AMT/NEWSLETTER

Competition

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Contents

1. The intersection between competition law and intellectual property law in the pharmaceutical industry: Text of a decision imposing a fine on Teva (European Commission)

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1.1. Introduction

The development of new medicines requires enormous investments of time and money. For instance, according to a research paper published by the Office of Pharmaceutical Industry Research[1], a period of over 10 years and billions of yen in investment are required to create a

1 A research institute established by the Japan Pharmaceutical Manufacturers Association, a group composed of pharmaceutical companies.
https://www.jpma.or.jp/english/index.html

new pharmaceutical product[2].

These costs have a significant impact on pharmaceutical companies that lead the drug development process, driving them to recover their investment through sales of these newly developed medicines. Accordingly, many pharmaceutical companies have attempted to establish a system to exclusively supply new pharmaceutical products for as long as possible, utilizing intellectual property rights, such as patent rights. In particular, a sudden drop in drug prices after the launch of generic products, known as a "patent cliff," is often observed in the sector, and it has been of significant importance for originator pharmaceutical companies to rely on their intellectual property, aiming to avoid or delay such a situation[3].

However, these attempts have been viewed as violating competition law (hereinafter the use of which expression refers to Japan's *Act on Prohibition of Private Monopolization and Maintenance of Fair Trade* and to equivalent regulations in other jurisdictions) in terms of anticompetitive effects, even if such conduct is permitted under intellectual property laws. This raises the issue of how competition law and intellectual property law intersect.

This article first outlines the circumstances underlying so-called reverse payment settlements, from the viewpoints of competition law, patent law, and pharmaceutical regulation. These settlements involve a patent holder paying an alleged infringer to settle a pharmaceutical patent infringement case and exemplifies the interplay between competition law and intellectual property law within the pharmaceutical industry. This article then introduces a recent case in Europe involving this interplay: the European Commission's decision dated October 31, 2024 (AT.40588 – Teva Copaxone).

1.2. Reverse payment settlements

There are cases in which an originator pharmaceutical company files a lawsuit against a generic drug manufacturer alleging that the production or sale of a generic drug infringes its patents. In such patent disputes between originators and generic drug manufacturers, the originator (patent holder) sometimes offers a settlement, providing financial benefits to the generic drug manufacturer in exchange for delaying the launch of the generic drug, which are called reverse payments or pay-for-delay settlements (hereinafter collectively referred to as "reverse payment

2 TAKAHASHI, Y et al. (2024) The overview of the development of medicines: The development period, the possibility of success and the development cost. Japan Pharmaceutical Manufacturers Association Research Paper Series, Nos. 82, 60, and 70, etc. https://www.jpma.or.jp/opir/research/rs_082/es9fc600000002xp-att/RESEARCH_PAPER_SERIES_No82.pdf (in Japanese)

3 The prices of new generic drugs in Japan are designated, in principle, at 50% of the prices of relevant originator drugs under the standard drug prices decided by the Ministry of Health, Labour and Welfare (Amendment on the standard drug prices, February 19, 2025). https://www.jpma.or.jp/opir/research/rs_082/es9fc600000002xp-att/RESEARCH_PAPER_SERIES_No82.pdf (in Japanese)

settlements")[4].

Although reverse payment settlements are a form of agreement concerning patent infringement disputes, there is a growing number of court cases in several jurisdictions, such as the United States, the European Union, and Korea, that have found this conduct to violate competition law. In particular, the United States is considered to be in a situation that facilitates reverse payment settlements due to a system called the Abbreviated New Drug Application ("ANDA") under the Hatch-Waxman Act. Therefore, the following paragraphs provide an overview of the reasons why such settlements have been prevalent in the United States.

ANDA enables the approval of generic drugs through a simplified process. Under this system, a generic drug manufacturer can complete the application procedures for the approval of new drugs by asserting that patents covering the originator drug are invalid or that the production and sale of the generic drug do not infringe the originator's patents (a process referred to as "Paragraph IV certification"). In addition, the generic drug manufacturer can exclusively market the generic product for 180 days if it is the first to obtain such approval among generic drug manufacturers because other generic drug manufacturers may not receive approval during that period.

When the generic drug manufacturer files an application based on a Paragraph IV certification, it must notify the patent holder (originator) of its application. Once notified, the patent holder may file a patent infringement lawsuit ("ANDA litigation") against it within 45 days of receiving the notification. If the patent holder files a lawsuit within this period, the approval process for the generic drug is suspended for 30 months, during which time the generic drug manufacturer may not receive approval unless a court finds that there is no infringement or that the patent is invalid. The consequences of ANDA can be summarized in the following table.

