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POSITION OF IP OF THE PHARMACEUTICAL BUSINESS IN JAPAN

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OUTLINES

1. Features of Medicinal Patents in Japan
2. Patent LCM Strategy of Innovator Companies
3. Early Entry Strategy of Generic Companies
4. Trend of Pharmaceutical business & the IP Strategy

FEATURES OF MEDICINAL PATENTS IN JAPAN

1. Substance Patent
2. Types of Medicinal Patent
3. Japan-Type Bolar Article
4. Patent Term Extension
5. Patent Linkage

Substance Patent

Introduction of the System into Japan in 1976

- Revision of Article 35 of the Patent Act
  - Deletion of not patentable reason on chemical substance – Item 1-3 of Article 35
  - Conventionally only method was permitted
- Limitation of Substance patent
  - Article 69, Paragraph 3 is newly introduced
  - Substance patent principally does not cover "medical act"

Substance Patent

Introduction of the System into Japan in 1976

- Revision of Article 69, Paragraph 3
  - A patent right for the invention of a medicine (refers to a product used for the diagnosis, therapy, treatment or prevention of human diseases, hereinafter the same shall apply in this paragraph) to be manufactured by mixing two or more medicines or for the invention of a process to manufacture a medicine by mixing two or more medicines shall not be effective against the act of preparation of a medicine as is written in a prescription from a physician or a dentist and the medicine prepared as is written in a prescription from a physician or a dentist.

Substance Patent

Introduction of the System into India in 2005

- Abolition of the old substance patent system
  - Revision in 1970
- "mail box application" during 1995 – 2004
  - Revision in 1995
- New Substance patent system since 2005
  - New Article 3 (d) is introduced in 2005
  - New form of an existing substance cannot be patented

