THE PHARMACEUTICAL INTELLECTUAL PROPERTY AND COMPETITION LAW REVIEW

Editor
Daniel A Kracov

THE LAWREVIEWS

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PREFACE

The pharmaceutical business is truly one of the most global industries, with many companies operating in dozens of countries with differing legal regimes and healthcare systems. In certain respects, the rules governing industry activities have largely become harmonised, such as in drug manufacturing and the conduct of clinical trials. However, in other areas the legal frameworks differ, and those nuances can require significant efforts to both optimise strategies and comply with requirements in local jurisdictions. In the areas of focus of this book – pharmaceutical intellectual property, including patent linkage and exclusivities, and related competition concerns – while general concepts may be shared across jurisdictions, it can be critically important to tailor approaches to the local legal environment.

Maximising the value of intellectual property can make the difference in deciding to pursue the development of an important new treatment, and in determining its sustained 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. 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 has been a constant source of political scrutiny, as well as patient and physician concern. With the ongoing covid-19 pandemic spurring an intense focus on intellectual property and pricing issues associated with vaccines and other needed treatments, the stakes have grown even higher.

Our objective in framing this volume is to give practitioners in the field a one-volume introduction to these critical issues in an array of jurisdictions. I would like to thank the authors for their 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 2020

Chapter 8

JAPAN

Atsushi Okada[1]

I OVERVIEW

In the pharmaceutical industry, IP and competition laws, and manufacturing and marketing approval processes play key roles, and are closely linked to one another. Section II describes the legislative and regulatory framework (such as marketing licences and authorisation, drug-pricing systems, and formats of patent infringement litigation and invalidation trial). Section III elaborates on approval and patent requirements regarding original drugs, generic drugs and biosimilar products. Section IV describes how patents and authorisation procedures are linked. Finally, Sections V and VI expound on competition law issues. We close with our conclusions in Section VIII.

II LEGISLATIVE AND REGULATORY FRAMEWORK

i Codified laws

The Japanese legal system is based primarily on codified law:

a for pharmaceutical regulations, the Act on Securing the Quality, Efficacy and Safety of Pharmaceuticals, Medical Devices, Regenerative and Cellular Therapy Products, Gene Therapy Products, and Cosmetics (the Pharmaceutical and Medical Device Act) provides various regulations on the development, manufacture, import, marketing, and proper use of drugs and medical devices;

b for the patent system, the Patent Act is the principal source of substantive law governing patents, including pharmaceutical patents. The Code of Civil Procedure and the Rules of Civil Procedure are the principal sources of law and regulation relating to the procedural aspects of patent litigation in Japan; and

c regarding competition, the Act on the Prohibition of Private Monopolisation and the Maintenance of Fair Trade (the Anti-Monopoly Act) prohibits anticompetitive activities, such as private monopolisation, unreasonable restraint of trade and unfair trade practices.

ii Licence for manufacturing or marketing businesses

A company that wishes to start a drug manufacturing or marketing business must obtain a manufacturing or marketing business licence from the relevant prefectural governor depending on the type of business, such as the following:

1 Atsushi Okada is a partner at Mori Hamada & Matsumoto.

a Type 1 drug manufacturing or marketing business licence: for the marketing of prescription drugs; or

b Type 2 drug manufacturing or marketing business licence: for the marketing of drugs other than prescription drugs.

iii Licence for manufacturing businesses

Further, a manufacturing business licence from the prefectural governor is necessary for each manufacturing category.

iv Manufacturing and marketing approvals (for each drug)

Approvals under the Pharmaceutical and Medical Device Act are required for individual formulations of drugs to market those drugs in Japan. Those approvals must be obtained from the Ministry of Health, Labour and Welfare (MHLW) prior to market launch by submitting data and documents to enable the MHLW to review product quality, and efficacy and safety of the drugs. In practice, the entire process of approval review of drugs approved by the MHLW, from review-related inspections and clinical trial consultations to review works, is undertaken by the Pharmaceuticals and Medical Devices Agency (PMDA), an independent administrative organisation established in 2004.

v Drug pricing system

The prices for drugs used in hospitals are determined by the government and indicated in the National Health Insurance (NHI) Price List, which is a list of drugs for which medical providers can be reimbursed under health insurance programmes.

