AMERICAN BAR ASSOCIATION
Antitrust Law Section

Intellectual Property Committee
tidBITS
Special Edition

MAY 19, 2022

Why the "first penguin" of Pay for Delay has not come in Japan
Anatomy of a Japan Paradox

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The views expressed in this article are the views of the author alone.

Summary
The reasons why it is difficult for actual reverse payments cases to arise in Japan include a low invalidation rate of the substance patent, the stable supply obligation after the launch of generic drugs, differences in Abbreviated New Drug Application (ANDA) under the Hatch-Waxman Act, and regulation on drug prices. However, the reasons why actual reverse payments cases have not arisen in Japan cannot be explained solely by system differences. Japanese companies' attitudes towards regulatory authority and their desire to avoid becoming the "first penguin"[2] may be the actual reason.

1. Introduction

A "reverse payment" is an agreement during the settlement of a patent infringement suit filed by the brand-name companies against the generic companies, where the brand-name companies make payments to the generic companies to delay the launch of the generic drugs.[3] In an ordinary settlement, the alleged infringer pays a settlement to the patentee, whereas in the above case the payment is done in reverse. It is also called "Pay for Delay" because it has the effect of delaying the market entry of generic drugs. Reverse payments may cause competition law

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[2] The "first penguin" is a commonly used phrase in Japan to depict a brave penguin who jumps into a dangerous sea at first among the group members.

[3] As described later reverse payments are not limited to the settlement in patent infringement lawsuits because it is theoretically possible to settle an invalidation trial for a substance patent or use patent by a reverse payment.

concerns when considered to be anticompetitive practices (cartels), done in order to delay the market entry of generic drugs.

In the United States, a number of judicial precedents on reverse payment have been issued,[4] including the Supreme Court decision in *FTC v. Actavis, Inc.*[5] in 2013. In Europe, following the decision of the European Commission and the judgment of the General Court,[6] the European Court of Justice (ECJ), the supreme court in matters of European Union (EU) law, rendered a judgement on January 30, 2020.[7] However, in Japan, no competition law cases have arose where reverse payments became a direct issue.[8] What caused this difference? This article considers why it is difficult for actual reverse payments cases to arise in Japan and the reason actual reverse payments cases have not arisen in Japan so far.[9]

2. The Reasons Why It is Difficult for Actual Reverse Payments Cases to Arise in Japan

(1) Former Concept

The report "Competition and Research and Development Incentives in the Pharmaceutical Market —Through Examinations of the Impact of the Entry of Generic Drugs on the Market" (Report), by Competition Policy Research Center (CPRC), contains interviews concerning the reasons why it is difficult for actual reverse payments cases to arise in Japan: (i) if the substance patent and use patent of brand-name drugs remains valid, approval for the manufacture and sale of generic drugs will not be granted by the patent linkage system in Japan; (ii) due to the drug price system, drug price reduction by a generic's entry is not severe and the share of the brand-

[4] Naoko Mariyama, *Beikoku hantorasutohō ni okeru ribāsupeimento no kisei [Antitrust Law Analysis of Reverse Payment Settlements]*, 68(1) THE DOSHISHA HOGAKU [THE DOSHISHA LAW REVIEW], 361 (2016).

[5] *FTC v. Actavis, Inc.*, 570 U.S. 136 (2013).

[6] Naoko Mariyama, *EU kyōsōhō ni okeru ribāsupeimento no kisei [Pay-for-Delay Settlements in EU Competition Law]*, 71(1) THE DOSHISHA HOGAKU [THE DOSHISHA LAW REVIEW], 491 (2019).

[7] Case C-307/18—*Generics (UK) Ltd. and Others v. Competition and Markets Authority* (Jan. 30, 2020) (summary at 2020 O.J. (C 137) 6), *available at* https://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:62018CJ0307&from=EN.

[8] As an example of a Japanese company was involved in reverse payments outside of Japan, Teva, Endo, and Teikoku settled with the State of California in the Pay for Delay lawsuit in July 2019. STATE OF CALIFORNIA DEPARTMENT OF JUSTICE, *Attorney General Becerra Secures Nearly $70 Million against Several Drug Companies for Delaying Competition and Increasing Drug Prices* (July 29, 2019), *available at* https://oag.ca.gov/news/press-releases/attorney-general-becerra-secures-nearly-70-million-against-several-drug.

[9] At the 2019 AIPPI World Congress "Pharma Session 1: Wait! Pay for Delay" held in London on September 16, 2019, I gave a lecture on Pay for Delay and participated in a panel discussion with a U.S. patent attorney, a European Commission officer, and a Belgian competition law attorney (AIPPI CONGRESS NEWS, Sep. 17, 2019). While panelists from the United States and Europe introduced a large number of judicial precedents, I introduced the reasons why it is difficult for actual reverse payment cases to arise and why such cases have not arisen so far in Japan because there are no judicial precedents to be introduced from Japan. The European Commission officer and the Belgian competition law attorney have repeatedly rivaled each other in court during proceedings relating to reverse payments.

