

Special Seminar
Innovation, Competition & Regulation
Law Center



**Pharmaceutical Industry,
IPR licensing and
Antitrust Regulations
in Japan**

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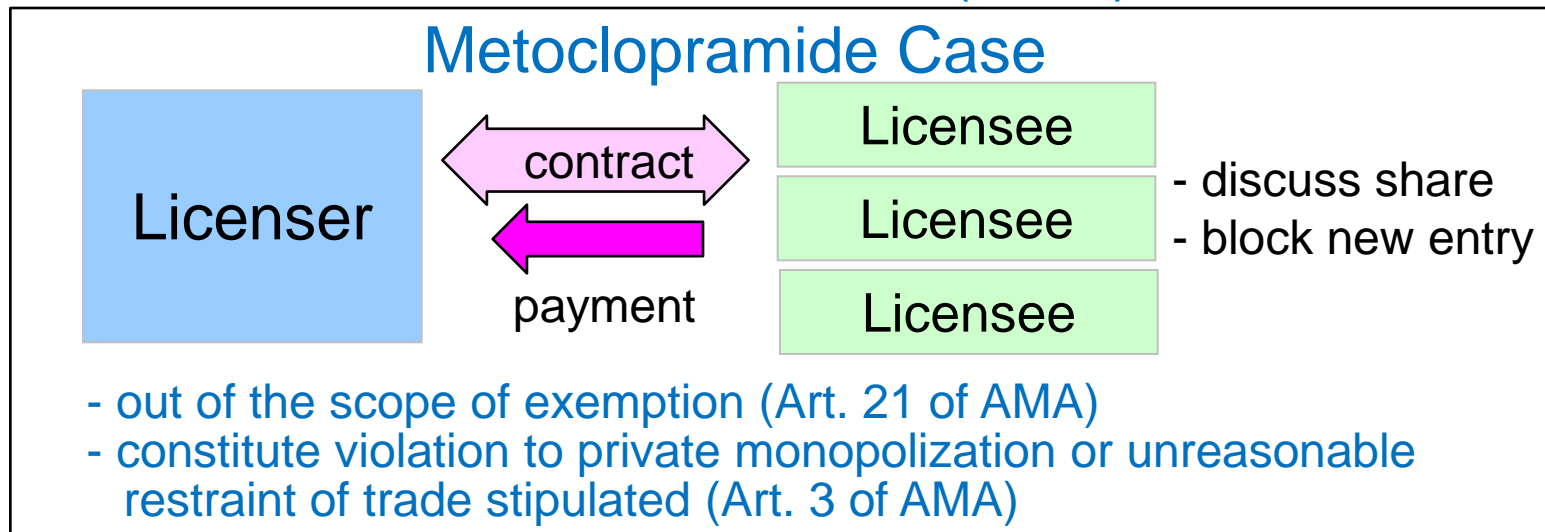
Introduction

No Reverse Payments happening in Japan

No court case

No JFTC decision

but one JFTC admonition case (1982)



*“there is no motivation for reverse payment,
because there is no economic rationality.”*

IP expert in pharmaceutical company

Introduction

- 1. Pharmaceutical Industry in Japan**
 - market
 - distribution system
 - similarity to the EU
- 2. IP and Antimonopoly Act in Japan**
- 3. Japanese Companies in US**
 - US cases Japanese companies involved
- 4. Case and Issues in Japan**

1. Pharmaceutical Industry in Japan

Market

Market Share of Generic Drugs in Japan (FY 2008)



Market scale : 8,370 billion yen
(approx. 80 billion US
dollar)

Share of generic drugs:
17.6% (quantity base)
6.8% (value base)

Not drastic expansion of share
Much smaller share than US
and most EU countries.

(Source) Japan Generic Medicines Association, May 2010

WHY SMALL SHARE?

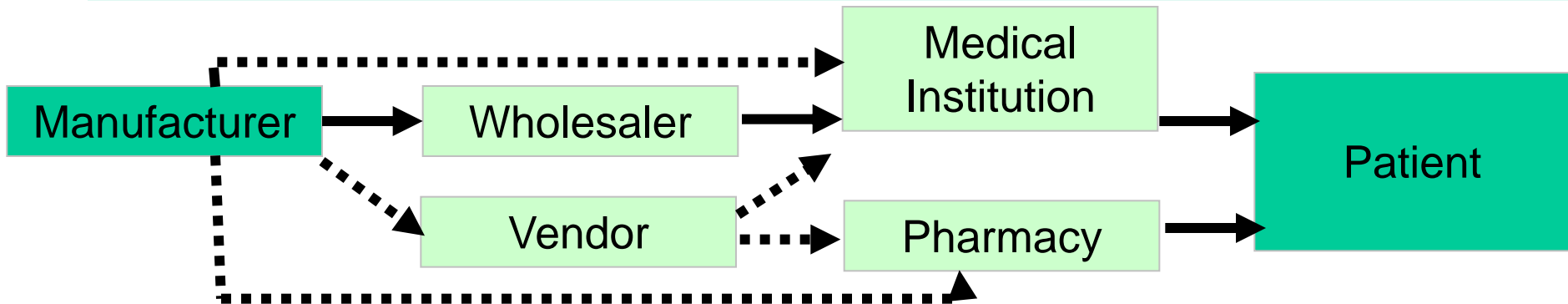
1. Pharmaceutical Industry in Japan

Why Small Share?