In principle, entries of new drugs in the NHI Price List are made four times a year, after those drugs have been approved. Entries of generic drugs in the NHI Price List are made twice a year. The prices are reviewed on a regular basis in light of market trends.

vi Patent infringement litigation – Japanese court system

Patent infringement cases are first tried in district courts. Judgments of district courts can be appealed to a high court and then to the Supreme Court. There is no jury system in Japan.

At first instance, two district courts have exclusive jurisdiction over patent cases. Claims of patent infringement occurring in eastern Japan are subject to the exclusive jurisdiction of the Tokyo District Court, and those occurring in western Japan are subject to the exclusive jurisdiction of the Osaka District Court. The Tokyo District Court has four special divisions and the Osaka District Court has two special divisions for intellectual property matters.

Appeals to high courts from district courts in patent infringement cases come under the exclusive jurisdiction of the Intellectual Property High Court (IP High Court), which was established in April 2005 as a special high court dealing with IP matters only. The IP High Court has four general divisions and one special division, and each division consists of five judges who hear and decide the cases.

Appeals to the Supreme Court from the IP High Court are filed with the Supreme Court. Supreme Court cases are usually heard by one of the three petty benches, each composed of five justices.

vii Format of court proceedings

To commence patent infringement litigation, the plaintiff must file a complaint with the court. The complaint must contain a specific allegation of the fundamental and evidentiary facts. The plaintiff must attach certain basic materials to the complaint, such as copies of material documentary evidence.

Once the complaint and summons are served, the defendant must file an answer – copies of material documentary evidence attached – with the court before the first hearing date. After studying the briefs submitted by the plaintiff and the defendant, the judge holds hearings involving both litigation parties about once a month at a courtroom or a meeting room to determine the disputed issues.

Patent infringement proceedings are divided into two stages: the first stage, where the court examines whether the subject product infringes the patent; and the second stage, where the court examines the amount of damages, if the plaintiff seeks damages.

During the first stage, the specifications of the accused product are determined, the technical scope of the patent is ascertained and a comparison of the structural requirements of the patent with the accused product is carried out. In addition, the judge often sets a date at the final phase of the first stage for a technical presentation by both parties to have a better understanding of the technical issues.

If, after hearing arguments and reviewing evidence from the parties, the judge reaches a conclusion in favour of the defendant, the judge will not move the case to the second stage and can close the trial. If the judge reaches a conclusion in favour of the plaintiff, the judge will sometimes disclose the conclusion to the parties and make a suggestion for settlement. In that event, the judge typically sets several hearing dates for settlement, suggests appropriate terms and tries to persuade the parties to make concessions. If the parties do not reach a settlement, the judge can move the case to the second stage or render an interlocutory judgment to conclude the first phase. If the plaintiff seeks only injunction without compensation for damages, the judge will close the trial and render a judgment.

As there is no jury system in Japan, judges alone hear and review all arguments and evidence. At the district courts, cases are usually heard by a panel of three judges.

In Japan, it is not common for judges handling patent cases to have scientific or technical backgrounds. To have a better understanding of the technical issues, judges can obtain support from court researchers who are technical experts (e.g., examiners of the Japan Patent Office (JPO)). In addition, an expert commissioner system was introduced with the amendment of the Code of Civil Procedure in 2003 to make further use of expert knowledge.

viii Patent invalidation proceedings – two-track system (JPO and courts)

The Patent Act grants the JPO the authority to determine patent invalidity. To invalidate a patent, a person must either file a trial with the JPO for invalidation or file an opposition with the JPO for cancellation. The former is a more popular forum, while the latter needs to be filed within six months from the patent's publication.

In a patent infringement litigation, a court can also deny enforcement of the patent at issue if there are grounds for invalidation (invalidity defence) (Patent Act, Article 104-3). However, a court judgment on patent invalidity under Article 104-3 is only binding on the parties to the particular case, and the JPO still has the authority to declare the general invalidity of a patent through a trial for invalidation.

Although the existence of two different procedural tracks for patent invalidation actions raises the issue of how contradictions between the decisions of the courts and the JPO may be resolved, the IP High Court, which is the appellate court for both infringement litigation and invalidation trials, is expected to apply consistent interpretations.

III NEW DRUGS AND BIOLOGICS – APPROVAL, INCENTIVES AND RIGHTS

i Drugs

Manufacturing and marketing approvals

As described in Section II, approvals under the Pharmaceutical and Medical Device Act are required for individual formulations of drugs to market the drugs in Japan.