For Generic Drug Manufacturers	For the Originators
Generic drug manufacturers can benefit from ANDA. ● ANDA simplifies the approval process for sales of generic drugs. ● If they apply first and win the ANDA litigation, they will be granted 180 days of exclusivity to sell their generic drugs. ● If they lose it, they may not be liable to compensate the originator (patent holder) because the initiation of the ANDA litigation suspends the approval procedure for 30 months, during which their product will not	**Originators can benefit from initiating ANDA litigation.** ● The initiation of ANDA litigation suspends the approval process for 30 months. **Originators can benefit from reverse payment.** ● If originators lose the ANDA litigation, especially if the patent is revoked, they will not be able to monopolize sales of the originator drug due to the entry of the generic drug. ● If they terminate the ANDA litigation before

4 KURITA, M. (2015) The abusive exercise of intellectual property rights and competition law: Settlements with reverse payments for pharmaceutical patents. Chiba University Hogaku Ronshu, Vol. 30(1)(2), 530.

be launched. Furthermore, preliminary investment in production is limited. **Generic drug manufacturers can benefit from accepting reverse payment.** ● It may be more reasonable economically to receive the reverse payment than to launch the generic drug and compete with the originator in the market. ***Therefore, despite the risk of ANDA litigation, an ANDA application is beneficial for generic drug companies.**	the final judgment by the settlement, they will maintain the price of the originator drug, even if they distribute the profit obtained from exclusive sales. ***Therefore, it will be beneficial to initiate ANDA litigation and enter into reverse payment settlements.**

As described above, it can be said that generic drug manufacturers have an incentive to use ANDA and accept reverse payment, and originator pharmaceutical companies have an incentive to file an ANDA litigation and make a reverse payment when an ANDA application is made. Moreover, originator pharmaceutical companies have an incentive to terminate ANDA litigation before a final judgment, even by making a reverse payment, to avoid an outcome in which they lose the ANDA litigation, in particular a finding that the patent is invalid. In addition, in the United States, which does not have an official drug price designation system, it is likely that the prices of originator drugs may fall significantly, which may strengthen the incentive to make a reverse payment.

Although there is no equivalent system to ANDA in Europe, originator pharmaceutical companies may file a patent infringement lawsuit against generic drug companies, and they may have an incentive to make reverse payments to delay the entry of generic drug companies while avoiding the risk of losing the patent infringement litigation. On the other hand, generic drug manufacturers may also have economic rationales for accepting reverse payments in that they can gain monetary benefits while evading the competition with originators.

A reverse payment is a kind of settlement between the patent holder (the originator pharmaceutical company) and the alleged infringer (the generic drug manufacturer). Delaying the entry of generic drug manufacturers on the basis of patent rights appears to be a legitimate enforcement of the patent right as an action that falls within the scope of the patent. On the other hand, it is also an agreement to delay the market entry between competitors — the originator pharmaceutical company and the generic drug manufacturers — and, from this perspective, this act can be viewed as an anticompetitive practice.

There are several court cases finding that reverse payments violate competition law in the United States and Europe. Firstly, in the United States, the Supreme Court, in FTC v. Actavis, held that a reverse payment violates competition law in cases where the amount of the payment is large and cannot be justified under the rule of reason. The judgments by the Court of Justice of the European Union in Generics (UK) v European Commission (Case C-588/16 P) and Lundbeck v.

European Commission (Case C-591/16 P)[5] made a decision similar to this ruling[6]. They found that a settlement in which the payment by the originator pharmaceutical company functions as an incentive for the generic drug manufacturer not to enter the market, and there are no possible reasons for such payment other than avoiding competition, may infringe competition law.

1.3. Overview of the European Commission's decision dated October 31, 2024 (AT.40588 - Teva Copaxone)

A recent case in which the intersection between competition law and intellectual property law in the pharmaceutical industry raised an issue is the European Commission's decision dated October 31, 2024, AT.40588 - Teva Copaxone (hereinafter the "Teva Decision"). In that decision, the Commission imposed a fine on Teva for violating Article 102 of the Treaty on the Functioning of the European Union ("TFEU"). Teva's divisional patent application strategy was found to constitute a violation of competition law. It should be noted that the Teva Decision found moreover that Teva's disparagement campaign infringed competition law, however, this article does not address that finding.

