acquisitions that substantially lessen competition in Korea and concentration of economic power.

In addition to major antitrust prohibitions, the MRFTA regulates unfair trade practices, including 'unjustly refusing to deal or treating a trading party in a discriminatory manner', 'unjustly excluding competitors' and 'unjustly inducing or coercing customers of a competitor to deal with oneself '.

While the KFTC has not specifically set priorities on any issues in the pharmaceutical field, in the meantime, pay-for-delay settlements have been sanctioned as unfair trade practices, and rebates provided by pharmaceutical companies have also been sanctioned as unfair solicitation of customers.

The KFTC undertakes market studies to reform existing anticompetitive regulations. In 2007, it conducted a market study on pharmaceutical companies and consulted with the MOHW to improve the PMS system and the real transaction price reimbursement system and to establish disposal procedures for prescription drugs.

In addition, the KFTC has recently taken an interest in unfair trade issues between pharmaceutical companies and distributors. In this regard, it created a standard agency agreement for the pharmaceutical industry in December 2019 and revised it in June 2022. The added clauses grant distributors the right to terminate the agreement in case of force majeure, including pandemic situations, and the pharmaceutical companies must alleviate or exempt delay charges in case of such force majeure events. There is no requirement to use the standard agency agreement, and using a different type of agreement would not automatically violate the Fair Trade Act; the KFTC merely recommends using this form of agreement.

In May 2024, the KFTC initiated a market study on medical device companies to investigate whether medical device companies unfairly supported their affiliates by distributing their products through such affiliates, and using these affiliates as a conduit for providing rebates. The KFTC is also investigating whether there are unfair trade practices such as excessive price reduction, pass-on of logistical cost or requiring of disadvantageous settlement conditions in the medical device field. The outcome of this market study is expected by the end of 2024.

An appeal filed against a sanction imposed by the KFTC will be heard by a court. An administrative suit with respect to the measures issued by the KFTC will be heard at the Seoul High Court, as the court of first instance, and the final appeal is heard by the Supreme Court. Under the MRFTA, a private person can also file a request for an injunction against an unfair trade act under the MRFTA. The court determines fair trade issues when they are brought up in civil suits or patent infringement suits between pharmaceutical companies.

Merger control

Up to now, there have not been many merger cases in the pharmaceutical field in which the KFTC has issued a corrective order.

In 2016, in a case where Boehringer Ingelheim acquired the animal medicine division from Sanofi, the KFTC used the marketing approval certificate issued by the Animal and Plant Quarantine Agency, which disclosed the animal species, administration method, efficacy and effect, as well as the classification system of the European Animal Health Study Centre, which codifies animal medicine according to therapeutic use, animal species, indications, etc., to establish the relevant product market. Because the local market is affected by different administrative procedures and approval conditions and different distribution systems, the KFTC limited the relevant market to that of Korea. Based on this, the KFTC recognised competition concerns in only two markets in Korea and imposed an order to sell related assets. When Bayer Korea acquired the over-the-counter drug business division of MSD Korea in 2015, the domestic market was selected as the relevant market, considering that it was necessary to obtain marketing approval from the MFDS to sell domestically. Based on this, the KFTC recognised there to be a competition restriction in the domestic market for non-prescription oral contraceptive drugs and issued an order to sell related assets.

With regard to pipeline products, there have been no cases in which the KFTC issued a corrective order recognising competition restrictions. In the case of Takeda's acquisition of

Shire's shares in 2018, there was future potential overlap in the area of inflammatory bowel diseases between Takeda's marketed product Entyvio (vedolizumab) and Shire's pipeline compound SHP647; however, the KFTC did not issue any corrective order after taking into account that:

1. it would take many years for SHP647 to be launched in Korea;
2. there is currently R&D on many competitive drugs other than SHP647; and
3. the exclusive rights on biological therapy for inflammatory bowel diseases in Korea have already lapsed or will soon lapse, resulting in the eventual commercialisation of various biosimilar treatment methods in Korea.

Companies must report a transaction to the KFTC, if they meet the size-of-parties test or the size-of-transaction test. The MRFTA, in addition to the size-of-parties test, regulates large-sized transactions that have an impact on competition in the relevant market in Korea, even when the target company does not satisfy the thresholds on assets or turnover for triggering a filing requirement in Korea.

Under the size-of-transaction test, a transaction will be subject to a merger filing if all the following requirements are met:

1. the value of the transaction is 600 billion won;
2. the acquirer satisfies the asset and turnover thresholds; and
3. the target, which does not satisfy the asset and turnover thresholds, has significant business activities in Korea.

'Significant business activities' refers to the following events occurring within three fiscal years immediately preceding the closing of the transaction: (1) the target has provided its products and services to more than 1 million customers per month in the relevant Korean market; or (2) the target has leased research facilities or hired researchers in Korea, and the relevant annual budget is 30 billion won or more.

The size-of-transaction tests are similar to the thresholds in place under the merger control regimes of Germany and Austria.

Anticompetitive behaviour

The MRFTA, in principle, does not apply competition laws to the legitimate exercise of exclusive intellectual property rights while enforcing applicable competition laws on the unfair exercise of intellectual property rights, thereby balancing out the application of intellectual property laws and competition laws. The KFTC sets out standards for fair business in its Review Guidelines on Undue Exercise of Intellectual Property Rights. The unfair exercise of intellectual property rights is handled by the Korean courts and the KFTC in accordance with these laws and guidelines.

The following are notable cases relating to the unfair exercise of intellectual property rights in the pharmaceutical field.

Cases related to pay-for-delay settlements

The plaintiff GSK acquired a patent on the manufacturing method of ondansetron, an antiemetic drug, based on which it marketed the drug Zofran. Dong-A Pharmaceutical independently developed ondansetron and launched its antiemetic drug Ondaron, containing the same active ingredient as Zofran. GSK then filed a patent infringement suit against Dong-A Pharmaceutical, and the two companies terminated the suit in 2000 by signing a drug licensing agreement that included a pay-for-delay settlement.

The KFTC determined that the collusion between the two pharmaceutical companies would exclude the cheaper generic drug (Ondaron) from the antiemetic drug market and prevent competing drugs from entering the market. As a result, it issued a corrective order and imposed a 5.173 billion won penalty on GSK.

The Supreme Court also recognised the KFTC's judgment with regard to the pay-for-delay settlement between GSK and Dong-A Pharmaceutical. It considered GSK's action to prevent the launch of a competing product, by providing Dong-A Pharmaceutical with economic benefits that were greater than the litigation costs during the patent litigation proceedings, as 'an act not considered to be a legitimate exercise of patent rights' and, therefore, to be subject to the Fair Trade Act.

In this case, 'an act not considered to be a legitimate exercise of patent rights' means an act that may appear to be exercising a patent right, but the substance of which is contrary to the fundamental purpose of the patent system. The Supreme Court held that this can be determined by considering various factors, such as the purpose and intent of the Patent Act, the content of the patent right and the impact the subject activity has on fair and free competition. Following this, Article 69-3 of the PAA was newly established on 13 March 2015. It expressly requires that if there is a settlement between a patent holder and a generic applicant with regard to a patent dispute of a drug, the settlement details must be reported to the MFDS and the KFTC.

Sham patent litigation

In pharmaceutical IP litigation, sham litigation generally means litigation based on an invalid patent. Korea has a dual-structure system in which patent infringement suits and patent invalidation suits are carried out separately; however, a Korean court has held that a court that hears a patent infringement case may determine whether there are clear grounds for patent invalidation even before a patent invalidity decision is confirmed, and that if it is clear that there are grounds for the patent at issue to be invalidated as a result of hearing the case, or if it is clear that the patent is certain to be invalidated, any request for injunctive relief or claim for damages with regard to that patent right is, in principle, considered an abuse of power and therefore, not allowed.

The Review Guidelines on Undue Exercise of Intellectual Property Rights, which contain the established rules by the KFTC, state that the following acts are highly likely to be considered an abuse of patent infringement action:

1. filing a patent infringement suit based on a patent that had knowingly been acquired fraudulently;

2. filing a patent infringement suit despite knowing that patent infringement cannot be established (e.g., knowing that the patent at issue is invalid); and
3. filing a patent infringement suit even though it is objectively obvious under socially accepted notions that patent infringement cannot be established.

The KFTC has recently found a domestic pharmaceutical company to have violated the MRFTA's restriction on 'unfair inducement of customers' by (1) abusing its patent rights to prevent the market entry of a competitor by filing a patent infringement claim, despite knowing that there was, in fact, no infringement; and (2) interfering with a competitor's business by filing a patent infringement action based on a patent registration obtained through the submission of fabricated materials.

The KFTC found that these activities of the pharmaceutical company constituted 'unfair inducement of customers' because they were aimed at interfering with customers' business transactions with the competitor so that customers would instead transact with the subject company. The KFTC imposed corrective orders and an administrative fine of around 2.3 billion won on the company and reported the company for criminal prosecution. The pharmaceutical company filed a lawsuit to revoke the KFTC decision, but the Supreme Court ruled in 2023 that the KFTC decision was legitimate.

Product switching and hopping (evergreening)

There are many cases in which the court has ruled in favour of domestic generic companies for the reason that the patents at issue were found invalid in cases where a patent infringement action was filed by a multinational pharmaceutical company, using the 'evergreening' strategy, which attempts to extend the patent term of the original patent by partially changing the chemical structure of the original drug or by broadening the scope of the patent.

Although there are no case precedents where the KFTC has sanctioned such activities, it is possible that product switching and hopping could fall under abuse of market dominance or unfair trade practice under the current Fair Trade Act, and thus a close watch on the developments in this area is necessary.

Authorised generics

In 2006, Daewoong Pharmaceutical's patent for the raw material of the original drug for the treatment of dementia (Gliatilin), which Daewoong had exclusively produced and sold, expired. When eight competitors tried to enter the market, Daewoong entered into a consignment agreement with another pharmaceutical company for the manufacture of a generic drug and had the consignee company be the first to have its generic drug listed to dominate the market. In addition, in return for Daewoong compensating for any losses, Daewoong had the consignee pharmaceutical company apply for a lower insurance drug price than what it could actually receive to interfere with the business activities of the other eight companies.

The KFTC found that Daewoong's actions amounted to tortious interference in business activities (Article 23(1)(5) of the Fair Trade Act) that delayed and obstructed the market

entry of the eight competitor companies. For those reasons, as well as other unfair trade issues, the KFTC issued a corrective order and imposed a fine on Daewoong.

Outlook and conclusions

While the KFTC has historically focused more on unfair solicitation practices by pharmaceutical companies (e.g., illegal kickback practices), we are seeing increasing attention on patent abuses and unfair arrangements between pharmaceutical companies and distributors. We expect to see more aggressive enforcement by the KFTC in the area of unfair interference in the business management of distributors, abuse of dominance issues and unfair practices relating to the transfer of patented technology improvements.

Endnotes

1 Article 88(1) of the Patent Act. Back to section

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Summary

Introduction

Taiwan's pharmaceutical industry is primarily engaged in the manufacturing of pharmaceutical products, including active pharmaceutical ingredients, Western medicine, oriental medicine and biologics. Generic Western medicinal products make up the largest portion and are also the category that receives the most registration applications.[1] However, government policy has been promoting originator activity in Taiwan with products being sold domestically and abroad, as well as licensing foreign pharmaceutical entities to operate in Taiwan. Furthermore, the race for vaccine development during the covid-19 pandemic has also jump-started new interest in biologics.