Marketing approvals require a review to determine whether the product in the application is suitable as a drug to be marketed by the marketing approval holder and a confirmation that the product has been manufactured in a plant that complies with Japan's good manufacturing practice. Approval items specified in the approval certificate are as follows:

a brand name;
b ingredients and quantities, or nature;
c manufacturing process;
d dosage and administration;
e indications;
f storage condition and shelf life;
g specifications and testing methods;
h manufacturing plant of the drug to be marketed; and
i manufacturing plant of the drug's ingredients.

Patent application

To obtain a patent right, a claimed invention needs to satisfy certain requirements as provided in the Patent Act, including:

a industrial applicability;
b novelty;
c inventive step; and
d description requirements (such as enablement, support and clarity requirements).

The JPO has published the Examination Guidelines for Patent and Utility Model (the Examination Guidelines) and the Examination Handbook for Patent and Utility Model (the Examination Handbook) on its website. In particular, Annex B, Chapter 3 of the Examination Handbook provides special considerations that are applicable to pharmaceutical inventions.

The novelty of a pharmaceutical invention is judged not only on the compound itself, but also on a new medicinal use based on the attributes of the compound. Therefore, even if the structure of a certain chemical compound is known to the public as of the filing date, a new patent can be granted for the same chemical compound if an inventor finds a new medicinal use.

The industrial applicability requirement is important as well in a pharmaceutical invention. A method of treating humans by surgery or therapy is not patentable in Japan because it does not meet the industrial applicability requirement. The Examination Guidelines also provide that diagnostic methods practised on the human body cannot be patented.

Patent term and extension

The patent term is in principle 20 years from the filing date of the application. However, if the patent cannot be implemented because of the need to obtain marketing approval under the Pharmaceutical and Medical Device Act, the patent term can be extended for a maximum of five years. The extension is for the period that the patented invention cannot be used, such as the period from the date of the start of clinical trials or the date of patent registration, whichever is later, until one day prior to the date on which the patentee receives approval for the drug.

Patentees who request an extension of the patent term must apply for the extension of registration to the JPO before the patent term expires and within three months of the date of receipt of drug approval. If it is anticipated that it will not be possible to obtain approval by six months and one day prior to the expiration date of the patent, a document showing necessary information must be submitted to the JPO.

Patent infringement

Literal infringement

A patentee has an exclusive right to work the patented invention commercially, and the unauthorised commercial working by a third party of a claimed invention constitutes patent infringement. Under the Patent Act, 'working' means the following acts (Patent Act, Article 2(3)):

a in the case of an invention of a product: the production, use, assignment, lease, export, import, or offer for assignment or lease of the product;

b in the case of an invention of a process: the use of the process; and

c in the case of an invention of a process for manufacturing a product: the use, assignment, lease, export, import, or offer for assignment or lease of the product manufactured by the process, in addition to the use of the process

The protection of patent rights is limited to the technical scope of the claimed invention. The technical scope of a patented invention must be determined based on the patent claims (Patent Act, Article 70(1)). The meaning of each term of the patent claim must be interpreted in consideration of the statements in the specifications and the drawings (Patent Act, Article 70(2)). Further, statements in the abstract must not be taken into consideration (Patent Act, Article 70(3)). These provisions confirm that the determination of the technical scope cannot deviate from the statements of the patent claims. In addition to the primary sources described above, there are several other supplemental sources used to interpret terms in claims, which have been confirmed in many court decisions, such as prior art, patent prosecution history and dictionaries.

Doctrine of equivalents

In the *Ball Spline Shaft Patent* case (24 February 1998), the Supreme Court held that the scope of patent protection can be extended beyond the literal wording of the claim to cover a technological idea that can be regarded as equivalent, even if the product in question does not literally infringe the patent (doctrine of equivalents). The doctrine of equivalents will be triggered if all of the following five requirements are fulfilled:

a the missing element is not an essential part of the patented invention;

b the purpose of the invention can be achieved and the same effect can be obtained even if this missing element is replaced;

c that replacement could be easily conceived by a person skilled in the art at the time of infringement;

d the accused product was not identical to a publicly known technology at the time of filing, or could not be easily conceived by a person skilled in the art at the time of filing; and

e there are no special circumstances relating to the accused product, such as where the accused product was intentionally excluded from the claims by the patentee during the filing procedure.

ii Generic and follow-on pharmaceuticals

Approval of generic drugs

A generic drug is a drug with the same active pharmaceutical ingredient, dosage form, strength, quality, indication, effect, direction and dose as the original drug. The original drugs are given a certain re-examination period at the time of approval. The applicant can apply for generic drugs after the re-examination period of the original drugs.