It was impressive to see the European Commission officer appealing to the audience with a strong sense of responsibility to think carefully about the huge amount of money given and received in reverse payments.

name drugs will not be reduced; and (iii) patent infringement lawsuits occur only after the launch of generic drugs.[10]

Professor Hiroyuki Odagiri, former Japan Fair Trade Commission (JFTC) Commissioner, gave the following reasons why it is difficult for actual reverse payments cases to arise in Japan: (1) ANDA's[11] 180-day exclusivity for a first filer does not exist; (2) even if a brand-name company is successful in preventing a first filer's entry, it cannot prevent the entry of others; (3) drug price reduction by a generic's entry is not as severe as it is in the United States; and (4) unlike ANDA's paragraph IV filing, patent linkage requires no infringement of the brand-name company's substance patent or use patent.[12]

The differences in ANDA under the Hatch-Waxman Act (Reason (1) and (2) above) and regulation on drug prices (Reason (3) above) could constitute reasons why it is difficult for

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[10] COMPETITION POLICY RESEARCH CENTER, JAPAN FAIR TRADE COMMISSION, IYAKUHINSIJŌ NI OKERU KYŌSŌ TO KENKYŪKAIHATSU INSENTIBU: JENERIKKU IYAKUHIN NO SANNYŪ GA SIJŌ NI ATAETA EIKYŌ NO KENSYŌ O TSŪJITE [COMPETITION IN THE PHARMACEUTICAL MARKET AND R & D INCENTIVES: THROUGH VERIFICATION OF THE IMPACT OF THE ENTRY OF GENERIC DRUGS ON THE MARKET], 19 (2015) *available at* https://www.jftc.go.jp/cprc/reports/index_files/cr-0115.pdf.

[11] ANDA is a generic drug application for approval based on the U.S. Hatch-Waxman Act. A manufacturer of generic drugs may file an ANDA application by proving that patent of the manufacturer of brand-name drugs is invalid or that the generic drug does not infringe the patent (Paragraph IV certification). The Hatch-Waxman Act is a bill bearing the names of Senator Orrin G. Hatch and Representative Henry A. Waxman, winning concessions between the brand-name companies and the generic companies. The bill allows the brand-name companies to extend the patent term, and besides the simplification of ANDA, it grants the generic companies 180 days of exclusive right to the company that first sells the generic drug.

JEREMY A. GREEN, "*GENERIC: THE UNBRANDING OF MODERN MEDICINE*" 86 (Illustrated ed. 2014), reveals the inside story of the negotiations in detail: "[T]he GPIA executive director, William Haddad, received a summons to visit the office of Rep. Waxman. The PMA, Waxman indicated, was interested in making a deal: if the generic industry *supported* patent extension for brand-name firms, the brand-name firms would support the extension of the ANDA approval pathway for all drugs."

[12] HIROYUKI ODAGIRI, INOBĒSHONJIDAI NO KYŌSŌSEISAKU [COMPETITION POLICY IN THE INNOVATION AGE: LAW AND ECONOMICS FOR RESEARCH, PATENTS AND PLATFORM] 78-79 (2016).