'Year in review' describes the most significant pharmaceutical policy developments in Taiwan in the past year. 'Legislative and Regulatory framework' covers the legal framework for Western medicinal products in Taiwan. 'New drugs and biologics – approval, incentives and rights' provides an overview of the registration and inspection process for new drugs, generics, biologics and biosimilars, and 'Patent linkage' describes the patent linkage regime. Competition law-related matters are covered in 'Competition enforcers' onward, including how merger filings are handled and recent key cases. 'Special considerations' introduces two bills related to regenerative therapy and the exemptions to the drug registration process.

Year in review

The National Health Insurance Administration (NHIA) announced a new parallel review system for new drugs effective January 2024 that would allow the new manufacturer of a new drug to simultaneously apply to the NHIA for reimbursement recommendations during the new drug registration process, thereby reducing the permit review and NHIA payment approval time. The NHIA has also established the 'Center for Health Policy and Technology Assessment' that is dedicated to the assessment of medical technologies in accelerating the review process of including new drugs in the National Health Insurance (NHI) package.[2]

The Taiwan Food and Drug Administration (TFDA) has initiated a three-year pilot programme for 'Combined Registration and Review of Rare Disease Drugs Approved in Advanced Countries' [3] to accelerate the market launch of rare disease drugs. Currently, the preliminary review by the TFDA's Review Committee for Rare Disease and Orphan Drugs-Drug Subcommittee may be completed in as few as 240 days.

On 28 June 2023, the Taiwan Fair Trade Commission (TFTC) announced an amendment on the types of mergers that no longer require a merger filing.[4] It is no longer necessary for foreign enterprises setting up or operating a joint venture outside of Taiwan to make a merger filing in Taiwan if such joint venture does not engage in any economic activity within Taiwan.

Legislative and regulatory framework

The competent authority for the pharmaceutical industry in Taiwan is the Ministry of Health and Welfare (MoHW), and various departments of the MoHW are responsible for specific aspects of the industry as it relates to public health. For example, the TFDA is responsible for the registration, approval and inspection of pharmaceutical products, and the NHIA is responsible for the mandatory national health insurance policy.

In terms of primary legislation, pharmaceutical products in Taiwan are governed by the Pharmaceutical Affairs Act (PAA) and other statutes and regulations promulgated pursuant to its authority. The PAA regulates the registration, inspection, sales, manufacturing, advertisement and administration of pharmaceutical products as well as the patent linkage regime for Western medicine.

Taiwan's Patent Act is the primary statute regarding the patent duration of pharmaceuticals. While pharmaceuticals receive the same 20-year duration for an invention patent under the Patent Act, the applicant may obtain a one-time, five-year extension[5] in recognition of the inability to make use of the patent during the drug registration approval process, and the testing and use of the invention for registration approval purposes are generally not regarded as infringing the patent.[6]

Due to their close relationship with national health insurance and public health, rules relating to the public purchasing of pharmaceuticals, such as the National Health Insurance Pharmaceutical Benefits and Reimbursement Schedule and the Regulations on Price Adjustments for National Health Insurance Reimbursed Drugs are promulgated by the NHIA pursuant to the National Health Insurance Act. In general, once the NHIA approves the inclusion of a drug under the national health insurance programme for the first time, the former is used to set the pricing, and subsequent price adjustments are made according to the latter in consideration of the prevailing market price and other factors.

For competition law, the main statute is the Taiwan Fair Trade Act (TFTA), which covers both restriction of competition conduct, such as abuse of a dominant market position and concerted action, as well as unfair competition conduct such as false advertising and counterfeit products. As described later in this chapter, outside of certain exceptions, the TFTA applies to all competition-related conduct among pharmaceutical entities.

New drugs and biologics – approval, incentives and rights

Drugs

New drug application and approval process

An application for a new drug (new chemical entity, NCE), new therapeutic compound or new method of administration), new dosage form, or new unit-dose requires the submission of the application materials pursuant to the Regulations for Registration of Medicinal Products (RRMP) to the TFDA, which will assemble a committee of experts to review the application.[7] If the data presented for review can sufficiently support the safety,

efficacy and quality of the new drug, then it may enter the Taiwan market. The review process takes on average just under one year to complete.

The TFDA has announced several reforms to increase the efficiency of the new drug review process in recent years. In addition to the general process, there are also several specialised review tracks and mechanisms:

1. A 'priority review mechanism': this track shortens the review process to 240 days for pharmaceutical products vital to maintaining the life and health of the people.
2. A 'simplified review process': this is for NCE drugs that have already been approved by the US Food and Drug Administration, the European Union European Medicines Agency or the Ministry of Health, Labour and Welfare of Japan. The review process may be shortened to 180 days or 120 days depending on the documentation from the approved jurisdiction.
3. An 'accelerated review process': this is to allow certain drugs to shorten the R&D period and enter the market more quickly via the use of substitute efficacy benchmarks and with proper scientific evidence support. The review process for such drugs may be shortened to 240 days per the 'priority review mechanism'.
4. 'Paediatric or rare severe disease': this also allows drugs targeting paediatric care or certain rare severe diseases to enter the market more quickly. The review process for such drugs may be shortened to 240 days per the 'priority review mechanism'.
5. 'Breakthrough in treatment': this is for drugs targeting rare or severe diseases that show a key breakthrough in preliminary clinical trials compared to current treatment methods. The review process for such drugs may be shortened to 240 days per the 'priority review mechanism'.[8]

For orphan drugs, there is an 'orphan drug determination' mechanism established under the Rare Disease and Orphan Drug Act (RDODA),[9] under which the candidate drug is submitted for review by the TFDA and the Review Committee for Rare Disease and Orphan Drugs. Once the drug passes the review, even if it has not yet completed the registration process, it is possible to apply for permission to import or manufacture the drug as long as certain conditions are met;[10] and if it has already been registered, it may be included under the national health insurance system upon application.[11] Other incentive programmes to promote the registration of orphan drugs include giving orphan drugs a 10-year permit during which the competent authority will not register any other orphan drug of the same type,[12] simplifying the documents needed to register an orphan drug,[13] and reducing the registration fee to about one-third of other ordinary drugs (see below).[14]

The new drug registration fees are codified in the Standards of Review Fees for the Registration of Western Medicines. For NCE drugs, the fee is NT$1.5 million; for new therapeutic compounds, the fee is NT$500,000, and for new dosage form or unit-dose drugs, the fee is NT$250,000.[15]

In addition, the TFDA is promoting a new parallel review system for five major categories of drugs to accelerate the review process and the NHIA reimbursement approval, which may now be applied concurrently with the review process.[16] The types of drugs eligible for the parallel review system include but are not limited to those that have undergone TFDA inspection and registration review and have been identified as meeting the criteria for the

aforementioned 'prioritised review', 'accelerated approval', 'paediatric drug or drug for rare severe disease' or 'breakthrough in treatment drugs'; and those that are not yet marketed internationally at the time of application for inspection and registration in Taiwan.

New drug pricing

The pricing of new drugs is determined pursuant to National Health Insurance Pharmaceutical Benefits and Reimbursement Schedule. Of particular note is the section added in 2018 by the MoHW on managed entry agreements (MEAs):[17] MEAs in Taiwan may be based on performance as well as finances to allow risk to be shared between the pharmaceutical firm or manufacturer and the NHIA in multiple ways so that the new drugs may reach the patients through the national health insurance programme as soon as possible. For example, in a performance-based MEA, the cost-sharing between the firm and the NHIA may be based on overall survival, median progression-free survival time, or the time efficacy of the treatment becoming measurable, while for a finance-based MEA, the firm may offer a fixed rebate, pay for the costs of the initial treatment period, or provide adjuvant medication.[18]

For orphan drugs, specialised drugs with no generic substitutes and other specialised drugs, the pricing rules are more flexible compared to those for other new drugs and in principle defer to the prevailing market price.[19]

Data exclusivity and market exclusivity protections

NCE drugs are entitled to a three-year data exclusivity period starting from the date the NCE permit is issued and a five-year market exclusivity period.[20] If the NCE drug has already been approved for launch in a foreign market, the registration of the NCE drug in Taiwan must be made within three years from the date it received market authorisation in the foreign market to enjoy the data exclusivity period in Taiwan.

For new indications, the data exclusivity period is two years from the time the TFDA approves the added or revised indication, and a market exclusivity period of three years;-[21] however, if the applicant is conducting clinical trials in Taiwan, the applicant would be entitled to five years of market exclusivity as a way to incentivise firms to conduct clinical trials in Taiwan. In addition, if the new indication has already been approved for market launch outside Taiwan, the registration of the new indication must be completed within two years of such foreign market authorisation to be entitled to the aforementioned data exclusivity period.

As mentioned, an approval for registration of an orphan drug comes with a term of 10 years, during which no other drug of the same type may be registered. After the 10-year period, an application can be submitted to the TFDA for an extension of up to five years, but the TFDA will start to accept applications to register other drugs of the same type.[22]

Generic and follow-on pharmaceuticals

The registration of generics in Taiwan follows the same general procedure as other drugs, with some minor differences, such as the documents to be submitted with the generics application, which depends on the type of generic in question (a 'drug under post-market

surveillance', 'ordinary generics' or 'medical gas').[23] The process typically takes about 180 days, but for drugs under post-market surveillance, the process will take about 210 days instead.[24] The fee is NT$140,000 for a drug under post-market surveillance, and NT$80,000 for other generic types.

The factors that affect the pricing of a 'BA/BE generic drug' or 'ordinary generics drug' include whether the national health insurance programme has already approved the corresponding branded drug, or another BA/BE or ordinary generic drug with the same specifications, as well as whether the patents of the branded drug are still in effect or whether the branded drug is still within the period of surveillance.[25]

As the generic applicant needs to submit a declaration[26] regarding the status of the patents of the corresponding branded drug, the applicant may declare that the patent rights of the branded drug should be invalidated, or that the generic drug does not infringe on such patent rights. The first generic applicant who makes the above declaration and can subsequently prevail in a patent infringement challenge action from the branded drug manufacturer or otherwise successfully work around the patent is entitled to a market exclusivity period of 12 months.[27] However, if the generic drug only differed from the branded drug due to skinny labelling, no such market exclusivity is granted.[28]

Biologics and biosimilars

Biologics

Registration of a biologic product is generally similar to that for new drugs. For NCE biologics, requesting a bridging study is mandatory unless credible clinical trials regarding its medical efficacy and safety for Taiwanese nationals have already been conducted, and data from pharmacokinetics (PK) studies of the product in relation to East Asian populations are available.[29] The information and documents needed by the TFDA for the registration review are stipulated in Article 41 of the RRMP.

On 16 October 2015, the TFDA announced that as long as the materials used and the manufacturing process and the quality control mechanisms are identical, an approval registration for a biological product (such as a vaccine) may list multiple manufacturers instead of one manufacturer per registration limit for other pharmaceutical products.[30]

The registration fee depends on the type of biological product: NT$1.5 million for blood serums, antitoxins or vaccines, or pharmaceutical products derived from genetic engineering; and NT$250,000 for previously reviewed biologics with different dosage units or different country of origin.[31]

Biologics that have been determined as suitable for therapeutic purposes and contain an NCE as defined in Article 7 of the PAA may be entitled to a three-year data exclusivity period as a new NCE drug.[32]

Biosimilars

To promote transparency in the registration process, the Biosimilar Registration Review Standards as promulgated by the MoHW stipulates the review standards and consideration factors by which the competent authority reviews an application to register

a biosimilar product. Pursuant to the TFDA's overview of the registration process on its website, the review period for a biosimilar product is 300 days.[33] In addition, the MoHW has also taken note of the unique features and potential therapeutic value of biosimilar monoclonal antibodies (mAbs) in recent years and published the Biosimilar Monoclonal Antibody Registration Review Standards to address the specialised scientific strategy and corresponding review standards applied in reviewing a biosimilar mAb registration application.