The Office of Generic Drugs, which forms part of the PMDA, is responsible for the approval review of generic drugs in Japan. The PMDA reviews the equivalence of generic and original drugs from the viewpoint of quality, efficacy and safety, based on submissions of the generic drug applicants. Whereas documents regarding the quality, pharmacology, pharmacokinetics, toxicity and clinical studies are required at the time of the original (new) drug application, only documents regarding specifications, test methods, accelerated testing and bioequivalence studies are required at the time of the generic drug application.

In principle, new generic drugs are approved and then entered into the NHI Price List twice a year.

Patent linkage

There is no explicit statutory patent linkage provision in the Patent Act or the Pharmaceutical and Medical Device Act. However, the authorities (i.e., the MHLW and the PDMA) consider the existence of patents in an unofficial manner in the review process of generic drug applications.

According to relevant administrative notices issued by the MHLW, generic drugs will not be approved until the substance patent or the application patent of the original drug expires and production of the active ingredient becomes possible. If only some of the indications or dosage and administration are patented, the generic drug application may be approved so long as it is marked with other indications, or dosage and administration. The formulation patent or the manufacturing method patent does not generally block approval of a generic drug.

Re-examination system

In Japan, the re-examination system protects original drugs in a way that is similar to the data exclusivity and the marketing exclusivity systems in the EU and the US. The re-examination system is aimed at the reconfirmation of the clinical usefulness of drugs by collecting information on the efficacy and safety of the drug during a specified period after approval.

During the re-examination period, the marketing approval holder must perform a post-marketing study of the new drug and report the results of the study to the MHLW. In addition, during the re-examination period, a generic drug applicant cannot obtain a marketing approval without filing clinical data that is more extensive than what was attached to the application for the original drug.

The re-examination period for each new drug is determined by the category of the product as follows:

a 10 years after the date of approval:
- orphan drugs;

b eight years after the date of approval:
- drugs containing new active ingredients;

c six years after the date of approval: and
- drugs with new routes of administration;

d four to six years after the date of approval:
- new combination drugs;
- drugs with new indications; and
- drugs with new dosages.

If an additional indication is obtained during the re-examination period, the re-examination period for the additional indication will be as follows:

a if the existing indication is a usual indication:
- four years or the residual period of the re-examination period for the existing indication, whichever is longer, if the additional indication is a usual indication;
- 10 years, if the additional indication is an indication of an orphan drug; and

b if the existing indication is an indication of an orphan drug:
- five years and 10 months, if the additional indication is a usual indication; and
- 10 years, if the additional indication is an indication of an orphan drug.

iii Biologics and biosimilars

A biosimilar product is a biotechnological drug product developed to be comparable to an original biotechnology-derived product (reference product). A biosimilar product can generally be developed on the basis of data that demonstrates the comparability between the biosimilar product and the reference product with respect to quality, safety and efficacy, or other relevant data.

For biological products, it is difficult to prove the equivalence of active ingredients with those of existing drugs, unlike chemically synthesised drugs. Therefore, the MHLW issued a 'Guideline for the quality, safety and efficacy assurance of biosimilar products' in 2009 to handle the challenge of regulating biosimilar products. Sponsors of biosimilar products are required to establish their own manufacturing process, to clarify the quality attributes, and to demonstrate the high similarity of these attributes to the reference products. In addition, the data of both clinical and non-clinical studies are required to demonstrate the biosimilar comparability.

In Japan, there is no special patent linkage mechanism applicable to biosimilar products, unlike patent dance pursuant to the BPCIA in the US.

IV PATENT LINKAGE

As described in Section III.ii, the Japanese patent linkage mechanism is unique from those embodied in the Hatch-Waxman Act in the US. There is no explicit statutory patent linkage provision in the Patent Act or the Pharmaceutical and Medical Device Act, but the authorities (i.e., the MHLW and the PDMA) consider the existence of patents in an unofficial manner in the review process of generic drug application. According to relevant administrative notices issued by the MHLW, generic drugs will not be approved until the substance patent or the application patent expires and production of the active ingredient becomes possible.