Regarding patent linkage in Japan; Katsumi Shinohara, *Nihongata patentorinkējiseido no shomondai(Jō)* [*Problems of Japanese Patent Linkage System (1)*], 80 LAW & TECHNOLOGY 29 (2018). Katsumi Shinohara, *Nihongata patentorinkējiseido no shomondai(Ge)* [*Problems of Japanese Patent Linkage System (2)*], 81 LAW & TECHNOLOGY 9 (2018); Katsumi Shinohara, *Wagakuni no shinposei no shinrihandan ni kansuru jakkan no kōsatsu* [*Some Considerations on the Trial and Judgement of the Inventive Step of Inventions in Japan*], 70(6) CHIZAIKANRI [INTELLECTUAL PROPERTY MANAGEMENT] 743, 752 (2020); Takamasa Ichihashi, *Nihon ni okeru patento･ringēji no un'youjitsumu*[*Practical Practice of Patent Linkage in Japan*], 89(8) HŌRITSU JIHŌ 35 (2017); Sachiko Masuda, *Patentorinkēij:Iyakuhin no anteikyōkyū to tokkyoseido ni kansuru ichikōsatu* [*Patent Linkage: A Study of Stable Supply and Patent System of Medicines*], 59(11) A.I.P.P.I. 818, 826 (2014). Masaho Ishino et al., *Nihon no patentorinkēji no un'yōjittai ni tsuite* [*Operational status of Patent Linkage*], 71(10) Patent 54 (2018); Masaho Ishino, *Iyakuhin no kaihatsu insentibu no tanpo to tokkyoseido･yakujiseido no arikata* [*Securing Drug Development Incentives and Ideal Patent/Pharmaceutical System*], 72(12) PATENT 163, 170 (2019); INSTITUTE OF INTELLECTUAL PROPERTY, Baioiyakuhin no chitekizaisanseidotō ni kakaru shogaikoku ni okeru jittaichōsa [SURVEY ON ACTUAL STATES IN FOREIGN COUNTRIES RELATED TO INTELLECTUAL PROPERTY SYSTEM OR THE LIKE OVER BIOPHARMACEUTICALS], 2017 Commissioned Project by the Economic Affairs Division, Health Policy Bureau, Ministry of Health, Labour and Welfare (2018) *available at* https://www.mhlw.go.jp/file/06-Seisakujouhou-10800000-Iseikyoku/0000202523.pdf; Yasuko Tanaka, *Beikoku hacchiwakkusumanhō tono hikaku kara mietekuru nihon no patentorinkēji no kadai* [*Patent Linkage Problem in Japan comparing with the US Hatch-Waxman Act*], 48(8) KOKUSAI SHŌJI HŌMU [International Business Law and Practice], 1094 (2020).

actual reverse payments cases to arise in Japan. What about the lack of an infringement requirement of the substance patent or use patent for patent linkage (Reason (4) above)?

(2) Substance Patent and Use Patent

For the substance patent and use patent, approval by the Ministry of Health, Labour and Welfare (MHLW) will not be granted unless the Japan Patent Office (JPO) issues an invalidation decision,[13] however it is possible to settle by reverse payments during an invalidation trial.[14] The generic companies undertake a stable supply obligation[15] after the launch of generic drugs. As

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[13] Iryōyōkōhatsuiyakuhin no yakujihōjō no shōninshinsa oyobi yakkashūsai nikakaru iyakuhintokkyo no atsukai ni tsuite [Approval examination of generic drug for medical treatment under the Pharmaceutical Affairs Law and handling of drug patents related to NHI price listing], Director of Economic Affairs Division, Health Policy Bureau, MHLW Notification No. 0605001; Director of Evaluation and Licensing Division, Pharmaceutical and Food Safety Bureau, MHLW Notification No. 0605014 of 2009; Shōninshinsa ni kakaru iyakuhintokkyojōhō no toriatsukai ni tsuite [Handling of drug patent information for approval examination], Pharmaceutical Affairs Bureau, MHW Notification No. 762 of 1994. There were cases in which generic drugs were not approved while decisions confirming invalidity of the patent exist, but there also were cases in which generic drugs were approved while decisions confirming the validity of the patent were made, no decision confirming invalidity of the patent existed, and the patent rights were still in effect. Therefore, the extension of the patent linkage in use patents is said to be unclear. Katsumi Shinohara, *Nihongata patentorinkējiseido no shomondai(Jō)* [*Problems of Japanese Patent Linkage System (1)*], 80 LAW & TECHNOLOGY 29, 33, 35 (2018); Katsumi Shinohara, *Wagakuni no shinposei no shinrihandan ni kansuru jakkan no kōsatsu* [*Some Considerations on the Trial and Judgement of the Inventive Step of Inventions in Japan*], 70(6) CHIZAIKANRI [INTELLECTUAL PROPERTY MANAGEMENT] 743, 753 (2020). The lack of clarity increases when the patent term is extended. In its judgement of Jan. 20, 2017 on the formulation patent of ELPLAT (oxaliplatin), the Intellectual Prop. High Ct judges described the scope of extended patent right as follows: The extended patent right covers not only the product (medicinal product) identified by "ingredient, quantity, dosage, administration, effectiveness, and efficacy" designated by the Cabinet Order Disposition, but also a product substantially identical to it as a medicinal product. The judgement also gives examples of where the "substantially identical" is found regarding the scope of extended patent right for substance patent, that is, the opponent's product is adding or converting a different ingredient other than the active ingredient based on the well-known art and conventionally used means at the time of applying for the Cabinet Order Disposition. Chiteki Zaisan Kōtō Saibansho [Intellectual Prop. High Ct.] Jan. 20, 2017, Hei 28 (ne) no.10046, 2361 HANREI JIHŌ [HANJI] 73. However, the scope of "substantially identical" is unclear. Whether the above case covers use patent is not exactly clear.