Since a biosimilar by definition is supposed to have no clinically meaningful difference from the reference pharmaceutical product, the approval process is focused on comparative testing and demonstrating such lack of clinically meaningful difference. The supporting materials therefore include physical, chemical and biological characteristics data as well as non-clinical and clinical therapeutic efficacy and safety testing data. The TFDA may also stipulate increased post-market launch supervision to make up for any deficiencies in the comparative testing data.[34]

The registration of a biosimilar in Taiwan will require the applicant to make a declaration regarding the status of the patents of the reference product. As is the case for generics, the first applicant of a biosimilar who manages to subsequently prevail in a patent infringement challenge action from the manufacturer of the reference product or otherwise successfully work around the patent is entitled to a market exclusivity period of 12 months.[35] Biosimilars that only differed from the reference product due to skinny labelling will not be entitled to this market exclusivity period.

Finally, the pricing for biosimilars is handled in the same way as generics, namely that it depends on whether the NHIA has already approved of biosimilars, branded biologics or reference products with the same composition.[36]

Patent linkage

The patent linkage regime for Western medicine in Taiwan was established pursuant to a Presidential Order amending Chapter IV-1 of the PAA on 31 January 2018. The MoHW then drafted the Regulations for the Notification of Drug Patent Linkage Agreements and the Regulations for the Patent Linkage of Drugs and also established online the Registration System for Patent Linkage of Drugs[37] to enable generics manufacturers to make drug patent inquiries, plan the market launch timing and make patent challenges. Branded drug manufacturers may also use the database to stay informed of how their patents are being used and take appropriate action to protect their patent rights.

When the TFDA is issuing a registration permit for a new drug, if the permit holder believes it is necessary to disclose information regarding the patents of the new drug, it shall visit the aforementioned Registration System for Patent Linkage of Drugs and upload the information within 45 days.[38] If the permit holder only obtained the patent after receiving the permit, the patent information may be uploaded within 45 days starting from the day after the date the patent for the new drug is published in the Patent Gazette.[39] The patents to be disclosed must be in relation to a patent for a substance, compound, formula or drug invention for therapeutic use.

As mentioned previously, when applying for registration of a generic drug, if the corresponding new branded drug involves a patent or patents for a substance, compound, formula or a drug invention for therapeutic use, the applicant for the generic drug is required to disclose to the TFDA the status of the patent rights between the generic drug and the new branded drug, which can take the following four forms:[40]

1. the branded drug has not disclosed any patent information (the P1 Declaration);
2. the patents of the branded drug have been extinguished (the P2 Declaration);
3. the patents of the branded drug are recognised, but the MoHW shall issue the permit for the generic drug once those patents have been extinguished (the P3 Declaration); or
4. the patents of the branded drug should be invalidated, or the generic drug is not infringing on those patents (the P4 Declaration).

If the generic drug applicant makes a P1 or P2 Declaration, once the application is found to be in order, the TFDA may issue the registration permit.[41] In the case of a P3 Declaration, the MoHW will issue the permit once the patents for the new branded drug have been extinguished.[42]

For a P4 Declaration, the generic drug applicant shall, within 20 days after the MoHW has notified the applicant that the application materials are in order, issue a written notification (a P4 Notice) to the holder of the registration permit for the new branded drug, the holder of the patents, the exclusive licensees of the patents, and the MoHW asserting the contents of the aforementioned P4 Declaration.[43]

If the patent holder or the exclusive licensee believes the generic drug applicant is infringing, they must initiate a patent infringement action within 45 days of their receipt of the P4 Notice and notify the TFDA of such.[44] The TFDA will initiate a 12-month moratorium on the issuance of the registration permit for the generic drug, but the review continues in the meantime.

If the court, in rejecting the infringement complaint, notes that there is a basis to invalidate the patents asserted in the case or that the generic drug applicant did not infringe on the patents, the TFDA will issue the registration permit for the generic drug;[45] if the applicant is the first applicant to achieve the above for the generic drug, the applicant would also be entitled to a 12-month market exclusivity period for the generic drug.[46] The same result would occur if the patent holder or the exclusive licensee failed to exercise their rights (e.g., failing to initiate the patent infringement action in a timely manner, or failing to disclose the patents on the Registration System for Patent Linkage of Drugs before initiating the infringement action) or other stipulated conditions occur.[47] On the other hand, if the court agrees that the generic drug is infringing during the moratorium period, the TFDA will only issue the registration permit after those patents have been extinguished.[48]

Competition enforcers

The TFTC is the competent authority of the TFTA. There are seven commissioners, including one Chairperson and one Vice-Chairperson serving four-year terms but with

staggered start and end dates between three commissioners and the other four to ensure the competent authority's independence. The commissioners' primary fields of expertise are law and economics. Commissioner meetings are held regularly to discuss and vote on issues, which are passed with a simple majority of the commissioners. Dissenting commissioners may also present their dissenting opinions.

When a TFTA violation also involves the violation of other laws, such as the Government Procurement Act in a government procurement case, the TFTA takes precedence over the other statute regarding any competition-related conduct unless the other statute prescribes otherwise, and only if such other language does not conflict with the legislative reasoning of the TFTA.[49] In actual practice, the TFTC often consults with the competent authority for the other statutes involved to work out the respective jurisdictions and scope of work. Between the TFTC and the MoHW, the only past understanding between the two authorities was for the MoHW to take the lead in false advertising cases. Due to the lack of clear jurisdiction delineation, it is possible for the TFTC and the MoHW to (at least initially) both become involved in a competition law matter involving pharmaceutical product manufacturers.

Merger control

Mergers in the TFTA are defined[50] as (1) a merger between two enterprises; (2) one enterprise acquiring an equivalent of more than one-third of the total number of voting shares or total capital of another enterprise; (3) one enterprise is assigned by or leaves from another enterprise the whole or the major parts of the business or assets of such other enterprise; (4) one enterprise jointly operating with another enterprise on a regular business; or (5) one enterprise directly or indirectly controls the business operations or makes human resources decision of another enterprise. Merger filings to the TFTC are required if (1) the merged enterprise will attain one-third of the market share; (2) one of the merging enterprises has one-quarter of the market share; or (3) one merging enterprise's sales turnover for the preceding fiscal year exceeds a certain threshold amount as announced by the TFTC (e.g., NT$40 billion combined global sales turnover, and at least two enterprises each attained a sales turnover in Taiwan of over NT$2 billion).[51] A fine of up to NT$50 million may be imposed on merging parties who fail to make a merger filing despite meeting the above requirements.[52]

Overall, merger prohibitions by the TFTC have been extremely rare in recent years. According to the TFTC's own statistics, of the 389 mergers that came before the authority from 2018 to March 2024, the TFTC only blocked two merger cases compared to 150 approvals (the merger review process was suspended in the remainder of cases due to incomplete application materials or other reasons).[53] The approvals include the following pharmaceutical firm mergers:

1. GlaxoSmithKline and Pfizer, 2019: the two firms declared the creation of a joint venture by each of their non-prescription drug consumer health businesses. The TFTC sought the opinions of the competent authorities of the industry, competitors and downstream transaction partners, and concluded that because the merger would only result in a limited increase of market share, and consumers would still have plenty of alternatives due to the large number of domestic and foreign

competitors in the relevant market, as well as how the clients are typically large transnational firms with sufficient bargaining power, there was no apparent restriction of competition concerns from the proposed merger.[54]

2. AbbVie Inc,Venice Subsidiary LLC and Allergan plc, 2019: the three firms filed their merger plan under which AbbVie would acquire 100 per cent of the shares and sole control of Allergan through its subsidiary Venice.[55] The TFTC concluded that since AbbVie and Allergan were not horizontally competing with each other, and the merger would not significantly change the market, there were no apparent restriction of competition concerns from the proposed merger.
3. Upjohn and Mylan, 2020: Pfizer spun off its subsidiary Upjohn, which then merged with Netherlands firm Mylan NV. The TFTC found that the two enterprises' products had many competitors, and all of the two enterprises' products were drugs covered by the NHIA, so the pricing for the patients was protected by the national health insurance programme. Furthermore, most of their downstream entities were large hospitals with sufficient bargaining power, so there was no basis to oppose the merger.[56]

Anticompetitive behaviour

In May 2021, the TFTC penalised two pharmaceutical companies for engaging in concerted action to mutually restrict each other's business activities. Lotus Pharmaceutical Co, Ltd (Lotus) entered into an exclusive distributor agreement with TTY Biopharm Co, Ltd (TTY) in 2009 in which TTY would be the exclusive distributor for Lotus' colon cancer drugs in Taiwan. Despite the agreement, TTY has never sold Lotus' drugs but its own colon cancer drugs instead, and neither party has ever alleged a breach of the agreement by the other party over a 12-year period. The TFTC concluded that even though Lotus' product had more competitive pricing compared to TTY's, TTY's failure to ever place an order for Lotus' drugs made it clear that the exclusive distributor agreement was merely a pretext for TTY to pay Lotus to stay out of the Taiwan market. Due to the considerable market shares of TTY in the colon cancer drug market in Taiwan, the conduct of TTY and Lotus was extremely harmful to the market order and punishable pursuant to the 'serious violation' provisions of the TFTA. Lotus and TTY were thus fined NT$65 million and NT$220 million respectively.[57]

The PAA[58] has a rule that requires a drug registration permit holder or applicant, a drug patent holder or an exclusive licensee to disclose to the MoHW any patent linkage-related settlement agreements or agreements among them that involve the PAA provisions on manufacturing, sales and marketing exclusivity periods within 20 days of the execution of such agreements. In addition, if the agreements involve reverse payment interests, the parties shall also notify the TFTC. The MoHW may notify the TFTC if it suspects the aforementioned agreements are in violation of the TFTA. However, as of the publicly available information by the end of March 2024 , the TFTC has yet to reach a decision in which it found a reverse payment interest agreement by pharmaceutical firms to be anticompetitive.

Special considerations

On 4 June 2024, the Legislative Yuan passed the Regenerative Medicine Act[59] and the Regenerative Medicine Product Regulations.[60] The Regenerative Medicine Act will regulate the R&D and promotion of regenerative medicine, manage regenerative medicine technologies and cell sources, and impose heavier fines on non-medical institutions advertising or carrying out regenerative medical treatment. The Regenerative Medicine Product Regulations monitor the entire life cycle of the derivative product, with mechanisms on conditional approvals, post-launch safety monitoring and relief measures for regenerative medicine product hazards.

Outlook and conclusions

To encourage the biotech pharmaceutical industry to engage in innovation and production in Taiwan, improve the people's right to health and the quality of medical care, the government is continuously implementing optimisation measures for the new drug registration and approval process to accelerate its overall pace. One example is the TFDA's new parallel review system, which entered into effect on 1 January 2024 and would greatly decrease the time needed for a new drug to become covered under the NHI programme. Efforts to accelerate and simplify the process to get new drugs to patients are thus expected to continue as in recent years.

While it may take some time for intended benefits (and/or issues) to manifest, the passage of the Regenerative Medicine Act and the Regenerative Medicine Product Regulations through the legislature in June 2024 is expected to provide a strong basis for biotech players involved in areas such as gene/cell therapy to start and grow their business in Taiwan.