Stable Supply is in question
Safety and Quality are in question
Information is limited

Distribution Route

- Brand drug manufacturers sell products to medical institutions via wholesalers
- Generic drug manufacturers sometimes sell products through vendors specialized in generic drugs.



(Source) Japan Fair Trade Commission "Report on Distribution of Pharmaceuticals", September 2006

1. Pharmaceutical Industry in Japan

Recommendation by JFTC to Stakeholders of Pharmaceutical Market

Japan Fair Trade Commission “Report on Distribution of Pharmaceuticals”, September 2006

The Ministry of Health, Labour and Welfare: continue to work for promoting generic drugs

Generic drug manufacturers: eliminate concerns of medical institutions

Brand drug manufacturers: no interference with generic drug

Doctors and pharmacists: in prescribing or preparing generic drugs for patients, explain well

Wholesalers: negotiate well and promote joint purchasing.

Medical institutions: higher cost consciousness. Reduce number of pharmaceutical items.

Manufacturers: no violation of the Antimonopoly Act (Resale price restriction).

The JFTC: will continue to pay attention to the industry.

1. Pharmaceutical Industry in Japan

Similar to EU in Patent Suit of Pharmaceuticals

Pharmaceutical Sector Inquiry Report, Communication from the Commission, July 2009

Hypothesis: **patent strategy** of brand manufacturers in general disturbs and **delays market entry** of generic drugs

Result of the inquiry:

No explanation of relation between **patent strategy and **delay of market entry** of generic drug.**

Rather, it account for market elements such as price and scale of new and generic drugs.

Impression of the report: competition policy can do almost nothing to promote earlier entry of generic drugs.

In Japan:

- Competition policy may not do very much, also
- In addition, patent cases are brought before the court only for the generic drugs already in the market (same as EU)

2. IP and Antimonopoly Act in Japan

Japan Fair Trade Commission “Guideline for the Use of Intellectual Property under the Antimonopoly Act” (September 2007)

Basis:

- Under IP systems, there are cases that **competition may be diminished** if a right-holder does not allow others to use its technology or grants license to use the technology on the condition that their R&D, production, sales, etc. are restricted
- When applying the Antimonopoly Act to the restrictions pertaining to the use of technology, it is important for competition policy to insulate competition in technologies and products from **any negative effect** caused by restrictions
- Effort should be made to facilitate competition through the intellectual property systems

Scope:

- intellectual properties concerned with technology
- specify the principles by which the Antimonopoly Act is applied to restrictions pertaining to the use of technology

3. Japanese companies in US

Any possibility for Japanese pharmaceutical companies to be involved in reverse payment in the US?

No. No economic rationality.

(Sales Manager of the US market in JPN Leading pharmaceutical manufacture)

Many cases Japanese pharmaceutical companies involved in the US regarding their patents

Takeda v. 8 US generic manufactures

- Takeda brought a patent infringement case against 8 generic companies (patent of diabetic medicine “Actos”)
- Conciliation in April 2010, and 3 generic manufactures would sell the generic products

Daiichi-Sankyo v. Apotex (Canadian generic manufacture)

- Conciliation in August 2010. Apotex was granted the license. (patent of anti-xerostomia medicine “Evinoxac”)

4. Cases and Issues in Japan (1/2)

- No Hatch-Waxman Act in Japan
- Generic pharmaceutical manufacture can start implementation of a patent held by brand manufacturer before expire date to prepare application, aiming to start selling after the patent expired (Patent Law Article 69: Limitations of patent right)
- “Evergreen strategy” has seen often.

Many patent litigations between brand pharmaceutical manufactures and generic manufactures.

- Aciclovir Case (Welcome/Glaxo v. Sawai) Tokyo High Court 2001.11.29
- Famotidine Case (Richter Gedeon v. 16 generic companies) Tokyo High Court 2004.4.28
- Nicardipine Case (Yamanouchi v. Taisho) Osaka High Court 2003.02.18
- Cefdinir Case (Astellas v. Taiyo) Intellectual Property High Court 2007.09.10
- Selbex Capsel Case (Eizai v. Taiyo) 2006 injunction of anticompetitive act
- Cravit Case (Daiichi-Sankyo v. 13 generic pharmaceutical producers) 2008.12.24

4. Cases and Issues in Japan (2/2)

Some of the cases have been settled by conciliation.

- Kuremegine Case (Kureha v. Nichi-Iko Pharmaceutical) Tokyo District Court found patent infringement of Nichi-Iko. Conciliation was agreed at IP High Court in January 2011
- Flomox Case (Shionogi v. Sawai) Conciliation was agreed at IP High Court in October 2010, but no disclosure

Regarding innovation and market entry, brand pharmaceutical manufactures and generic manufactures have been struggling to solve conflicts by court decision and conciliation. However, it seems not much discussion or consideration from viewpoint of competition policy in this context

Patent Law v. Pharmaceutical Act

- “IP Promotion Program 2009”
- Administrative litigation by Takeda against Patent Office decision in April 2008. IP High Court held for Takeda in May 2009, and Supreme Court affirmed in April 2011

Thank you very much!

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