With the expiration of the term of the substance patent, applications for manufacturing and marketing approval of the generic company are permitted for the part excluding the indications subject to the remaining use patents (basic indication application, or skinny labelling). Kōhatsuiyakuhin ni okeru kōnōkōkatō no zesei ni tsuite [Correction of generic drug indications], Director of Economic Affairs Division, Health Policy Bureau, MHLW Notification No. 0622001; Director of Evaluation and Licensing Division, Pharmaceutical and Food Safety Bureau, MHLW Notification No. 0622001 of 2006; Kōhatsuiyakuhin ni okeru kōnōkōkatō ni kansuru toriatsukai ni tsuite [Handling of generic drug indications], Director of Economic Affairs Division, Health Policy Bureau, MHLW Notification No. 0329-1; Director of Evaluation and Licensing Division, Pharmaceutical and Food Safety Bureau, MHLW Notification No. 0329-4 of 2012.

[14] Therefore, the fact that "patent infringement lawsuits occur only after the launch of generic drugs," COMPETITION POLICY RESEARCH CENTER, JFTC, *IYAKUHINSIJŌ NIOKERU KYŌSŌ TO KENKYŪKAIHATSU INSENTIBU: JENERIKKU IYAKUHIN NO SANNYŪ GA SIJŌ NI ATAETA EIKYŌ NO KENSYŌ O TSŪJITE* [*COMPETITION IN THE PHARMACEUTICAL MARKET AND R & D INCENTIVES: THROUGH VERIFICATION OF THE IMPACT OF THE ENTRY OF GENERIC DRUGS ON THE MARKET*], 19 (2015) *available at* https://www.jftc.go.jp/cprc/reports/index_files/cr-0115.pdf, cannot be a reason why it is difficult for actual reverse payment cases to arise in Japan.

[15] Kōhatsuiyakuhin no anteikyōkyū ni tsuite [Stable supply of generic drug], Director of Economic Affairs Division, Health Policy Bureau, MHLW Notification No. 0310003 of 2006. Generic companies have to continuously manufacture and sell generic drugs for at least five years in principal, securing the necessary inventory at all times. Once it accepts a complaint regarding stable supply, the MHLW provides necessary investigations and improvement guidance to generic companies. When improvement guidance is given in writing, the company's name and the content of the improvement guidance will be made

the product is not yet launched and thus the stable supply obligation does not exist during an invalidation trial, a stable supply obligation will not be an obstacle to accept a brand-name company's reverse payments settlement offer for generic companies. Therefore, irrespective of the lack of an infringement requirement of the substance patent or use patent for patent linkage (Reason (4) above), reverse payments cases could arise theoretically.

However, as no substance patents have been invalidated so far,[16] in reality, the incentive for the generic companies to file for an invalidation trial and the incentive for the brand-name company to settle by reverse payments is not high. Therefore, for the substance patent, a low invalidation rate may be the reason why it is difficult for actual reverse payments cases to arise in Japan, not the lack of an infringement requirement of the substance patent for patent linkage (Reason (4) above).

For the use patent, the invalidation rate may not be a reason, because there are many cases in which use patents have been invalided.[17] Therefore, it is difficult to attribute the reason of why it is difficult for actual reverse payment cases to arise in Japan to the lack of an infringement requirement of the use patent for patent linkage (Reason (4) above) or the actual situation of invalidation trials.

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public, and if improvement cannot be achieved, NHI price listing applications from that company may not be accepted. The MHLW recently announced a policy to introduce a framework to carefully check the stable supply system at the time of supplementary listing for generic companies that repeat problems such as delays or shortages in supply. *GE syūsaiji no anteikyōkyūkakunin o kyōka e 12gatsu tuiho kara, kyōkyūchien・keppin kurikaesu kigyōnado taishō* [*Strengthen Checking the Stable Supply for Generic drugs Listings. From December Supplementary Listing, for Manufacturers of Generic with Repeated Delays or Shortages in Supply*], NIKKAN YAKUGYO, June 17, 2020, 04:30AM, https://nk.jiho.jp/article/152462. In addition, the MHLW started an additional framework to have companies, who caused delays or shortages in supply with the items in the latest two lists, i.e. in the last December and in this June, submit a memorandum when listing new items this December promising they will voluntarily postpone the supplementary listing in next June if supplying problem with newly listed items occurs.

[16] We have represented in the invalidation trials for the substance patent, Tokkyochō [JPO] June 19, 2015, Mukou 2014-800022, SHINKETSU KENSAKU [SHINKETSU KENSAKU]1, https://www.j-platpat.inpit.go.jp/a0100, concerning substance patent of Rosuvastatin, and Tokkyochō [JPO] June 30, 2015, Mukou 2014-800145, SHINKETSU KENSAKU [SHINKETSU KENSAKU]1, https://www.j-platpat.inpit.go.jp/a0100, concerning substance patent of Olanzapine, both of which were dismissed. Regarding the substance patent of Rosuvastatin, there is another case, Chiteki Zaisan Kōtō Saibansho Daigōgi [the Grand Panel of Intellectual Prop. High Ct.], Apr. 13, 2018, Hei 28 (gyō ke) no.10182 and Hei 28 (gyō ke) 10184, 2427 HANREI JIHŌ [HANJI] 91, where the trial decision confirming the validity of the patent is affirmed.