Endnotes

1 The 2023 Biotech Industry White Paper published by the Bureau of Industrial Development of the Taiwan Ministry of Economic Affairs, p. 68; Statistics on the volume of drug licences (up to December 2023) of 'Results of Drug Management Innovation in Fiscal Year 2023' available from the TFDA's website: https://www.fda.gov.tw/TC/siteNews.aspx?sid=38&id=78 (last visited on 4 June 2024). Back to section

2 "Continuing to Improve the Health Insurance Coverage Review Process and Expanding Patient Care" on the NHIA website, https://www.nhi.gov.tw/ch/cp-13145-a2d49-3255-1.html (last visited on 23 May 2024).- Back to section

3 The TFDA's Yao-Zi-121409688 letter attached to the notification on the TFDA's website: https://www.fda.gov.tw/TC/siteListContent.aspx?sid=2984&id=45677 (last visited on 23 May 2024) Back to section

4 The TFTC's public announcement on "Merger Types to Which Paragraph 1 of Article 11 of the Fair Trade Act Does Not Apply" and " Fair Trade Commission Disposal Directions (Guidelines) on Handling Merger Filings". Back to section

5 Article 53(1)–(3) of the Patent Act. Back to section

6 id. Article 60. Back to section

7 Article 7 of the PAA, Article 39 of the RRMP. Back to section

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Summary

Introduction

This chapter provides an overview of the US frameworks for drug and biologic approvals, exclusivities and patent linkages, as well as the processes for addressing intellectual property disputes associated with applications for generic and biosimilar products. It also provides an overview of how these processes and associated strategies may come under antitrust scrutiny. Overall, the complex US legal frameworks in these areas are designed to strike a balance between encouraging innovation while incentivising timely patent challenges and market entry of competitors.

Year in review

The year 2024 has been marked by the continued implementation of a new framework for the drug price negotiations under the critical Medicare programme pursuant to the Inflation Reduction Act. The terms of that legislation have, for certain products, created important new considerations in drug and biologic life cycle management, both in in terms of the timeline for recouping investment before such negotiations occur, particularly for small molecules, and development decisions relating to next generation products and orphan drugs. In addition, both the US Congress and the Federal Trade Commission are pressing challenges to certain patenting practices, as well as increased scrutiny of transactions. Those dynamics, combined with the election year dynamics in the US, have resulted in an extremely dynamic and challenging environment.

Legislative and regulatory framework

The primary legislation governing the regulation of drug products is the Federal Food, Drug, and Cosmetic Act (the FD&C Act), codified at Title 21 of the US Code (USC), while the primary legislation governing biologic products is the Public Health Service Act (the PHS Act), codified at Title 42 of the USC. The implementing regulations of the Food and Drug Administration (FDA) are published in Title 21, Chapter I of the Code of Federal Regulations.

Congress has also passed significant legislation to encourage innovation and incentivise development of new drug products, and to lower costs, including the Drug Price Competition and Patent Term Restoration Act of 1984 (the Hatch-Waxman Amendments), which amended the FD&C Act to establish the generic drug approval pathway, and the Biologics Price Competition and Innovation Act (BPCIA), which amended the PHS Act and established an abbreviated licensure pathway for biologic products. As noted, the enactment of the Inflation Reduction Act drug price negotiation framework is now another significant influence on regulatory strategy, particularly for small molecules and orphan products.

In addition to incentives in the form of statutory exclusivities, the US patent system grants exclusive rights to make, use, sell or import into the US inventions for which a patent has been granted. Section 35 of the USC governs the US Patent and Trademark Office (USPTO), and the rights and remedies available under the patent system. The Leahy–Smith America

Invents Act, signed into law in 2011, amended Section 35 of the USC to implement, among other changes, a first-to-file system.

The nominal term of a US patent is 20 years from the filing date of the earliest priority application filed in the USPTO.[1]

In the United States, participants in the pharmaceutical sector are also subject to the antitrust laws, which influence how participants may contract with each other, how they may enforce and acquire patents, how they may settle litigation and how they may market their products, as well as how they act in regard to a number of other areas. The key antitrust laws impacting the pharmaceutical sector are:

1. Section 1 of the Sherman Antitrust Act,[2] which bans unreasonable contracts or conspiracies in restraint of trade;
2. Section 2 of the Sherman Antitrust Act,[3] which outlaws monopolisation or attempts at monopolising any aspect of interstate trade or commerce;
3. Section 7 of the Clayton Antitrust Act,[4] which bans mergers or acquisitions that may substantially lessen competition, or tend to create a monopoly; and
4. Section 5 of the Federal Trade Commission Act,[5] which outlaws 'unfair methods of competition' and 'unfair or deceptive acts or practices'.

New drugs and biologics – approval, incentives and rights

Drugs

Overview

To market a new prescription drug in the United States, an applicant must submit a new drug application (NDA) to the FDA for the agency's review and approval, and the agency must find that the drug is safe and effective for its intended use. There are two primary types of NDAs – a '505(b)(1)' NDA and a '505(b)(2)' NDA.[6]

A 505(b)(1) NDA is an application containing full reports of investigations demonstrating that the drug is safe and effective. A 505(b)(2) NDA is an application that contains full reports of safety and effectiveness, but where at least some of the information essential to approval comes from studies that were not conducted by or for the applicant, and for which the applicant does not have a right of reference.[7]

A sponsor submitting a 505(b)(2) NDA can also rely on the FDA's previous finding of safety and efficacy for an approved drug or published literature, or both, subject to the patent certification and exclusivity provisions of Hatch-Waxman.[8]

When an applicant submits an NDA for the FDA's review, it must pay the agency a 'user fee'.[9] As part of the establishment of user fees by Congress, the FDA sets corresponding

review performance goals, including timelines for review after a two-month filing period – 10 months for standard review and six months for priority review – and goals for the percentage of applications to be reviewed.[10] The FDA seeks to expedite the development and review of applications for drugs and biologics that address an unmet medical need in the treatment of a serious or life-threatening condition, and administers four programmes to facilitate this goal – fast-track designation,[11] breakthrough therapy designation,[12] accelerated approval[13] and priority review – as well as a special breakthrough programme for regenerative medicine advanced therapies.[14] The benefits of these programmes vary, and some overlap, but can include enhanced interaction with the FDA during the development process, and rolling review or a shorter review period.

Exclusivity

To incentivise drug development and reward innovation, the FD&C Act and the FDA's regulations provide for periods of data and marketing exclusivity.[15] This exclusivity can delay or prevent the review and approval of certain types of follow-on drug applications for a certain period and may run concurrently with other types of exclusivity.

Exclusivity differs from patent protection, and periods of exclusivity can run concurrently with patent terms. The FDA publishes information about a drug's exclusivity and patents in a publication typically referred to as the Orange Book.[16]

New chemical entity exclusivity

An NDA is eligible for five-year new chemical entity (NCE) data exclusivity if the application contains a drug, no active moiety of which has previously been approved by the FDA in an NDA.[17] During this period of exclusivity, no 505(b)(2) NDA nor abbreviated new drug application (ANDA) that contains the same active moiety may be submitted before the expiry of five years from the date of approval of the NDA with exclusivity, except that a 505(b)(2) NDA or ANDA, containing a certification of patent invalidity or non-infringement (a 'Paragraph IV' certification) may be submitted after the expiry of four years from the date of approval of the NDA. The FDA may, however, review and approve a subsequent 505(b)(1) NDA that contains the same active moiety during the pendency of NCE exclusivity.[18]

'Three-year' new clinical investigation exclusivity

A 505(b)(1) or 505(b)(2) NDA or efficacy supplement that contains a previously approved active moiety may be eligible for a three-year period of exclusivity if the application contains 'reports of new clinical investigations (other than bioavailability studies)' that are 'essential to the approval of the application' and were 'conducted or sponsored by the applicant'.[19] During the exclusivity period, the FDA may not approve a subsequent 505(b)(2) NDA or an ANDA referencing that application that contains the same active moiety for the exclusivity-protected conditions of approval.[20] This exclusivity does not block a 505(b)(1) NDA, nor does it block a subsequent 505(b)(2) NDA that does not seek approval for the exclusivity-protected indication. Additionally, such exclusivity does not block an ANDA that is permitted to 'carve out' the exclusivity-protected information from its labelling.

Orphan drug exclusivity

Drugs and biologics that receive orphan designation from the FDA prior to application submission and are approved for the orphan-designated use may be eligible for seven years of 'orphan drug' marketing exclusivity.[21] Unless the FDA has previously approved the 'same drug for the same use or indication', during the period of exclusivity, it generally may not approve another sponsor's application for the 'same drug' for the 'same use or indication' unless the subsequent drug demonstrates clinical superiority.[22]

Paediatric exclusivity

A drug or biologic may be eligible for a six-month 'add-on' to new or existing exclusivities, or patent protection if the applicant performs a paediatric study[23] that fairly responds to a written request[24] issued by the FDA, the studies have been conducted in accordance with commonly accepted scientific principles and protocols, and have been reported in accordance with filing requirements, and the FDA makes an exclusivity determination at least nine months before the expiry date of the patent and/or exclusivity protection to which the paediatric exclusivity will attach. For drugs, paediatric exclusivity applies to exclusivity and patents, whereas for biologics, paediatric exclusivity only applies to exclusivity.[25] This paediatric exclusivity applies not only to the product or indication that was studied in the paediatric population but also to all of the applicant's formulations, dosages and indications for products that contain the same active moiety.

For patent protection, paediatric exclusivity does not extend the term of the patent or the term of a patent extension, but rather the period during which the FDA cannot approve an ANDA or a 505(b)(2) NDA that certifies to a patent listed in FDA's Orange Book.

GAIN Act exclusivity

Title VIII of the Food and Drug Administration Safety and Innovation Act, entitled the Generating Antibiotic Incentives Now (GAIN) Act, was implemented in Section 505E of the FD&C Act and provides for incentives to develop antibacterial and antifungal drug products to treat serious or life-threatening infections (qualified infectious disease products (QIDPs)). Drug products submitted in a 505(b)(1) or 505(b)(2) NDA or efficacy supplement that are designated as QIDPs before application submission and that are approved for the designated use are eligible for a five-year extension or add-on of exclusivity.[26] GAIN exclusivity can extend a period of NCE exclusivity, three-year exclusivity or orphan drug exclusivity, and the GAIN exclusivity extension can be further extended by paediatric exclusivity.[27]

Generic drugs

Generic drugs are approved by the FDA through the ANDA pathway, outlined in Section 505(j) of the FD&C Act, as amended by the Hatch-Waxman Amendments.[28] An ANDA must reference an approved 'reference listed drug' product, and rely on the FDA's finding of safety and efficacy for the drug, rather than providing independent evidence of safety and efficacy in the application.

Subject to limited exceptions, the ANDA must contain the same active ingredient, conditions of use, route of administration, dosage form, strength and (with certain permissible differences) labelling as the listed drug upon which the application relies and must demonstrate bioequivalence to such drug.[29] The FDA's review and approval of ANDAs may be prevented or delayed by exclusivity and patent protection for the listed drug that the ANDA references.