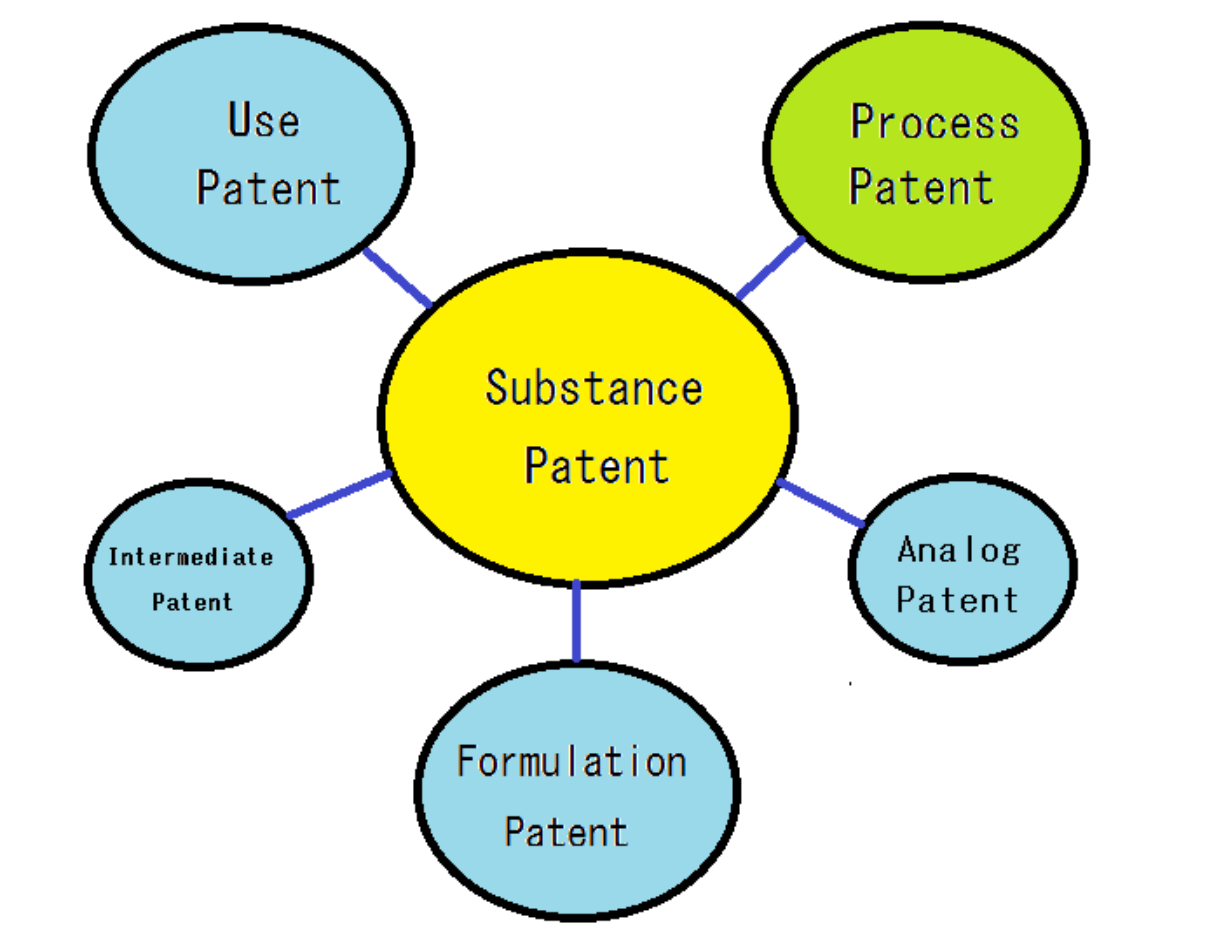
Substance Patent

Expansion of the protection of medicines

- Conventionally
  - Method for production could be patented – process patent
  - Process patent can be avoided by another process
- Litigation cases on process patents
  - Cimetidine case – SmithCline vs Fujimoto
  - Patentee's "oxy method" for manufacturing cimetidine
  - Damages – JPY2,560,000,000