In addition, as described in Section III.i, the patent term extension is linked to marketing approval. If the patent cannot be implemented because of the need to obtain marketing approval under the Pharmaceutical and Medical Device Act, the patent term can be extended for a maximum of five years.

Unlike the US and other jurisdictions, Japan has no prelaunch patent litigation process prior to a generic drug or biosimilar product launch. Although there is an ex ante coordination mechanism where both original and generic drugs manufacturers should communicate to resolve potential patent issues and then report the results to the MHLW before the entry of a generic drug in the NHI Price List is made, this mechanism does not work effectively in most cases. Therefore, invalidation proceedings before the JPO are generally the forum of choice to challenge patents.

V COMPETITION ENFORCERS

The pharmaceutical industry is, similar to other industries, subject to the Anti-Monopoly Act, which prohibits anticompetitive activities such as private monopolisations, unreasonable restraints of trade and unfair trade practices. The Japan Fair Trade Commission (JFTC) has regulatory power to conduct investigations and issue orders under the Anti-Monopoly Act.

The JFTC has established various guidelines as well. For example, the Guidelines for the Use of Intellectual Property under the Anti-Monopoly Act are often referenced in the context of how the Anti-Monopoly Act applies to licensing transactions.

The Guidelines stipulate that restrictions, such as those against granting a licence, can be deemed as private monopolisation in the case of deviation from the purpose of intellectual property systems.

As for patent infringement litigation, there are to date no statutory laws or court decisions ruling that a violation of the Anti-Monopoly Act by a patentee constitutes a defence against patent infringement. However, under the abuse of rights doctrine, a court can deny enforcement of a patent if this enforcement would result in a serious violation of the Anti-monopoly Act. For example, the IP High Court applied the abuse of rights doctrine in a decision of 16 May 2014 and denied injunctive relief where the patentee had issued a fair, reasonable and non-discriminatory (FRAND) declaration, and regarding the claim for damages, only granted an amount equivalent to a royalty under this FRAND declaration.

VI ANTICOMPETITIVE BEHAVIOUR

In Japan, there are no competition law cases related to intellectual property and involving originators and generics manufacturers, such as reverse payments (pay-for-delay settlements) or product hopping. This is partly because there is no active retail price competition in the market and Japan's patent linkage mechanisms are totally different from those in the US.

However, the government has been strongly promoting the use of generic drugs, and the JFTC has a strong interest in how the Anti-Monopoly Act should be applied to reverse payments and other issues in the pharmaceutical industry, as evidenced by its publication of a report titled 'Competition and Research and Development Incentives in the Pharmaceutical Market – Through Examinations of the Impact of the Entry of Generic Drugs on the Market' in October 2015. If the share of generic drugs continues to grow and the pressure of competition from generic drugs increases, incentives for engaging in reverse payments may increase and we need to keep closely monitoring the future trend of competition laws in the pharmaceutical field.

VII OUTLOOK AND CONCLUSIONS

Patent disputes and transactions play a key role in the pharmaceutical industry, and there are various unique mechanisms such as Japanese patent linkage and re-examination mechanisms, which sometimes draw criticisms partly due to the lack of international harmonisation. Although there are no significant proposed developments in legislature at this stage, we should continuously monitor the trends in patent invalidity, the scope of the doctrine of equivalents, how the patent linkage works in the context of biosimilar products and development of competition law enforcements.

Appendix 1

ABOUT THE AUTHORS

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Mori Hamada & Matsumoto

The principal practice areas of Atsushi Okada are intellectual property, information technology, pharmaceutical regulations, data protection and cybersecurity. He was educated at the University of Tokyo and Harvard Law School. He serves as a member of the committee (and the chair of a working group) on AI and data contract guidelines for the Japanese government (METI). He is co-head of the firm's healthcare, fintech and robotics practices. His extensive writings on pharmaceutical laws include 'Q&A: Digital Health and Law'. He is recognised as one of the leading individuals in *The Legal 500: Asia Pacific* (2019–2020), *Best Lawyers in Japan* (2019–2020), *Asialaw Leading Lawyers* (2020), *IAM Patent 1000* (2020) and Nikkei's 'Most Successful Lawyers in 2019'.

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