An outline of the case is as follows. Teva is a pharmaceutical company that markets Copaxone, a medicine for multiple sclerosis, and holds a number of patents covering glatiramer acetate, the active ingredient of Copaxone. Teva made multiple divisional patent applications on a staggered timeline, shortly before the expiration of the relevant patents. When the likelihood increased that the European Patent Office ("EPO") would issue a decision invalidating those patents in opposition proceedings initiated by generic drug manufacturers, Teva strategically withdrew the patents to avoid such decisions, a practice referred to as the "Divisional Game" (hereinafter "Teva's divisional patent strategy"). By virtue of these acts, Teva created a situation in which the validity of patents was uncertain unless it withdrew all the patents pertaining to its divisional applications, and then prolonged that situation. The European Commission held that this act violated Article 102 of TFEU and imposed a fine on Teva. Teva appealed to the Court of Justice of the European Union (Case T-19/25[7]).

The essence of the European Commission's decision relating to Teva's divisional patent strategy is as follows. First of all, as a prerequisite for applying Article 102 of TFEU, Teva held a dominant position (or dominance) in the market of glatiramer acetate in European countries. Since the enforcement of intellectual property rights can be limited by competition law, if Teva's act hindered its competitors' entry into the market and did not serve as a legitimate reason, it will have violated competition law. It was found that Teva's act hindered the entry of competitors' medicines with an anti-competitive effect, and no grounds to justify its act were discerned. Therefore, it did not constitute competition on the merits and was not a competitive act.

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5 https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=celex:62016CJ0591

6 MARIYAMA, Naoko. (2021) Reverse payment patent settlement agreements under the Antimonopoly Act. Patent Studies, Nos.72, 52.

7 https://eur-lex.europa.eu/eli/C/2025/1126/oj

The European Commission's decision is important because it viewed Teva's conduct of filing several staggered applications of divisional patents and strategically withdrawing the patents as a single and continuous infringement. Teva's act is composed of two aspects: (i) filing divisional patent applications that include overlapping content in a staggered manner to prolong the period during which patents with overlapping content can be exerted, even if the patents are withdrawn[8]; and (ii) withdrawing patents to avoid the invalidation of a series of patents relating to applications covering overlapping contents in the case that patents are about to be invalidated as a result of opposition and the EPO's examination. It can be said that Teva artificially created a situation in which the validity of patents pertaining to divisional applications was uncertain by the combination of these two types of conduct.

The European Commission held that Teva's divisional patent strategy has an anti-competitive effect by hindering market entry, since it enabled Teva to enforce its patent rights, thereby deviating from the purpose of the patent system and artificially prolonging the examination. The European Commission did not accept the justification asserted by Teva.

1.4. Does the abuse of divisional applications give rise to concerns under Japan's *Act on Prohibition of Private Monopolization and Maintenance of Fair Trade*?

The European Commission regarded Teva's divisional patent strategy as misuse of divisional patents. The divisional application itself is a generally accepted mechanism, as specified in Article 44, Section 1 of Japan's *Patent Act*.

Would an act similar to Teva's divisional patent strategy raise issues under Japan's *Act on Prohibition of Private Monopolization and Maintenance of Fair Trade* (hereinafter "Japan's Antimonopoly Act")? In conclusion, it appears unlikely that abusive divisional applications like Teva's divisional patent strategy will occur in Japan, and therefore it is unlikely that issues under Japan's Antimonopoly Act will arise. This can be attributed to differences in the patent systems in Japan and Europe.

First of all, it can be considered that Japan's Patent Act excludes double patenting in a relatively strict way. Article 39, Section 1 of Japan's Patent Act states, "If two or more patent applications claiming identical inventions are filed on different dates, only the applicant that filed the patent application on the earliest date may be granted a patent for the invention claimed." This provision articulates that "identical inventions" cannot be patented. Regarding the definition of "identical," the examination guidelines of Japan's Patent Office ("JPO") describe that this includes cases of sharing substantial identity (Part 3, Chapter 4, Section 3.2.1 of the Examination Guidelines for Patent and Utility Model in Japan).

By contrast, the European Patent Convention ("EPC") does not articulate a rule prohibiting double

8 The Teva Decision pointed out that Teva recognized that its patents pertaining to the divisional applications had weaknesses in terms of their validity (para. 1069).

patenting. Instead, the EPO's examination guidelines reflecting EPO's decision dated June 22, 2021 (G0004/19)[9], merely indicate that a European patent application can be refused if it claims the same subject-matter. No specific standards defining the "same subject-matter" are provided in these guidelines.