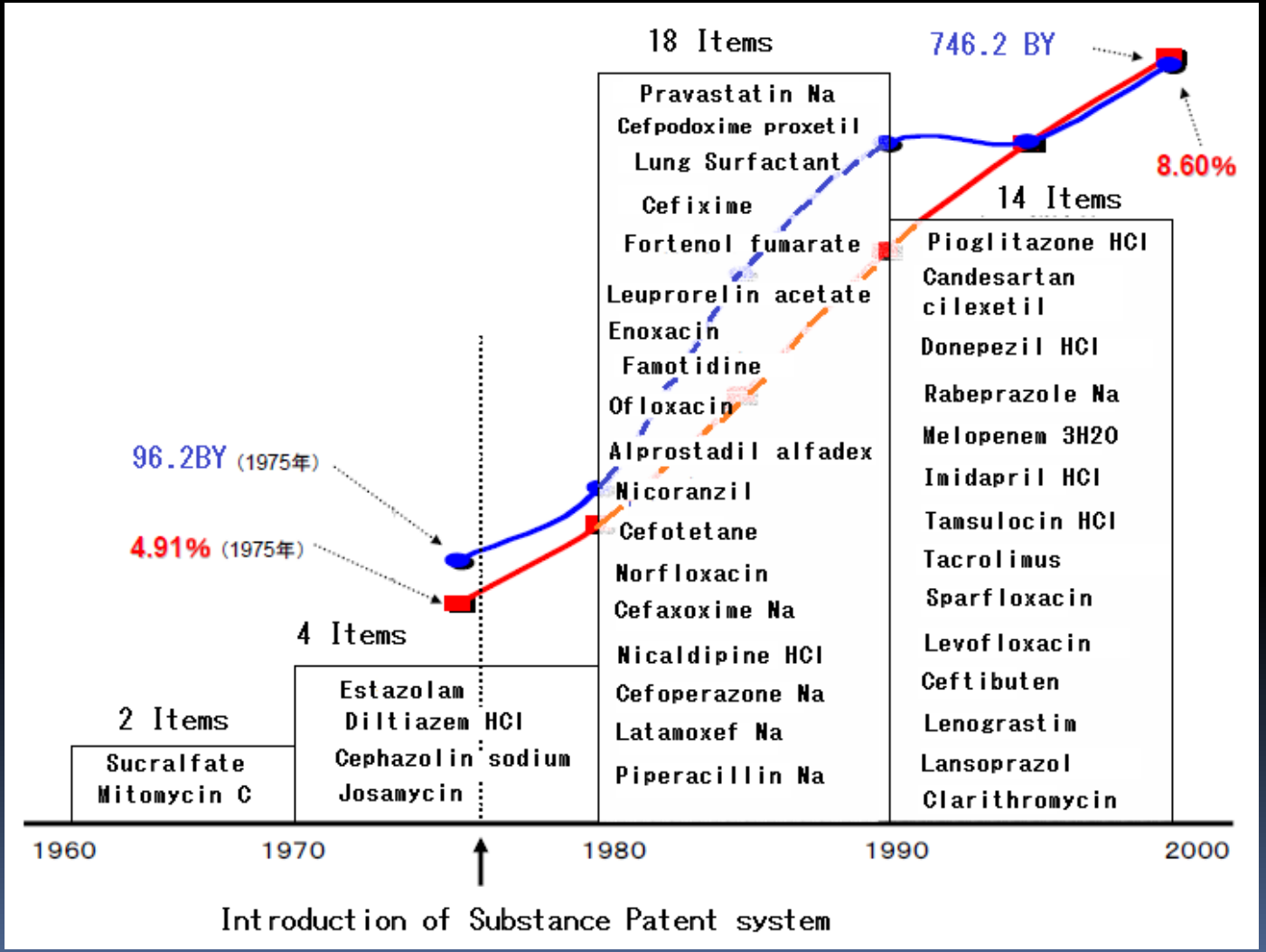
Substance Patent

Change in Patent LCM of innovator companies



Substance Patent

Incentives for R&D of innovator companies



Types of Medicinal Patent

Categories of invention - Article 2, Paragraph 1, Item 3

Category	Tangible thing	Pure method	Method for production
Example	Substance, chemical compound, composition, machine, computer program	Method for screening, measurement or telecommunication	Method for producing an active pharmaceutical ingredient
Working acts covered by the category	in the case of an invention of a product (including a computer program, etc., the same shall apply hereinafter), producing, using, assigning, etc. (assigning and leasing and, in the case where the product is a computer program, etc., including providing through an electric telecommunication line, the same shall apply hereinafter), exporting or importing, or offering for assignment, etc. (including displaying for the purpose of assignment, etc., the same shall apply hereinafter) thereof	in the case of an invention of a process, the use thereof	in the case of an invention of a process for producing a product, in addition to the action as provided in the preceding item, acts of using, assigning, etc., exporting or importing, or offering for assignment, etc. the product produced by the process

Types of Medicinal Patent

Kinds of "medicinal inventions"

- Principally
  - Medical method cannot be patented
- Examples
  - Chemical compound, composition, formulation, analogs (e.g., polymorph), etc.
- Usage & dosage inventions
  - Usage & dosage inventions can be patented
  - Revision of JPO Guidelines in 2007

Types of Medicinal Patent

"medicinal invention" defined in JPO Guidelines

- Medicinal invention
  - A medicinal invention here means "an invention of a product" which intends to provide a new medicinal use (Note 2) of a material (Note 1), based on discovering an unknown attribute of the material
  - (Note 1) "A material means a component used as an active ingredient, including a compound, a cell, a tissue and a chemical substance (or a group of chemical substances) whose chemical structure is not specified, such as an extract from a natural product, and a combination thereof. Hereinafter, the material concerned is referred to as "compounds etc."

Types of Medicinal Patent

"Dosage & Administration" inventions

- JPO guidelines revised in 2007
  - Note 2, (ii) was added

- (Note 2) "A medicinal use" means (i) an application to the specific disease or (ii) an application to the specific disease in which dosage and administration such as dosing time, dosing procedure, dosing amount or administration areas (hereinafter referred to as "dosage and administration") is specified.

Japan-Type Bolar Article

Not introduced into the Patent Act

- Hatch-Waxman Act (US) in 1984
  - The Drug Price Competition and Patent Term Restoration Act of 1984
- Revision of Patent Act in 1987
  - Only Patent term extension system in 1988
  - Bolar article was not introduced
- Supreme Court Decision in 1999
  - 24 court decisions during 1996 – 1999
  - Case No. Hei. 10 (JU) 153

Japan-Type Bolar Article

Supreme Court Decision in 1999

- Gist of Case No. Hei. 10 (JU) 153
  - Working of a patent Invention for the purpose of necessary experiments for the application of an approval of a generic drug under Article 14 of Pharmaceutical Affairs Law does correspond to the working under Article 69 of the Patent Act, so the working of the patent invention does not constitute an infringement of the patent.

Japan-Type Bolar Article

Supreme Court Decision in 1999

- Gist of Case No. Hei. 10 (JU) 153
  - Article 69 (1) of the Patent Act
    - Limitations of patent rights
  - A patent right shall not be effective against the working of the patented invention for experimental or research purposes.

Patent Term Extension

Features of the system

- Hatch-Waxman Act in 1984
  - The Drug Price Competition and Patent Term Restoration Act
  - Bolar Article (U.S. Patent Act Article 271 (e)(1))
- Patent period extension system in 1987
  - Only Patent term extension system was introduced into Article 67
    - Preferable for innovator companies
  - Hei.10 (ju) 153: introduction of Japanese Bolar Article