[17] Chiteki Zaisan Kōtō Saibansho [Intellectual Prop. High Ct.] Dec. 25, 2019, Hei 31(gyō ke) no. 10006 and Hei 31 (gyō ke) no. 10058, SAIBANSHO SAIBANREI JŌHŌ [SAIBANSHOWEB]1, http://www.courts.go.jp, Chiteki Zaisan Kōtō Saibansho [Intellectual Prop. High Ct.] Oct. 22, 2018, Hei 29 (gyō ke) no. 10106, SAIBANSHO SAIBANREI JŌHŌ [SAIBANSHOWEB]1, http://www.courts.go.jp, Chiteki Zaisan Kōtō Saibansho [Intellectual Prop. High Ct.] Oct. 11, 2018, Hei 29 (gyō ke) no. 10165 and Hei 29 (gyō ke) no. 10192, SAIBANSHO SAIBANREI JŌHŌ [SAIBANSHOWEB]1, http://www.courts.go.jp, Chiteki Zaisan Kōtō Saibansho [Intellectual Prop. High Ct.] Nov. 16, 2016, Hei 27 (gyō ke) no. 10166, SAIBANSHO SAIBANREI JŌHŌ [SAIBANSHOWEB]1, http://www.courts.go.jp, Chiteki Zaisan Kōtō Saibansho [Intellectual Prop. High Ct.] Oct. 16, 2013, Hei 24 (gyō ke) no. 10419, SAIBANSHO SAIBANREI JŌHŌ [SAIBANSHOWEB]1, http://www.courts.go.jp, Chiteki Zaisan Kōtō Saibansho [Intellectual Prop. High Ct.] Apr. 11, 2012, Hei 23 (gyō ke) no. 10148, SAIBANSHO SAIBANREI JŌHŌ [SAIBANSHOWEB]1, http://www.courts.go.jp, Chiteki Zaisan Kōtō Saibansho [Intellectual Prop. High Ct.] Mar. 23, 2011, Hei 22 (gyō ke) no. 10256, 2111 HANREI JIHŌ [HANJI] 100, Chiteki Zaisan Kōtō Saibansho [Intellectual Prop. High Ct.] Sep. 30, 2009, Hei 20 (gyō ke) no. 10366, SAIBANSHO SAIBANREI JŌHŌ [SAIBANSHOWEB]1, http://www.courts.go.jp, Chiteki Zaisan Kōtō Saibansho [Intellectual Prop. High Ct.] Mar. 1, 2007, Hei 17 (gyō ke) no. 10818, SAIBANSHO SAIBANREI JŌHŌ [SAIBANSHOWEB]1, http://www.courts.go.jp, etc.

(3) Formulation Patent and Method Patent

How about formulation and method patents which are not listed in Reason (4) above?

(a) Advance Adjustment

For formulation patents and method patents, the Japanese patent linkage system requires an advance adjustment between the brand-name company and the generic company before a National Health Insurance (NHI) price listing.[18] At this advance adjustment stage, a generic company can withdraw its NHI price listing[19] and delay the launch of generic drugs by "adjustment." Thus, irrespective of the patent linkage system, reverse payments cases could arise theoretically.

However, because of the lack of exclusivity and difficulty precluding entry for multiple generic competitors (Reasons (1) and (2) above), multiple generic companies can enter the market simultaneously and a brand-name company usually does an advance adjustment with multiple generic companies. Unless a brand-name company adjusts with all these generic companies, a generic drug's entry will not be enjoined. Thus, a brand-name company would need to pay multiple generic companies to delay the launch. If this expense does not match the profit of enjoining the generic drugs' entry, the brand-name company will lose any incentive to make such a payment. If at least one generic company does not accept settlement, this generic company will acquire market share in advance. Thus, a generic company's incentive to accept reverse payments will not be high unless all the generic companies accept such an offer. Therefore, at the advance adjustment stage, the lack of exclusivity and difficulty precluding entry for multiple generic competitors (Reasons (1) and (2) above), may be the reasons why it is difficult for actual reverse payments cases to arise in Japan.[20]

