THE PHARMACEUTICAL INTELLECTUAL PROPERTY AND COMPETITION LAW REVIEW

FOURTH EDITION

Editor
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THE LAWREVIEWS

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PREFACE

Despite the industry's critically important response to the covid-19 pandemic, which saved millions of lives around the world, the attacks on industry – and science – continue. The pharmaceutical business is under unprecedented pressure – pricing is a constant focus of new legislation, patenting and business strategies are under continual scrutiny, and regulatory and compliance burdens are growing. Combine that complexity with the fact that pharmaceuticals are truly one of the most global industries, with many companies operating in dozens of countries with differing legal regimes and healthcare systems, and you have a 'perfect storm' for industry lawyers.

While there has been significant harmonisation in certain areas, the nuances of these local frameworks require careful attention from both a strategic planning and operational perspective in order to achieve business objectives across jurisdictions. Maximising the value of intellectual property can make the difference in deciding whether to pursue the development of an important new treatment, and in maintaining success in the marketplace. Similarly, a 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 are all too familiar, this is an area of significant enforcement activity around the world, with large fines being imposed and transactions thwarted if applicable legal constraints are not heeded. Moreover, the links between intellectual property, such as exclusivities, and drug pricing and affordability are a constant source of political scrutiny, as well as patient and physician concern.

Our objective in structuring this updated volume is to give practitioners in the field a one-volume introduction to these critical issues in an array of 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 success. I would like to thank the authors for their renewed contributions to this edition of *The Pharmaceutical Intellectual Property and Competition Law Review*; they have produced what we believe is a very useful tool for managing global risks in this area.

Daniel A Kracov
Arnold & Porter
Washington, DC
August 2023

Chapter 7

JAPAN

Yoko Kasai and Junko Wakabayashi[1]

I OVERVIEW

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.

II LEGISLATIVE AND REGULATORY FRAMEWORK

i 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.

ii 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

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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.

iii 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.

iv 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:

a 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,[2] which covers horizontal restraints, including cartels.

b 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.[3]

c Unfair trade practices: acts designated by the AMA or the Japan Fair Trade Commission (JFTC) that may impede fair competition,[4] 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.

2 Article 2, paragraph 6 of the AMA.

3 Article 2, paragraph 5 of the AMA.

4 Article 2, paragraph 9 of the AMA.

III NEW DRUGS AND BIOLOGICS – APPROVAL, INCENTIVES, AND RIGHTS

i 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:

a 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

b 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:

a severity of the target disease;

b clinical utility;

c the number of patients is fewer than 50,000 or the target disease is an 'intractable disease' in Japan; and

d 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 that are developed in Japan at the earliest possible time. The following are the designation criteria for SAKIGAKE:

a the product should be innovative;

b the product should target a serious disease;

c the product should have expected prominent effectiveness or significant improvement of safety; and

d 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:

a severity of the target disease;
b clinical utility;
c 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
d 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 file an application for 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 has the opportunity

to re-examine the safety and efficacy of the drugs. The holder of a 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:

a 10 years for orphan drugs;
b 10 years for drugs requiring a pharmacoepidemiological evaluation;
c eight years for drugs containing new active ingredients;
d six years for new combination drugs;
e six years for drugs with a new route of administration;
f 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
g 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.

ii 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 in an unofficial manner 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.

iii 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.[5] 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.

5 '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).

IV 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:[6]

a the active ingredient of the original drug is not protected by a valid patent on the expected approval date of the generic drug; and

b 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

6 '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).

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 so-called regimen patent, which relates to an invention characterised by dosage and administration. As a result, in order 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[7]). 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.

7 20 January 2017, case No. 2916 (ne) 10046.

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.

V 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.[8] 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.[9] Also, victims whose interests are likely to be harmed by unfair trade practices have the right to demand an injunction.[10]

VI 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

8 The JFTC's 'Policy on Criminal Accusations and Investigation of Criminal Cases in Violation of the Antimonopoly Act' (7 October 2005).

9 Articles 25 and 26 of the AMA.

10 Article 24 of the AMA.

acquisitions having a total consideration exceeding ¥40 billion and a potential impact on domestic customers or business.[11] 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 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:

a integration of Bristol-Myers Squibb Company and Celgene Corporation;[12]

b acquisition by Takeda Pharmaceutical Co, Ltd of shares in Shire plc;[13]

c business swap between the Sanofi Group and Boehringer Ingelheim Group;[14] and

d acquisition of business from GlaxoSmithKline Co, Ltd by Novartis AG.[15]

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.

VII 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.

11 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).

12 JFTC Major Business Combination Cases for FY 2019, Case 1, published on 22 July 2020.

13 JFTC Major Business Combination Cases for FY 2018, Case 3, published on 19 June 2019.

14 JFTC Major Business Combination Cases for FY 2016, Case 4, published on 14 June 2017.

15 JFTC Major Business Combination Cases for FY 2014, Case 4, published on 10 June 2015.

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.[16]

i 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.[17] 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[18] 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.'[19]

ii 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.[20]

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.[21]

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

16 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.

17 Article 21 of the AMA.

18 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).

19 Intellectual Property Guidelines Part 4, 2(3).

20 Article 2, paragraph 9, item 4 of the AMA.

21 JFTC Consultation Case for FY 2000, Case 4.

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.[22]

iii 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.[23]

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.[24]

iv 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:[25]

a 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.

b 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.

VIII OUTLOOK AND CONCLUSIONS

In the 2023 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

22 JFTC Consultation Case for FY 2001, Case 2.

23 2021 (Nin) No. 2, 'In Re: Alcon Japan Ltd' (Released 26 March 2021).

24 2020 (Nin) No. 1 'In Re: Nihon Medi-Physics Co., Ltd' (Published 1 March 2020).

25 The JFTC's 'Survey Report on the Distribution of Prescription Drugs' on 27 September 2006.

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.

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, in order 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 in an effort 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.