Teva's divisional patent strategy includes filing a divisional application with overlapping content. The permissibility of this application under the JPO's examination practice regarding divisional patents need not be considered here[10]. However, in any case, the Teva Decision did not find a violation of competition law on the grounds that Teva's act (i) constituted a prohibited double patent application (para. 1095). Instead, its concern was that Teva filed, in a staggered manner, overlapping divisional applications that carry the risk of being invalidated for the same reason, and thereby shifted the timing of patent grants, resulting in opposition proceedings, in which similar invalidation reasons could be given, taking place consecutively rather than in parallel.
In the JPO's examination, it appears possible that the examination for opposition to a granted patent takes place consecutively, prolonging the period during which the validity of patent rights is uncertain, under the circumstance in which several patents can be enforced, if applicants obtain several divisional patents at different times by filing applications on a staggered schedule.

Rather, for comparison, attention should be paid to the differences between Europe and Japan regarding the opposition proceedings for a patent (proceedings initiated by third parties raising doubts about a patent's validity).

In Europe, unlike Japan, a patent holder may be able to prolong a situation in which the validity of patents is uncertain if opposition proceedings are initiated.

Article 113, Section (2) of the EPC states that the EPO shall examine the patent only in the text submitted to it or agreed to by the proprietor of the patent. This also applies to the opposition proceedings. In the opposition proceedings for a patent, if the patentee withdraws approval for documents regarding the patent, such as the claims or the description of the patent, the patent must be revoked (Part D, Chapter VI, 2.2 Revocation of the patent of the EPO's guidelines for examination). In this case, the EPO can no longer conduct an examination of the patent, and the examination is terminated. Therefore, the examination on the validity of the patent comes to an end without reaching a binding conclusion. In other words, a patentee can control, to some extent, when the opposition proceedings are terminated.

In contrast, in Japan, the examinations for the opposition to a granted patent are held under the inquisitorial system (Article 113 and Article 120-2, Section 1 of Japan's Patent Act), and the examination of evidence can be conducted on the JPO's own initiative (Article 120 and Article 150, Section 1 of Japan's Patent Act). Unlike the opposition proceedings at the EPO, a patent

9 https://www.epo.org/en/legal/guidelines-epc/2025/g_iv_5_4.html

10 If JPO were to admit such a divisional application, an act such as Teva's act (i), above, might not be impossible to envisage in Japan. However, even if that were the case, the possibility of Teva's act (ii), above, would still be at issue.

holder cannot terminate the proceedings at its own discretion by withdrawing its approval of the text[11].

Once the opposition proceedings were initiated, Teva revoked its patents by withdrawing its approval of the patent texts, and it prolonged the examination by withdrawing the approval as late as possible[12]. As set out above, since Teva's act (ii) relied on the opposition proceedings at the EPO, the same conduct may not be possible in Japan with its different system.

As described above, it is conceivable that a situation similar to Teva's act (i) might arise. However, it may be difficult to reproduce Teva's act (ii) in Japan. Therefore, it would be implausible to suggest that a similar issue might arise in Japan, so long as we assume a context in which Teva's acts (i) and (ii) in the Teva Decision are evaluated as integrated conduct[13].

Regarding the question of whether the abusive use of divisional applications violates Japan's Antimonopoly Act, the interplay between the Patent Act and Japan's Antimonopoly Act must be considered, since the divisional application is a system governed by the Patent Act.
Article 21 of Japan's Antimonopoly Act states that "The provisions of this Act do not apply to acts found to constitute an exercise of rights under the Copyright Act, Patent Act, Utility Model Act, Design Act, or Trademark Act." Regarding the relevant authority's interpretation of this provision, guidelines of Japan's Fair Trade Commission ("Guidelines for the Use of Intellectual Property under the Antimonopoly Act"[14]) state that Japan's Antimonopoly Act applies to any act that is not considered to be an exercise of rights, and to any act that is not recognized substantially as the exercise of rights even if it may appear to be so.