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[18] Iryōyōkōhatsuiyakuhin no yakujihōjō no shōninshinsa oyobi yakkashūsai nikakaru iyakuhintokkyo no atsukai ni tsuite [Approval examination of generic drug for medical treatment under the Pharmaceutical Affairs Law and handling of drug patents related to NHI price listing] Director of Economic Affairs Division, Health Policy Bureau, MHLW Notification No. 0605001, and Director of Evaluation and Licensing Division, Pharmaceutical and Food Safety Bureau, MHLW Notification No. 0605014 of 2009, and accordingly partially revised Shōninshinsa ni kakaru iyakuhintokkyojōhō no toriatsukai ni tsuite [Handling of drug patent information for approval examination] Pharmaceutical Affairs Bureau, Ministry of Health and Welfare Notification No. 762 of 1994, Kōhatsuiyakuhin no yakkakijun eno shūsaitō ni tsuite [NHI price listing of generic drug] Notification No. 0722-1 Director of Economic Affairs Division, Health Policy Bureau, MHLW of 2020 and Senpatsuhinkigyō to Kōhatsuhinkigyō no tōjishadōsi niyoru jizenchōsei ni tsuite [Advanced adjustment between brand-name and generic companies] Federation of Pharmaceutical Manufacturers' Associations of JAPAN Notification No. 507 of 2020.

[19] The procedure for NHI price listing of a generic drug is to submit NHI price listing application by the manufacturer or the distributor who wishes to list the generic drug. The price list application for the generic drugs approved under the Act on Securing Quality, Efficacy and Safety of Products Including Pharmaceuticals and Medical Devices by February 15 and August 15 (if the day falls on Saturday or Sunday, it shall be the weekday closest to that day) should be submitted by March 10 and September 10 respectively of the year. NHI price listings are issued normally in June and December. Iryōyōkōhatsuiyakuhin no yakkakijunshūsaitō ni kakaru toriatsukai ni tsuite [Handling of prescription drugs regarding the NHI price listing etc.] Health Policy Publication No. 0207-2 and Health Insurance Bureau Notification No. 0207-2 of 2020.

[20] Therefore, if a system to secure first-filer advantage is established in order for the generic company that precedes to file a request for a trial for invalidation not to suffer from free riding by other generic companies that do not file requests for trials for invalidation, a side effect to increase incentive for reverse payment will occur.

(b) After the Launch

Under the patent linkage system for substance and use patents, approval will not be granted if the substance and use patents exist,[21] whereas under the advance adjustment system for formulation patents and method patents, even if a brand-name company and generic companies cannot adjust, generic companies can apply for NHI price listing at their own legal risk.[22] Thus, advance adjustment system for formulation patents and method patents is not as strong as patent linkage system for substance patents and use patents (Reason (4) above). Therefore, in many cases no adjustment is made,[23] the generic drugs are launched,[24] and the brand-name company files a patent infringement lawsuit.[25] During this infringement lawsuit, reverse payment cases could arise theoretically.

However, in reality, as the generic company launches at their own legal risk, they will try to comply with the stable supply obligation after the generic drug launch, decreasing any incentives

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[21] *See* Director of Economic Affairs Division, Health Policy Bureau, MHLW, and Director of Evaluation and Licensing Division, Pharmaceutical and Food Safety Bureau, MHLW, *supra* note 12; Pharmaceutical Affairs Bureau, Ministry of Health and Welfare, *supra* note 12.

[22] *See* Director of Economic Affairs Division, Health Policy Bureau, MHLW, and Director of Evaluation and Licensing Division, Pharmaceutical and Food Safety Bureau, MHLW, *supra* note 18; Pharmaceutical Affairs Bureau, Ministry of Health and Welfare, *supra* note 18; Director of Economic Affairs Division, Health Policy Bureau, MHLW, *supra* note 18; Federation of Pharmaceutical Manufacturers' Associations of JAPAN, *supra* note 18.

[23] Shinohara says in his *Nihongata patentorinkējiseido no shomondai(Ge)* [*Problems of Japanese Patent Linkage System (2)*], 81 LAW & TECHNOLOGY 9, 12 (2018) that there are few cases in which a patent dispute is finally settled through a settlement agreement, etc. due to advance adjustments between the parties concerned. From my experiences, it is difficult to find an agreement by advance adjustments in cases of severe conflict of view between the parties, and in that sense, advance adjustments appear to be nothing more than a ceremony performed before launch.

[24] Shinohara points out in his *Wagakuni no shinposei no shinrihandan ni kansuru jakkan no kōsatsu* [*Some Considerations on the Trial and Judgement of the Inventive Step of Inventions in Japan*], 70(6) CHIZAIKANRI [INTELLECTUAL PROPERTY MANAGEMENT] 743, 753 (2020) that there are various problems with the patent linkage system in Japan itself. Before the expiration of the term of patent rights (including extended patent rights), generic companies seem to be cautious to apply NHI price listing and sell generic drugs, supposedly due to fear of patent infringement suits. He presumes the background is that the companies are concerning whether the non-infringement decision of the regulatory authority without involvement of patent experts will be maintained in the judicial review.