Similar to prescription drugs and biologics, generic drug applications are subject to user fees.[30] The FDA also publishes a commitment letter paired with the Generic Drug User Fee Amendments authorisation, in which it sets goals for reviewing a certain percentage of ANDAs within a specific period, and may prioritise the review of certain ANDAs if they serve a public health priority, meet a prioritisation factor outlined in the relevant Manual of Policies and Procedures or are designated as a competitive generic therapy.[31]

ANDAs are eligible for two types of ANDA-specific exclusivity periods – 180-day 'patent challenge' exclusivity[32] and 180-day competitive generic therapy (CGT) exclusivity.[33]

On the one hand, 180-day patent challenge exclusivity provides ANDA applicants with an incentive to challenge a listed drug's patents by providing 180 days of exclusivity to the first applicant that submits a substantially complete application containing a 'Paragraph IV' certification to the listed drug's patent or patents.[34] During the exclusivity period, which commences on the date of the first commercial marketing of the ANDA, the FDA may not approve an ANDA containing a Paragraph IV certification that references the same listed drug.[35]

On the other hand, 180-day CGT exclusivity is intended to incentivise the development of generic drugs that are not 'protected by patents or exclusivities and for which there is inadequate generic competition'.[36] It provides a 180-day period of exclusivity for the 'first approved applicant of a drug with a CGT designation for which there were no unexpired patents or exclusivities listed in the Orange Book' when the ANDA was submitted.[37] During this exclusivity period, which starts on the date of the first applicant's first commercial marketing, the FDA may not approve an ANDA that is the same as the CGT ANDA.[38]

Biologics and biosimilars

Innovator (reference) biologics

Unlike small molecule drugs that are approved under Section 505 of the FD&C Act, biologics are approved under Section 351 of the PHS Act.[39] Licences for such 'reference' biologics are obtained by submitting a biologics licence application (BLA) pursuant to Section 351(a) of the PHS Act and implementing regulations.[40]

Approval of the BLA is based on a determination that the product is safe, pure and potent (the equivalent of safety and effectiveness for a drug), and the facility in which the product is manufactured, processed, packed or held meets standards designed to assure such safety, purity and potency.[41] The PDUFA user fees that apply to drugs also apply when a reference product BLA is submitted to the FDA for review. Likewise, the FDA's review commitments outlined in the PDUFA commitment letter apply to reference product BLAs, as do the expedited development and review pathways (e.g., fast-track).[42]

Like drugs, biologic products are also eligible for periods of exclusivity, although fewer types of exclusivity apply to biologics.[43] Significantly, the FDA may neither approve an application for a biosimilar or interchangeable biologic that references the innovator biologic (reference product exclusivity) during 12 years of exclusivity starting from the date of first licensure of the reference product,[44] nor receive a biosimilar or interchangeable biologic for review until four years after the date of the reference product's first licensure;-[45] however, the statute significantly limits 'evergreening' of products through the filing of subsequent supplemental applications for only minor changes in the product.

Reference products that receive orphan designation are also eligible for seven years of orphan drug exclusivity, as described in 'Orphan drug exclusivity'.[46] Reference products are also eligible for a six-month paediatric exclusivity add-on to existing reference product exclusivity (both to the 12-year and four-year periods noted above) or orphan drug exclusivity.[47]

Biosimilar and interchangeable biologics

The PHS Act, as amended by the BPCIA, provides for an abbreviated pathway for the 'licensure of biological products as biosimilar or interchangeable'.[48] An application for a biologic product submitted under Section 351(k) must include information to demonstrate that:

1. the biologic is highly similar to the reference product;
2. the biologic and the reference product utilise the same mechanism of action for the conditions of use prescribed, recommended or suggested in the proposed labelling to the extent that the mechanism is known for the reference product;
3. the conditions of use prescribed, recommended or suggested in the labelling for the biologic have been previously approved for the reference product;
4. the route of administration, dosage form and strength of the biologic are the same as the reference product; and
5. the 'facility in which the biological product is manufactured, processed, packed or held meets standards designed to assure that the biological product continues to be safe, pure, and potent'.[49]

A biosimilar licensed under Section 351(k) must be 'highly similar to the reference product, notwithstanding minor differences in clinically inactive components' and have 'no clinically meaningful differences' from the reference product in terms of safety, purity and potency.-[50] The FDA reviews the totality of the evidence in making a licensure determination for these products. Biosimilar and interchangeable biologic product applicants must also pay a user fee to the FDA in connection with submitting a licence application and are subject to review performance goals.[51]

A product deemed by the FDA to be an interchangeable biologic should meet additional statutory criteria for product evaluation and testing so that it can be, subject to state law, substituted for the reference product at the pharmacy level without the involvement of the prescriber. An interchangeable product is expected to 'produce the same clinical result as the reference product in any given patient' and if the product is administered more

than once to a person, 'the risk in terms of safety or diminished efficacy of alternating or switching between use of the [interchangeable] product and the reference product is not greater than the risk of using the reference product without such alternation or switch'.-[52] However, FDA has recently adopted the position that a separate demonstration of interchangeability via such studies is generally unnecessary for most biosimilar products.

The first interchangeable biologic is eligible for a period of exclusivity during which the FDA shall not determine that a follow-on biosimilar product is interchangeable for any condition of use until the earlier of:

1. one year after the first commercial marketing of the first interchangeable biologic for a particular reference product;
2. 18 months after a final court decision on all patents in an infringement lawsuit against the first applicant of the first approved interchangeable biologic or dismissal of such case; or
3. 42 months after approval of the first interchangeable biologic, if the first applicant has been sued for patent infringement and the litigation is still ongoing during the period, or 18 months after approval of the first interchangeable biologic if the first applicant has not been sued.[53]

Patent linkage

Introduction

Patents are a property right granted by the USPTO to an invention, which for a new drug or biologic product, may include, for example, its composition, associated formulations, methods of manufacturing, and dosing or treatment regimens.

Under the US patent code, 'whoever without authority makes, uses, offers to sell, or sells any patented invention, within the United States or imports into the United States any patented invention during the term of the patent, therefore, infringes the patent'.[54] The US patent code also makes it an act of infringement to:

1. 'actively induce' infringement by another,[55] to contributorily infringe a patent;[56]
2. supply without authority from the US components of a patented invention or a component of a patented invention especially made or adapted for use in a patented invention so as to cause them to be combined in such a manner that would infringe the patent if that combination occurred in the United States;[57] and
3. import into the United States a product made by a process patented in the United States.[58]

A US patent grants its holder the right to obtain as a remedy for infringement injunctive relief 'in accordance with the principles of equity'[59] and damages 'adequate to compensate for the infringement, but in no event less than a reasonable royalty'.[60]

To be eligible for patent protection, the invention must be considered new, useful, non-obvious and directed to one of the statutory classes of patentable subject matter.[61] Courts in the United States have interpreted the statutory categories of invention to exclude laws of nature, natural phenomena and abstract ideas.[62]

The patent includes a specification, which must include a written description of the invention and set forth the manner and process of making and using the invention such that a person of skill in the art would be enabled to practice the invention.[63] The patent must also include one or more 'claims' that distinctly point out the subject matter that the patent applicant regards as his or her invention.[64]

A patent in the United States is now granted to the first inventor to file an application, as opposed to the previous system that granted patent rights to the first party to invent. The grant of a patent right is separate from the grant of marketing exclusivity. As a patent may be granted anytime during the development of a drug product, periods of exclusivity and patent terms may or may not run concurrently.

The nominal term of a US patent is 20 years from the date of filing of the earliest priority application filed in the USPTO.[65] A patent may be entitled to an additional term, called a patent term adjustment (PTA), to compensate for delays by the USPTO in examining the patent application in accordance with a statutory formula set out in 35 USC Section 154(b).

Separately, upon FDA approval, a patent claiming a drug product or a method of using a drug product may receive a patent term extension (PTE), to accommodate for the time the drug product was subject to a regulatory review period.[66] The application for a PTE must be filed within 60 days of FDA approval of the drug product.[67]

Only one patent may receive a PTE for any product subject to a regulatory review period,[68] with the extent of the PTE governed by a statutory calculation based on the sum of one-half the number of days that the product was in the testing phase[69] and the total number of days that the application for marketing approval was under review after the patent was issued, and less the number of days that the applicant was not diligent in proceeding for approval.[70] A PTE cannot exceed 14 years after the date of regulatory approval or five years after the date of nominal patent expiry.[71]

As explained in 'Biosimilar and interchangeable biologics', the Hatch-Waxman Amendments provided for the approval of generic versions of innovator drugs by the filing of an ANDA. In 2009, the BPCIA was enacted to provide for the approval of biosimilar versions of innovator biologic drugs. Both statutes provide for a mechanism of litigating and resolving disputes raised by the innovator's patents prior to the launch of the generic or biosimilar product, although the mechanisms are very different.

Patent linkage under the Hatch-Waxman Amendments

Under 21 USC Section 355(b)(1), the owner of an NDA is required to file with the application the patent number and the expiry date of any patent that claims the drug for which the applicant submitted the application or that claims a method of using such drug and with respect to which a claim of patent infringement could reasonably be asserted if a person not licensed by the owner engaged in the manufacture, use or sale of the drug. The patent information provided by the NDA owner is listed for the approved drug along with regulatory exclusivity information in the Orange Book.[72]

The listing of patents in the Orange Book facilitates the resolution of patent disputes raised by ANDA filers under 21 USC Section 355(j).[73] Generic applicants filing ANDAs are required to make one of the following four 'certifications' with regard to patents listed for the approved drug in question:

1. that such patent information has not been filed;
2. that such patent has expired;
3. of the date on which such patent will expire; or
4. that such patent is invalid or will not be infringed by the manufacture, use, or sale of the new drug for which the application is submitted;[74]

The last of these is the Paragraph IV certification.

The filing of an ANDA with a Paragraph IV certification with regard to a patent is a statutory act of infringement of that patent under 35 USC Section 271(e)(2); however, 35 USC Section 271(e)(1) generally excludes from infringement activities that are 'solely for uses reasonably related to the development and submission of information under a Federal law which regulates the manufacture, use, or sale of drugs or veterinary biological products'.

Infringement under Section 271(e)(2) is sometimes referred to as an 'artificial' act of infringement because the generic company has not yet sold a product covered by any of the Orange Book-listed patents. Within 20 days of the FDA's acceptance of an ANDA containing a Paragraph IV certification, the ANDA applicant is required to provide written notice to the NDA owner and each owner of the challenged patents that the ANDA has been filed along with the ANDA filer's detailed basis for its opinion that any of the listed patents are invalid or will not be infringed.[75]

In addition, ANDA applicants can include a statement in their ANDAs that a listed patent directed to a method of use of an approved drug product does not claim a use for which the ANDA applicant is seeking approval.[76] The ANDA applicant then omits or carves out the patented use from its proposed label for its generic product.

In general, by using this 'skinny' label approach, the ANDA applicant may avoid infringement liability with respect to a patent claiming only the use that has been carved out;[77] however, litigation over whether a generic label is skinny enough to avoid infringement can be fact intensive.[78]

If the NDA owner files an infringement action within 45 days of the receipt of a Paragraph IV notice, FDA approval of the generic application is stayed for 30 months while the patent dispute is litigated.[79] For new drugs that have NCE exclusivity (explained in "New chemical entity exclusivity'), the stay of FDA approval extends until seven-and-a-half years after NDA approval.[80] A court may order that this period be shorter or longer 'because either party to the action failed to reasonably cooperate in expediting the action'.[81]

The 30-month stay of generic approval provides time for the NDA owner and ANDA filer to litigate patent issues prior to final FDA approval of the ANDA and therefore prior to sales of the generic drug. The actions are generally tried to the court and not a jury because there are no monetary damages prior to generic launch; however, if the generic launches 'at risk'

because, for example, the 30-month stay has expired, and damages are therefore at issue, the case can be tried to a jury.

If an Orange Book-listed patent is held valid and infringed, the district court will order that the effective date of generic approval will not be earlier than the expiry date of the patent. The district court can also grant injunctive relief to prevent the commercial manufacture, use, offer to sell or sale within the United States, or importation into the United States of the infringing product and can also award monetary damages if there has been a commercial sale of the generic product.[82]

Decisions of the district courts in Hatch-Waxman patent litigations are appealable to the US Court of Appeals for the Federal Circuit.