A divisional application does not appear to fall within the "exercise of rights" because it is an act of applying for a patent and, thus, is a prerequisite to the acquiring of rights. However, the exercise of rights and divisional applications are similar acts in that both involve conduct that uses the patent system. In addition, considering that the purpose of this provision is to apply Japan's Antimonopoly Act to conduct that departs from the purpose of the patent system, Japan's

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11 In opposition proceedings at the JPO, proceedings are terminated in cases where the patent is treated as never having existed, such as cases where the patent is invalidated in an invalidation trial or where all claims are deleted by a request for correction (JPO Trial Handbook 67-11). Accordingly, even before the JPO, a patentee can terminate opposition proceedings by filing a correction by means of which all claims are deleted without any determination as to the patent's validity. However, as for the case in which a patent is invalidated in an invalidation trial, such a trial needs to be filed for in the first place. Moreover, the period during which a request for correction may be filed is prescribed by statute (Article 120-5 of the Patent Act). Therefore, it is difficult to imagine that a situation where a patentee might strategically time the termination of proceedings in order to prolong the proceedings, as described in the Teva decision, is likely to arise.

12 Please refer to paragraphs 61 to 67 in the Teva Decision.

13 Considering the Japanese practice regarding double patents, it is unlikely that an act equivalent to act (i) could be conducted in Japan.

14 https://www.jftc.go.jp/dk/guideline/unyoukijun/chitekizaisan.html (in Japanese)

Antimonopoly Act is applicable to abusive divisional applications that go beyond the purpose of the patent system.

1.5. Conclusion

As discussed above, although it is considered unlikely that a similar case to the one at issue in the Teva Decision would arise in Japan, it is noteworthy that the decision held that a divisional application, which is an ordinary patent practice, may violate competition law. Furthermore, the intersection between competition law and intellectual property law may provide fertile ground for new issues in the pharmaceutical industry, and it is expected that there will be other cases in which such an intersection serves as a springboard for new issues in the future. In the utilization of their intellectual property rights, business operators in this industry will need to constantly keep in mind whether such utilization may give rise to issues from the viewpoint of competition law.

2. Recent Publications

- *Lexology Panoramic - Intellectual Property & Antitrust 2026 (Japan Chapter)*
  Dec 2025 (Yusuke Nakano Atsushi Yamada Ryo Murakami) Law Business Research Ltd.
  Link here

- *GCR - Market Review Merger Control 2025 – Japan*
  Nov 2025 (Yusuke Nakano Vassili Moussis Kiyoko Yagami) Law Business Research Ltd.
  Link here

- *Competition-IP Interface: Transactions, Collaboration, and Unilateral Conduct (Japan)*
  Nov 2025 (Vassili Moussis Ryoma Kojima Yuri Shindo) Thomson Reuters
  Link here

- *Abuse of Dominance in Japan*
  Nov 2025 (Vassili Moussis Yoshiharu Usuki Yuri Shindo) Thomson Reuters
  Link here

- *Competition Law in Digital Markets (Japan)*
  Nov 2025 (Vassili Moussis Ryoma Kojima Yuri Shindo) Thomson Reuters
  Link here

- *Merger Remedies Guide - Edition 6 (Japan chapter)*
  Oct 2025 (Vassili Moussis Yoshiharu Usuki Kiyoko Yagami) Law Business Research Ltd
  Link here

3. News (Achievements)

In the latest rankings of an internationally recognized rating medium, our firm was ranked the highest (Band 1 / Tier 1) in a number of practice areas, including competition law, as in the previous year. In the Competition/Antitrust category of Chambers Asia-Pacific 2026 (published December 2025), our firm was ranked Band 1 in the firm category, and six of our lawyers were ranked in the individual listings — the most of any Japanese law firm.
Our other recent achievements are as follows:

- The Legal 500 Asia Pacific 2026
  Yusuke Nakano Vassili Moussis Etsuko Hara
  Link here

- Chambers Asia-Pacific 2026
  Hideto Ishida Yusuke Nakano Atsushi Yamada Vassili Moussis Etsuko Hara Takeshi Suzuki
  Link here

- The Nikkei " Top-performing Lawyer " in 2025
  Yusuke Nakano Kiyoko Yagami

- asialaw 2025
  Yusuke Nakano
  Link here

- Lexology Index: Japan 2025
  Hideto Ishida Shigeyoshi Ezaki Yusuke Nakano Atsushi Yamada Vassili Moussis Etsuko Hara Takeshi Suzuki Yoshiharu Usuki Kiyoko Yagami
  Link here

- The A-List: Japan's Top 100 Lawyers
  Yusuke Nakano
  Link here

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