[25] Tōkyō Chihō Saibansho [Tokyo Dist. Ct.] June 12, 2019, Hei 30 (wa) no. 28391, SAIBANSHO SAIBANREI JŌHŌ [SAIBANSHOWEB]1, http://www.courts.go.jp, concerning formulation patent of Fosrenol (Lanthanum carbonate hydrate), Chiteki Zaisan Kōtō Saibansho [Intellectual Prop. High Ct.] Apr. 4, 2018, Hei 29 (ne) no. 10090, SAIBANSHO SAIBANREI JŌHŌ [SAIBANSHOWEB]1, http://www.courts.go.jp, concerning formulation patent of Livalo (Pitavastatin calcium hydrate), SaikōSaibansho [Sup.Ct.] Mar. 24, 2017, Hei 28 (ju) no. 1242, 1672 SAIBANSHO JIHŌ [SAIJI] 3, concerning method patent of Oxarol (Maxacalcitol), Chiteki Zaisan Kōtō Saibansho [Intellectual Prop. High Ct.] Jan. 20, 2017, Hei 28 (ne) no. 10046, 2361 HANREI JIHŌ [HANJI] 73, concerning formulation patent of Elplat (Oxaliplatin), Chiteki Zaisan Koto Saibansho [Intellectual Prop. High Ct.] Dec. 8, 2016, Hei 28 (ne) no. 10031, SAIBANSHO SAIBANREI JŌHŌ [SAIBANSHOWEB]1, http://www.courts.go.jp, concerning formulation patent of Elplat (Oxaliplatin), Ōsaka Chihō Saibansho [Osaka Dist. Ct.] Dec. 22, 2011, Hei 22 (wa) no. 12227, SAIBANSHO SAIBANREI JŌHŌ [SAIBANSHOWEB]1, http://www.courts.go.jp , concerning formulation patent of Ebastel (Ebastine), Tōkyō Chihō Saibansho [Tokyo Dist. Ct.] Nov. 26, 2008, Hei 19 (wa) no. 26761, 2036 HANREI JIHŌ [HANJI] 125, concerning formulation patent of Glucobay (Acarbose), Tōkyō Chihō Saibansho [Tokyo Dist. Ct.] Jan. 28, 1999, Hei 8 (wa) no. 14833 and Hei 8 (wa) no. 14828, 1664 HANREI JIHŌ [HANJI] 109, and Ōsaka Chihō Saibansho [Osaka Dist. Ct.] Sep. 17, 1998, Hei 8 (wa) no. 8927, 1664 HANREI JIHŌ [HANJI] 122 , concerning formulation patent of Voltaren (Diclofenac sodium), etc.

to accept reverse payments from the brand-name company. Therefore, after launch, the stable supply obligation may be the reason why it is difficult for actual reverse payments cases to arise in Japan.

3. The Reasons Actual Reverse Payments Cases have not Arisen in Japan So Far

What is the reason actual reverse payments cases have not arisen in Japan so far? Europe shares the same system as Japan in that no ANDA exists and regulation on drug prices does exist, however actual reverse payments cases have arisen in Europe.[26] Thus, differences in the system alone cannot fully explain the reason actual reverse payments cases have not arisen in Japan.

In my view, Japanese companies' attitude towards regulatory authority may be the actual reason. Japanese companies have a mentality of fearing offending MHLW by not complying with a stable supply agreement and wish to avoid being a "first penguin" while the JFTC is monitoring.[27]

4. Conclusion

The JFTC has a strong interest in reverse payments[28] and is planning actively to apply the Antimonopoly Act.[29] Indeed, the JFTC unofficially interviewed several pharmaceutical companies regarding reverse payments. Around six years have passed since the CPRC report was issued and the government's goal of generic manufacturers achieving an 80% share of the market

[26] *See* Mariyama, *supra* note 4, at 491 and note 5.

[27] It is presumed that the same applies to foreign-affiliated companies that have Japanese subsidiary, i.e., Japanese subsidiary's intention that they do not want to offend regulatory authority are given priority over the foreign headquarters' intention.

[28] However, there is no mention of reverse payment in KAZUYUKI SUGIMOTO, *DEJITARUJIDAI NO KYŌSŌSEISAKU* [*COMPETITION POLICY IN THE DIGITAL AGE*] (2019), Kazuyuki Sugimoto, Chairman of the JFTC, Reiwa 2-nen Nentō shokan [2020 New Year Message] (Jan. 2020), *available at* http://www.jftc.go.jp/houdou/kouenkai/nentouh2020.html,and Kyodai IT no hankyōsōkōi "gensei ni taisyo", Furuya kōtoriiinchō [*Furuya announces JFTC deal strictly with IT giants' anticompetitive practices*] NIKKEI, (Sept. 17, 2020), *available at* https://www.nikkei.com/article/DGXMZO63979360X10C20A9EE8000/.