The BPCIA

Like the Hatch-Waxman Amendments, the BPCIA provides for a mechanism for innovator companies and biosimilar applicants to litigate patent disputes prior to the commercial sale of the biosimilar product. The filing of an application for a biosimilar version of an innovator biologic product is also an artificial act of infringement, and the innovator company has available to it similar remedies if such infringement is proven.[83]

However, the patent dispute resolution mechanism for biosimilar applicants, set out in 42 USC Section 262(1), is very different from the mechanism under the Hatch-Waxman Amendments. In addition, unlike the Hatch-Waxman Amendments, the BPCIA's patent dispute resolution mechanism is not linked to FDA approval of the biosimilar application, and no stay of FDA approval is triggered by BPCIA litigation.

The BPCIA provides a mechanism that commences when the biosimilar applicant provides a copy of its application to the RPS under a confidentiality arrangement.[84] Within 60 days of receipt of a biosimilar application, the reference product sponsor (RPS) provides a list of patents for which it 'believes a claim of patent infringement could be reasonably asserted' against the biosimilar product.[85] The RPS must also provide this patent list to the FDA (not later than 30 days after the patent list has been provided to the biosimilar applicant), for listing in the Purple Book.[86]

Thereafter, the BPCIA provides for a multi-step phased process by which the parties provide infringement and validity contentions with regard to the listed patents[87] and exchange further lists of patents with a goal of reaching agreement on a list of patents that the parties will litigate with respect to the biosimilar applicant's proposed product.[88] Once the parties decide on the patents to be litigated, whether through agreement or through the statute's additional mechanisms for narrowing the list of litigated patents, the RPS has 30 days within which to file suit.[89] During this process, the biosimilar applicant controls the number of patents that will be litigated;[90] however, the RPS will be able to file suit on at least one of its patents within 30 days after the final exchange of lists.[91]

Owing to the number of steps provided by the BPCIA, the process has come to be known as the 'patent dance', which, if carried out to completion, lasts up to 250 days. The process initially permits the biosimilar applicant to control the number of patents owned or controlled by the RPS that will be litigated, although the RPS will be permitted under the process to sue on at least one of its patents;[92] however, the BPCIA also requires that the biosimilar applicant provide a 180-day notice of commercial marketing, following which

the RPS may seek a preliminary injunction to prevent commercial sale by the biosimilar applicant with respect to any of the patents the RPS included on its initial list, but were not included in the litigation resulting from the patent dance procedure.[93]

Accordingly, the BPCIA procedures provide for the possibility of two phases of potential patent litigation, a first phase under which the biosimilar applicant can limit the litigation to a single RPS patent, and a second phase under which the RPS can bring a suit on the remaining patents that it initially listed.

In Sandoz, Inc v. Amgen, Inc (2017),[94] the US Supreme Court held that a biosimilar applicant cannot be required to provide its biosimilar application to the RPS and can therefore forgo the patent dance procedure, in whole or in part; however, a biosimilar applicant that does not provide the RPS with its application is subject to an immediate declaratory judgment action by the RPS on any patent that 'claims the biological product or the use of the biological product'.[95] In the same decision, the Supreme Court held that a biosimilar applicant may provide its 180-day notice of commercial marketing before the FDA licenses its biosimilar product.

Under 35 USC Section 271(e)(4), if the RPS prevails in patent litigation on a patent, the district court can grant injunctive relief to prevent the commercial manufacture, use, offer to sell or sale within the United States or importation into the United States of the infringing product, and 'shall' order a permanent injunction under certain circumstances.[96] Notably, however, unlike in Hatch-Waxman litigation, injunctive relief is not mandated by statute unless a final court decision[97] of infringement of the patent is issued prior to expiry of regulatory exclusivity for the RPS.

As in the Hatch-Waxman Amendments, monetary damages can only be awarded if there has been infringing commercial activity with respect to the biosimilar product.[98] If the RPS fails to bring a suit on any patent included on the negotiated list under 42 USC Section 262(l)(4) or (5) within the specified 30-day period, the RPS is limited to a reasonable royalty as its sole and exclusive remedy for infringement of that patent.[99]

Decisions of the district courts in BPCIA patent litigations are appealable to the US Court of Appeals for the Federal Circuit.

Competition enforcers

US antitrust laws[100] can be enforced by the federal government, state governments and by private parties injured by an alleged antitrust violation. Federal enforcement in the United States is shared by the Antitrust Division of the US Department of Justice (DOJ) and the US Federal Trade Commission (FTC).[101] The DOJ and the FTC split antitrust enforcement regarding merger control and civil anticompetitive conduct largely by industry, with the FTC handling both merger control and civil anticompetitive conduct for the pharmaceutical sector.[102] The DOJ is responsible for criminal antitrust enforcement in all industries, including the pharmaceutical sector.

Individual state attorneys general also have civil antitrust enforcement powers in the pharmaceutical sector. State attorneys general can bring actions under federal antitrust laws regarding conduct occurring in or affecting their state and have the power to enforce their individual states' own antitrust laws.[103]

Private plaintiffs may enforce federal antitrust laws by filing civil action claims against parties for violating the antitrust laws.[104]

Merger control

Federal enforcers, state enforcers and private parties have standing to challenge mergers or acquisitions affecting interstate commerce under Section 7 of the Clayton Act.[105] A transaction violates Section 7 of the Clayton Act if it may substantially lessen competition or tend to create a monopoly.

In general, an actionable harm to competition may occur if, post-transaction, the combined firm has the ability and incentive to raise prices, decrease supply, reduce innovation or product quality – either unilaterally or in coordination with other firms – or harm competition by foreclosing competitors from supply inputs or outlets for their products.[106] Potential harms to competition are more likely to occur if the parties already compete or are likely to compete in the future.[107]

Merger analysis frequently focuses on competitive effects within defined product and geographic markets. Product markets are defined around products and their substitutes, usually by application of the 'hypothetical monopolist' test (HMT). The HMT includes in a product market the products to which a customer would switch in response to a small price increase by a hypothetical monopolist of the relevant products.

In the pharmaceutical industry, this has resulted in various product market definitions, sometimes limited to a narrow market, including only a branded drug and its generic equivalents or biosimilars, or even just a market of generic drugs. In other cases, the market may include all drugs that treat a given indication using a particular mechanism of action or even more broadly as all drugs used to treat the indication.[108] Product markets may also include products still in the research and development stage that may compete in the future.

If the merging parties' products compete now or may in the future, the antitrust authorities examine whether any loss of competition from the transaction is likely to result in anticompetitive effects. This includes analysing the parties' and other competitors' existing or projected market shares and the levels of market concentration both pre- and post-merger. The antitrust authorities will also explore whether a transaction impacts the ability and incentive of the merging parties to engage in conduct that would limit the ability of others to compete in the marketplace. In addition, the antitrust authorities will consider whether entry or expansion by third parties would be timely, likely and of a sufficient magnitude to offset any competitive harm arising from the transaction.

Finally, if the antitrust authorities determine that a transaction is likely to result in anticompetitive effects, they will consider whether the transaction will lead to cognisable efficiencies that would offset any competitive harm.[109] To be cognisable, efficiencies must be both merger-specific and verifiable.[110]

Anticompetitive behaviour

Patents and antitrust law

Patent law provides pharmaceutical patent owners (in most cases, branded drug companies) with the limited right to exclude others but does not exempt them from antitrust scrutiny. Pharmaceutical patent owners have been the subject of litigation in many cases regarding alleged anticompetitive conduct through various means, including, but not limited to, reverse payment settlements, product switching, brand-for-generics strategies (B4G), sham litigation and bundled discounts. These examples are not exhaustive; there may be other antitrust theories of harm advanced by both antitrust authorities and private plaintiffs.

'Reverse payment' settlements

The Hatch-Waxman Act creates a framework for generic drug companies to challenge patents quickly.[111] It also provides generic companies with a research exemption to develop generic drugs lawfully while the original brand's patent is still in effect.[112]

Patent disputes between branded and generic companies often settle. The settlements commonly involve the parties negotiating entry dates for the generic product either at or before the branded drug's loss of exclusivity (LOE), based on anticipated litigation costs and respective litigation risk assessments.

In 'reverse payment' settlements, the plaintiff branded drug company pays the defendant generic drug company as part of the settlement.[113] In FTC v. Actavis, the Supreme Court held that reverse payment settlements are subject to antitrust scrutiny because they may harm competition by delaying the entry of the generic competitor.[114]

Lower courts have extended Actavis to non-cash 'payment' consideration,[115] such as an agreement by the branded drug company not to launch an authorised generic for a certain period.[116]

Product switching

Product switching (product hopping) may occur when a branded drug company reformulates a branded drug at or near LOE and encourages patients and doctors to switch to the new product.[117] Product switching can be either a 'soft switch' (when the original drug remains available to patients) or a 'hard switch' (when the original drug is made unavailable or significantly more difficult for patients to obtain).

While the introduction of a new and improved product is not unlawful, a hard switch that removes the older product from the market may create significant antitrust risk because it can eliminate demand for the original branded drug before generics can enter the market and thus exclude generic competition.[118]

B4G

A B4G strategy includes offering to a pharmaceutical benefit manager deeper discounts on branded drugs at or near LOE in exchange for preferred formulary placements. B4G

strategies can be pro-competitive and pro-patient because they reduce prices of branded drugs for consumers, but they may also create antitrust risk to the extent that the brand goes beyond securing formulary placement by offering lower prices and contractually limits competition from generic drugs.

Other market circumstances can affect the antitrust risk from B4G strategies; for example, risk may be higher when customer co-pays are higher for branded drugs than for the non-preferred generic (usually because the customer's pharmaceutical benefit programme requires a higher co-pay for branded products) or if agreements between a branded manufacturer and pharmaceutical benefit programmes are long-term and cover a substantial portion (at least 30 per cent) of a given market.

Sham petitioning and litigation

Under the Noerr-Pennington doctrine, parties are generally immune from liability under antitrust laws for engaging in actions to influence government decision-making (e.g., government petitioning, lobbying and litigation), even if the action they are seeking would limit competition;[119] however, branded drug companies may face antitrust liability for engaging in such conduct if their actions were a sham.

In general, litigation will be found a sham only if the claim is 'objectively baseless' and – if baseless – the litigation itself, rather than the outcome of the litigation, harms competition.[120] The same test has been applied to the petitioning of regulatory bodies (e.g., delaying introduction of a competing product while the FDA considers a 'citizen petition').[121]

Bundled discounts

Companies sometimes offer discounts for purchasing multiple types of products at one time.[122] This strategy is often pro-competitive because it lowers prices;[123] however, a bundling strategy can create antitrust risk if it makes it more difficult for a seller of only one of the bundled products to compete, in particular if the competitor to the bundle is forced to sell its products below cost to be able to compete with the bundle.[124]

Special considerations

A unique challenge in the United States has been the role of well-placed Members of Congress in directly pressuring pharmaceutical companies -- along with the FTC -- to delist certain device patents listed under the Hatch-Waxman framework, to lower pricing for products such as insulin and inhalers. In addition, FDA has preliminarily approved a State of Florida plan for implementation of a scheme for drug importation from Canada. In the current highly political environment such steps are increasingly undertaken with little regard for the impact of such efforts on the value of incremental innovation, or the role of parties such as pharmacy benefit managers in significantly increasing the actual costs to patients.