[29] COMPETITION POLICY RESEARCH CENTER, JFTC, IYAKUHINSIJŌ NI OKERU KYŌSŌ TO KENKYŪKAIHATSU INSENTIBU: JENERIKKU IYAKUHIN NO SANNYŪ GA SIJŌ NI ATAETA EIKYŌ NO KENSHŌ O TSŪJITE [Competition in the Pharmaceutical Market and R & D Incentives: Through Verification of the Impact of the Entry of Generic Drugs on the Market], 108 (2015) *available at* https://www.jftc.go.jp/cprc/reports/index_files/cr-0115.pdf, and COMPETITION POLICY RESEARCH CENTER, JFTC, IYAKUHINSIJŌ NIOKERU KYŌSŌ TO KENKYŪKAIHATSU INSENTIBU: JENERIKKU IYAKUHIN NO SANNYŪ GA SIJŌ NI ATAETA EIKYŌ NO KENSHŌ O TSŪJITE (GAIYŌ) [Competition in the Pharmaceutical Market and R & D Incentives: Through Verification of the Impact of the Entry of Generic Drugs on the Market (Summary)], 3 (Oct. 7, 2015) *available at* https://www.jftc.go.jp/houdou/pressrelease/h27/oct/151007_files/151007gaiyou.pdf.

by September 2020 was accomplished.[30] As this report points out,[31] incentives for engaging in reverse payments may increase and an actual case may arise.[32]

Since the low invalidation rate of the substance patent and the stable supply obligation after the launch of generic drugs will not change in the future, reverse payments cases will not arise in the future during an invalidation trial about a substance patent after the launch of generic drugs. Thus, should reverse payments cases arise at all, they are expected to arise during an invalidation trial and subsequent litigation rescinding the trial decision on a use patent in the advance adjustment stage for formulation and method patents before the launch of generic drugs.[33] It is desirable to clarify any future reverse payments in Japan by judicial judgment, as in the United States and Europe. How Japan-specific factors, in comparison with the United States and Europe, influence the decision is worthy of attention.

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[30] Cabinet Decision, Keizaizaiseiun'ei to kaikaku no kihonhōshin 2017 ni tsuite [Basic Policy on Economic and Fiscal Management and Reform], 36 (June 9, 2017) *available at* https://www5.cao.go.jp/keizai-shimon/kaigi/cabinet/2017/2017_basicpolicies_ja.pdf, and MHLW, Kōhatsuiyakuhin (jenerikkuiyakuhin) no shiyōsokushin ni tsuite [Promotion of the use of generic drugs], *available at* https://www.mhlw.go.jp/stf/seisakunitsuite/bunya/kenkou_iryou/iryou/kouhatu-iyaku/index.html.

As of June 22, 2020, due to impact of the COVID-19, etc., the government prospect of holding an 80% share (quantity basis) of generic drugs by September 2020 was becoming uncertain. *See Kōhatsuhin mokuhyō "80%", 9-gatsu tassei wa futōmei ni korona･jishukaishū･ōgatahin tsuiho de* [*Holding an 80% of Generic Drugs by September Become Uncertain by COVID-19, Voluntary Recall and Large Supplementary Listing*] NIKKAN YAKUGYO (June 22, 2020, 00:30AM), https://nk.jiho.jp/article/152597. However, as of March 2020, it was found that the share of generic drugs exceeded 80% on a quantity basis (new index). MHLW, Reiwagannendo chōzaiiryōhi (densanshoribun) no dōkō [Expenses for prescription medicines in 2019 (Computerized data)], 4 (Aug. 28, 2020) *available at* https://www.mhlw.go.jp/topics/medias/year/19/dl/gaiyo_data.pdf.

[31] *See* COMPETITION POLICY RESEARCH CENTER, JFTC *supra* note 30.

[32] The following is not a reverse payment case, but a normal price cartel case. On June 4, 2019, the JFTC issued a cease-and-desist order and surcharge payment order to KOA ISEI Co., Ltd. under the provisions of the Antimonopoly Act. This is the first cartel case of generic drugs. Although the case is small, it reflects a recent situation in the pharmaceutical industry. With close to an 80% share of generic drugs by September 2020, the upward growth generic companies enjoyed has slowed down due to drug price reduction and intensified price competition, and companies are seeking survival measures. This deteriorating profit environment in the generic drug industry would have affected the situation in this case.

[33] Due to the unclear scope of the extended patent right, reverse payments may arise even during the extended term of the substance patent and the use patent.

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