Outlook and conclusions

In the coming year, we expect a continued focus in the United States on the pricing of drug and biologic products, as well as patenting and competition in the pharmaceutical marketplace. Although much depends on the outcome of the upcoming election in the U.S. – which has significantly intensified the rhetoric and demands made upon the pharmaceutical industry – there will inevitably further bipartisan efforts to address demands for more affordable treatments. Hopefully those efforts will focus more on intermediaries in the U.S. healthcare system that largely increase drug costs instead of the companies that invest in the development innovative treatments for patients.

Endnotes

1 35 USC Section 154. Back to section

2 15 USC Section 1. Back to section

3 15 USC Section 2. Back to section

4 15 USC Section 18. Back to section

5 15 USC Section 45. Back to section

6 21 USC Section 355. The NDA pathway is primarily used for prescription drugs, though companies that intend to market an over-the-counter drug that does not comply with the terms of the applicable monograph may submit an NDA for the FDA's review and approval. Back to section

7 21 USC Section 355(b)(1), (b)(2). Back to section

8 Food and Drug Administration (FDA), Draft Guidance for Industry, Applications Covered by Section 505(b)(2) (October 1999) at 2–3. Back to section

9 21 USC Section 379h. The Prescription Drug User Fee Act (PDUFA), which authorises the FDA to collect fees from human drug and biologics companies, must be reauthorised every five years. Back to section

10 See FDA, PDUFA Reauthorization Performance Goals and Procedures Fiscal Years 2023 Through 2027. Back to section

11 21 USC Section 356(b). Back to section

12 21 USC Section 356(a). Back to section

13 21 USC Section 356(c). See also 21 CFR Part 314, subpart H. Back to section

14 FDA Guidance for Industry, Expedited Programs for Serious Conditions – Drugs and Biologics (May 2014); 21 USC Section 360n (Tropical Disease Priority Review Voucher); 21 USC Section 360ff (Rare Paediatric Disease Priority Review Voucher). Back to section

15 The Federal Food, Drug, and Cosmetic Act (the FD&C Act) and the FDA regulations also provide for incentives to develop drugs for rare diseases (those that affect fewer than 200,000 people in the United States), including rare diseases that affect paediatric populations. See, for example, 21 USC, Part B – Drugs for Rare Diseases or Conditions; 21 CFR Part 316, Subpart C – Designation of an Orphan Drug. The FDA's Office of Orphan Products Development administers the Orphan Drug Designation programme and the Rare Paediatric Disease Priority Review Voucher programme. Designation of a drug as an 'orphan drug' provides drug sponsors with incentives such as tax credits for qualified clinical tests, waiver of prescription drug user fees and exclusivity. Back to section

16 FDA, 'Approved Drug Products with Therapeutic Equivalence Evaluations' (the Orange Book). Back to section

17 21 USC Section 355(c)(3)(E)(ii), (j)(5)(F)(ii). The FDA's regulations interpret an active moiety as 'the molecule or ion, excluding those appended portions of the molecule that cause the drug to be an ester, salt . . . or other noncovalent derivative . . . of the molecule, responsible for the physiological or pharmacological action of the drug substance'. 21 CFR Section 314.3(b). Back to section

18 21 USC Section 355(c)(3)(E)(ii), (j)(5)(F)(ii); 21 CFR Section 314.108(b)(2). Back to section

19 21 USC Section 355(c)(3)(E)(iii). Back to section

20 21 USC Section 355(c)(3)(E)(iii)–(iv), (j)(5)(F)(iii)–(iv); 21 CFR Section 314.108(b)(4)–(5). Back to section

21 21 USC Section 360cc(a); 21 CFR Section 316.31(a). The FDA's regulations provide that an orphan-designated drug will receive exclusivity only if 'the same drug has not already been approved for the same use or indication'. 21 CFR 316.3(a)(12). Back to section

22 Where the FDA has previously approved the 'same drug' for the 'same use or indication', to be eligible for orphan drug exclusivity, the sponsor must demonstrate that its product is clinically superior to any previously approved drug that is the 'same drug'. 21 USC Section 360cc(c). 'Same drug' is defined in the FDA's regulations at 21 CFR Section 316.3(b)(14), and for a small molecule drug, it means a 'drug that contains the same active moiety as the previously approved drug and is intended for the same use as the previously approved drug . . . except that if the subsequent drug can be shown to be clinically superior to the first drug, it will not be considered to be the same drug'. 21 CFR §316.3(b)(3). The decision in Catalyst Pharms, Inc v. FDA, 14 F.4th 1299 (11th Cir. 2021) could have significantly broadened the scope of orphan drug exclusivity and potentially required that a 'same drug' competitor demonstrate clinical superiority to obtain approval for any indication within a prior approved orphan product's designation, even if the prior applicant did not obtain the full designated indication in labelling. In January 2023, however, the FDA issued a Federal Register notice clarifying its approach to orphan drug exclusivity following the Catalyst decision. Consistent with the court's decision, the FDA set aside its approval of the drug at issue in the case. But, the FDA announced that while the agency is complying with the court's order in Catalyst, the FDA intends to continue to apply its regulations tying the scope of orphan drug exclusivity to the uses or indications for which a drug is approved to matters beyond the scope of that order. Specifically, the FDA intends to continue to apply its long-standing regulations tying the scope of orphan drug exclusivity to the uses or indications for which the orphan drug was approved. Congress is currently considering legislation that would address the Catalyst decision and codify the FDA's long-standing interpretation of the Orphan Drug Act to ensure that orphan drug exclusivity applies only to the same approved use or indication within a rare disease or condition, instead of the same disease or condition. ^ Back to section

23 For purposes of paediatric exclusivity, a paediatric study means 'at least one clinical investigation (that at [the FDA's] discretion, may include pharmacokinetic studies) in paediatric age groups (including neonates in appropriate cases) in which a drug is anticipated to be used, and, at [the FDA's] discretion, may include preclinical studies'. 21 USC Section 355a(a). ^ Back to section

24 A written request is a document issued by FDA requesting submission of a study or studies intended to provide meaningful health benefits in the paediatric population. ^ Back to section

25 21 USC Section 355a(b)(2), (c)(2). Exclusivity that may be extended includes NCE exclusivity, three-year exclusivity, orphan drug exclusivity, reference product exclusivity, and Generating Antibiotic Incentives Now exclusivity. Patents that may be extended are those that claim the drug or a use for such drug that is or will be listed in the Orange Book. ^ Back to section

26 21 USC Section 355f(a); FDA Draft Guidance for Industry, Qualified Infectious Disease Product Designation Questions and Answers (May 2021) at 7–8. ^ Back to section

27 See 21 USC Section 355f(a), (b). ^ Back to section

28 21 USC Section 355(j). Back to section

29 21 USC Section 355(j)(2)(A)(i)–(v), (j)(2)(C); 21 CFR Section 314.94(a). An example of differences in labelling is where the applicant is not seeking approval for a condition of use that is protected by patent or exclusivity. See 21 USC Section 355(j)(2)(A)(viii); 21 CFR Section 314.94(a)(8)(iv). Generic drugs may also differ from the listed drug in terms of inactive ingredients. Back to section

30 21 USC Section 379j-42. Back to section

31 Generic Drug User Fee Amendments Reauthorization Performance Goals and Program Enhancements Fiscal Years 2023–2027; FDA Center for Drug Evaluation and Research, Manual of Policies and Procedures, Manual of Policies and Procedures 5240.3 Rev. 6 (5 October 2022); and FDA Guidance for Industry, Competitive Generic Therapies (October 2022) at 9. Back to section

32 21 USC Section 355(j)(5)(B)(iv). Back to section

33 21 USC Section 356h(b)(3), (e)(2); 21 USC Section 355(j)(5)(B)(v). Back to section

34 There can be more than one first applicant, and ANDA applicants can 'share first-applicant status'. FDA Draft Guidance for Industry, 180-Day Exclusivity: Questions and Answers (January 2017) at 4. Back to section

35 21 USC Section 355(j)(5)(B)(iv)(I). Back to section

36 FDA Guidance for Industry, Competitive Generic Therapies (October 2022) at 3. Back to section

37 ibid. Back to section

38 An ANDA that is the same drug as the CGT may be approved and commence marketing before the CGT commences marketing. id. at 15. Back to section

39 42 USC Section 262. Back to section

40 42 USC Section 262(a); 21 CFR Part 601. Back to section

41 42 USC Section 262(a)(2)(C). See also 21 CFR Section 601.2(d). Back to section

42 21 USC Section 356(a)-(c); 21 CFR Part 601, Subpart E. Back to section

43 For example, biologics are eligible for QIDP designation and receipt of priority review, although biologics are not eligible for GAIN exclusivity. Back to section

44 42 USC Section 262(k)(7)(A). Exclusivity is not available for a biologic licensed under section 351(a) of the Public Health Service Act (the PHS Act) if it is a supplement to the reference product, or a 'subsequent application filed by the same sponsor or manufacturer of the biological product (or a licensor, predecessor in interest, or other related entity) for a change (not including a modification to the structure of the biological product) that results in a new indication, route of administration, dosing schedule, dosage form, delivery system, delivery device, or strength; or a modification to the structure of the biological product that does not result in a change in safety, purity, or potency'. 21 USC Section 262(k)(7)(C). Back to section

45 42 USC Section 262(k)(7)(B). Back to section

46 21 USC Section 360cc(a)(2). If the reference product also has 12-year exclusivity, the FDA may not license the biosimilar or interchangeable biologic until the expiry of the orphan exclusivity or 12-year exclusivity, whichever period is later. FDA Draft Guidance for Industry, Reference Product Exclusivity for Biological Products Filed Under Section 351(a) of the PHS Act (August 2014) at 2. Back to section

47 42 USC Section 262(m)(2), (m)(3). Back to section

48 42 USC Section 262(k). Back to section

49 42 USC Section 262(k)(2)(A)(i). Back to section

50 42 USC Section 262(i)(2). Back to section

51 21 USC Section 379j-52. The applicable user fees are known as biosimilar user fee amendment fees. See Biosimilar Biological Product Reauthorization Performance Goals and Procedures Fiscal Years 2023 Through 2027. Back to section

52 42 USC Section 262(k)(4). Back to section

53 42 USC Section 262(k)(6). Back to section

54 35 USC Section 271(a). Back to section

55 35 USC Section 271(b). Back to section

56 35 USC Section 271(c). Back to section

57 35 USC Section 271(f)(1). Back to section

58 35 USC Section 271(g). Back to section

59 35 USC Section 283. Back to section

60 35 USC Section 284. Back to section

61 35 USC Section 101, 102. Back to section

62 See Alice Corp Pty Ltd v. CLS Bank Int'l, 134 S. Ct. 2347, 2354, 110 USPQ2d 1976, 1980 (2014). Back to section

63 35 USC Section 112(a). Back to section

64 35 USC Section 112(b). Back to section

65 35 USC Section 154. Back to section

66 35 USC Section 156. Back to section

67 35 USC Section 156(d)(1); 37 CFR Section 1.720(f). Back to section

68 A PTE is available under 35 USC Section 156 for both small molecule drug products and large molecule biologic products approved under the Biologics Price Competition and Innovation Act (BPCIA), provided that the 'permission for the commercial marketing or use of the product after such regulatory review period is the first permitted commercial marketing or use of the product'. 35 USC Section 156(a)(5)(A). Back to section

69 The 'testing phase' refers to the time period defined in 37 CFR Section 1.775(c)(1). Back to section

70 See 37 CFR Section 1.775. Back to section

71 35 USC Section 156. Back to section

72 If a patent issues after NDA filing but before approval, 'the applicant shall amend the application to include the information'. 21 USC Section 355(b)(1). Under the applicable regulations, the amendment is to be made within 30 days of patent issuance. 21 CFR Section 314.53(d)(1). If a patent issues after NDA approval, the NDA 'holder shall file such information . . . not later than thirty days after the date the patent involved is issued'. 21 USC Section 355(c)(2). Back to section

73 Essentially the same patent dispute resolution mechanism applies to 505(b)(2) NDAs.- Back to section

74 21 USC Section 355(j)(2)(A)(vii). Back to section

75 21 USC Section 355 (j)(2)(B)(ii)–(iv). Back to section

76 21 USC Section 355(j)(2)(A)(viii). Back to section

77 See, for example, GlaxoSmithKline LLC v. Teva Pharms USA, Inc., 25 F.4th 949 (Fed Cir. 2022), certiorari denied at Teva Pharms USA, Inc. v. GlaxoSmithKline LLC, 2023 WL 344748 (May 15, 2023). Back to section

78 ibid. Back to section

79 21 USC Section 355(j)(5)(B)(iii). Back to section

80 21 USC Section 355(j)(5)(F)(ii). Back to section

81 21 USC Section 355(j)(5)(B)(iii). Back to section

82 35 USC Section 271(e)(4). Back to section

83 35 USC Section 271(e)(2), (e)(4), (e)(6). In addition, the exclusion from infringement under 35 USC Section 271(e)(1), discussed above with regard to the Hatch-Waxman Act, for activities 'solely for uses reasonably related to the development and submission of information under a Federal law which regulates the manufacture, use, or sale of drugs or veterinary biological products' also applies to biologic products. Back to section

84 42 USC Section 262(l)(1), (l)(2). Back to section

85 42 USC Section 262(l)(3)(A). Under 35 USC Section 271(e)(2)(C)(i), the filing of the application becomes an act of infringement of the patents that the reference product sponsor (RPS) includes on its list under 42 USC Section 262(l)(3). See Sandoz, Inc v. Amgen, Inc, 134 S.Ct. at 1664, 1673. If the RPS omits a patent that 'should have been included' on its initial patent list, it may not bring an action for infringement of that patent with respect to the biological product. 35 USC Section 271(e)(6)(C). This provision encourages the RPS to be expansive on the patents it includes on its list at the outset of the patent exchange process. If there are newly issued or licensed patents, the RPS can add those patents to its list within 30 days after issuance or in-licensing. 42 USC Section 262(l)(7). Back to section

86 42 USC Section 262(k)(9)(A)(iii). Unlike the Orange Book, the Purple Book does not list any patents until the RPS and a biosimilar applicant first reach this step of the BPCIA's patent dispute resolution procedures. In further contrast to the Orange Book, the patents listed in the Purple Book are patents asserted to cover the biosimilar product and need not necessarily cover the reference product. See 42 USC Section 262(l)(3)(A)(i). Consequently, the list of patents asserted to cover one biosimilar product may not be entirely identical to the list of patents asserted to cover a second biosimilar product. Back to section

87 42 USC Section 262(l)(3)(B) and (C). Back to section

88 42 USC Section 262(l)(4). Back to section

89 42 USC Section 262(l)(6)(A) and (B); 42 USC Section 262(l)(5)(B). Back to section

90 42 USC Section 262(l)(5)(A) and (B)(ii). Back to section

91 42 USC Section 262(l)(6)(B); 42 USC Section 262(l)(5)(B)(ii)(II). Back to section

92 ibid. Back to section

93 42 USC Section 262(l)(8). Back to section

94 134 S.Ct. 1664 (2017). Back to section

95 42 USC Section 262(l)(9)(C). Under 35 USC Section 271(e)(2)(C)(ii), the filing of the application becomes an act of infringement with respect to the patents that the RPS could have listed under 42 USC Section 262(l)(3). See Sandoz v. Amgen, 134 S.Ct. at 1673. Under the BPCIA, the RPS cannot bring a declaratory judgment action against a biosimilar applicant that does provide its application and engages in the steps of the patent dance; however, if the biosimilar applicant fails to complete an action in the patent dance, the RPS can file a declaratory judgment action with respect to any of the patents it included on its initial list. 42 USC Section 262(l)(9)(A–C). Back to section

96 35 USC Section 271(e)(4)(D) provides that if the RPS obtains a final court decision finding patent infringement by a biosimilar product, 'the court shall order a permanent injunction prohibiting any infringement of the patent by the biological product involved in the infringement until a date which is not earlier than the date of the expiration of the patent that has been infringed under paragraph (2)(C)' provided that 'the biological product has not yet been approved because of [reference product exclusivity under] section 351(k)(7)' of the Public Health Service Act. Back to section

97 "Final court decision" is defined as a final decsion of a court from which no appeal (other than a petition to the United States Supreme Court for a write of certiorari) has been or can be taken. Back to section

98 35 USC Section 271(e)(4)(C).' Back to section

99 35 USC Section 271(e)(6)(B). Back to section

100 US antitrust laws include: Section 1 of the Sherman Antitrust Act, 15 USC Section 1, which bans unreasonable contracts or conspiracies in restraint of trade; Section 2 of the Sherman Antitrust Act, 15 USC Section 2, which outlaws monopolisation or attempts at monopolising any aspect of interstate trade or commerce; Section 7 of the Clayton Antitrust Act, 15 USC Section 18, which bans mergers or acquisitions that may substantially lessen competition or tend to create a monopoly; and Section 5 of the Federal Trade Commission Act, 15 USC Section 45, which outlaws 'unfair methods of competition' and 'unfair or deceptive acts or practices'. Back to section

101 Only the Federal Trade Commission (FTC) has the authority to enforce the FTC Act. The Antitrust Division of the Department of Justice (DOJ), state governments and private parties are not permitted to bring a suit under the Act. Back to section

102 The FTC sometimes works with the FDA to identify potentially anticompetitive conduct in the pharmaceutical sector. Back to section

103 Depending on the state, the attorney general may enforce the antitrust laws seeking relief on behalf of the state itself or as a representative of the people (i.e., as parens patriae) or both. Back to section

104 15 USC Section 15. Back to section

105 15 USC Section 18. The Hart-Scott-Rodino Antitrust Improvements Act of 1976 requires parties to transactions meeting certain criteria to file pre-merger notifications with both the FTC and the DOJ. 15 USC Section 18(a). Back to section

106 For both horizontal mergers (i.e., mergers among companies at the same level of the supply chain) and vertical mergers (i.e., mergers among companies at different levels of the supply chain), the 'substantial lessening of competition' standard is implemented through the application of the federal antitrust authorities' Merger Guidelines. See DOJ and FTC, Merger Guidelines (2023). Back to section

107 The competitive analysis also includes an assessment of whether any efficiencies from the transaction would outweigh any potential anticompetitive effects. Back to section

108 Compare complaint at 2, In the Matter of Teva Pharmaceutical Industries Ltd and Allergan PLC, Docket No. C-4589 (FTC 15 September 2016) (defining product market by the molecule, which refers to the equivalency of brands and generics) with complaint at 2, In the Matter of Bristol-MyersSquibb Company and Celgene Corp, Docket No. C-4690 (Fed. Trade Comm'n 13 January 2020) (defining product market by the indication or method of action). Back to section

109 Horizontal Guidelines at 30. Back to section

110 ibid. Back to section

111 21 USC Section 355; 35 USC Section 271(e)(1). Back to section

112 21 USC Section 355(c)(3)(D)(i)(I)(aa), (j)(5)(C)(i)(I)(aa) and 35 USC Section 271(e)(5); 21 USC Section 355(c)(3)(C) and (j)(5)(B)(iii); FDA Guidance for Industry: 180-Day Exclusivity When Multiple ANDAs are Submitted on the Same Day (July 2003) at 2. Back to section

113 See FTC v. Actavis, Inc., 570 US 136, 136-37 (2013). Back to section

114 id. at 154–58. See also Impax Labs, Inc. v. FTC, 994 F.3d 484 (5th Cir. 2021) (upholding the FTC's first fully litigated post-Actavis challenge to an allegedly unlawful 'reverse payment' settlement). Back to section

115 See King Drug Co. of Florence, Inc. v. Smithkline Beecham Corp., 791 F.3d 388, 409 (3d Cir. 2015) (holding that an agreement by the branded drug company not to launch an authorised generic for a certain period was considered a large and unjustified reverse payment) and Rochester Drug Co-Operative, Inc v. Warner Chilcott Co. (In re Loestrin Fe Antitrust Litig.), 814 F.3d 538, 552 (1st Cir. 2016) ('Although the value of non-cash reverse payments may be much more difficult to compute than that of their cash counterparts . . . antitrust litigation already requires courts to make intricate and complex judgments about market practices'), which overturned district court rulings that Actavis only applied to cash payments. See also In re Lipitor Antitrust Litig., 46 F. Supp. 3d 523, 543 (D.N.J. 2014) ('non-monetary payment must be converted to a reliable estimate of its monetary value' using 'a reliable foundation used within the industry'). Back to section

116 See King Drug Co. of Florence, Inc., 791 F.3d at 409. Back to section

117 id. Back to section

118 See New York v. Actavis PLC, 787 F.3d 638, 654 (2d Cir. 2015) (finding 'hard switch' unlawful because 'when a monopolist combines product withdrawal with some other conduct, the overall effect of which is to coerce consumers rather than persuade them on the merits and to impede competition its actions are anticompetitive under the Sherman Act') (internal citation omitted). Back to section

119 See California Motor Transp. Co. v. Trucking Unlimited, 404 US 508, 510 (1972); United Mine Workers v. Pennington, 381 US 657, 669 (1965); ER Presidents Conference v. Noerr Motor Freight, 365 US 127, 136 (1961). The Noerr-Pennington doctrine states that acts of initiating litigation and other means of petitioning the government are immune from federal antitrust laws, even if these acts may lead to a monopoly or restraint on trade. Back to section

120 Professional Real Estate Investors, Inc. v. Columbia Pictures Indus, Inc., 508 US 49, 50 (1993). Back to section

121 In re DDAVP Direct Purchaser Antitrust Litig, 585 F.3d 677, 694 (2d Cir. 2009). Back to section

122 See, for example, Collins Inkjet v. Eastman Kodak Co., 781 F.3d 264, 274 (6th Cir. 2015) (affirming the lower court ruling to enjoin Kodak's policy to charge lower prices for printers to customers who also bought Kodak brand ink). Back to section

123 See, for example, Atl. Richfield Co. v. USA Petrol Co., 495 US 328, 340 (1990) ('Low prices benefit consumers regardless of how those prices are set, and so long as they are above predatory pricing levels, they do not threaten competition'); Collins Inkjet, 781 F.3d at 271 ('Competitive sellers generally aim to make their products significantly cheaper than their competitors, and there is nothing inherently wrong with doing so via differential pricing'); Cascade Health Sols. v. PeaceHealth, 515 F.3d 883, 894-96 (9th Cir. 2008) ('[W]e should not be too quick to condemn price-reducing bundled discounts as anticompetitive, lest we end up with a rule that discourages legitimate price competition'). Back to section

124 See Cascade Health Sols v. PeaceHealth, 515 F.3d at 899 (describing the 'discount attribution test' asking whether an equally efficient competitor offering only a single product could profitably match the total discount offered on the bundle); LePage's Inc. v 3M, 324 F.3d 141, 155 (3d Cir.) (holding that bundling is anticompetitive when it "foreclose[s] portions of the market to a potential competitor who does not manufacture an equally diverse group of products and who therefore cannot make a comparable offer."). Back to section

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