Patent Term Extension

Features of the system

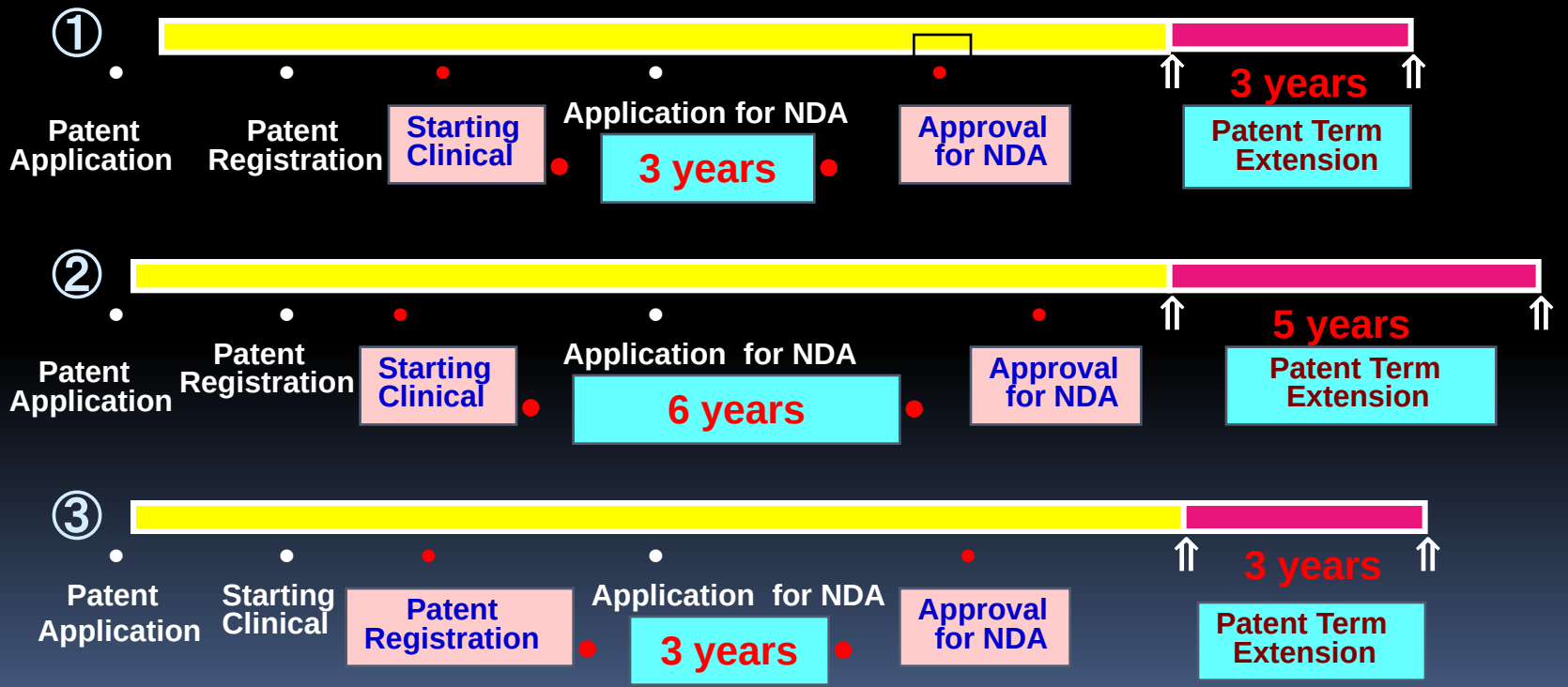
- Article 67 (2) of the Patent Act
  - Where there is a period during which the patented invention is unable to be worked because approvals prescribed by relevant Acts that are intended to ensure the safety, etc. or any other disposition designated by Cabinet Order as requiring considerable time for the proper execution of the disposition in light of the purpose, procedures, etc., of such a disposition is necessary to obtain for the working of the patented invention, the duration of the patent right may be extended, upon the filing of a request for the registration of extension of the duration, by a period not exceeding 5 years.

Patent Term Extension

Features of the system

3 Patterns of patent term extension

depending on the Date of Clinical Trial Start, Patent Registration, and Approval



Patent Term Extension

Features of the system

- Article 67Bis was added
- JPO Guidelines were newly established
  - ⇒ Innovator companies
  - patent term extension shall be granted on basis of the earliest approval only
  - From the viewpoints of the active ingredients or efficacy/effect
  - ⇒ Generic companies
  - Extendable more than twice per patent

Patent Term Extension

Supreme Court decision in 2011

- Decisions of the court
  - Maintained the JPO Board decisions based on the JPO Guidelines
- PACIF capsules case decision in 2011
  - Hei. 21 (Gyo Hi) 324 – 326
  - patent relates to a release-controlling compositions
  - In case precedent drug is not covered by any claim of the concerning patent even if the drugs are the same in both active ingredient and efficacy/effect, the patent extension of the concerning patent can be granted.

Patent Term Extension

Revised JPO Guidelines in 2011

- First disposition
  - the present disposition is the first disposition within the scope determined by the "matters falling under the matters to define the invention (and the use)" of the drug product or agricultural chemical that was the subject of the present disposition.
- Matters falling under …
  - The "matters falling under the matters to define the invention (and the use)" means all matters specified in the approval certificate or the registration card, etc., falling under the matters to define the patented invention (if the matters to define the patented invention does not include any matters specifying use, this means all matters specified in the approval certificate or the registration card, etc., falling under the matters to define the patented invention and falling under the use.

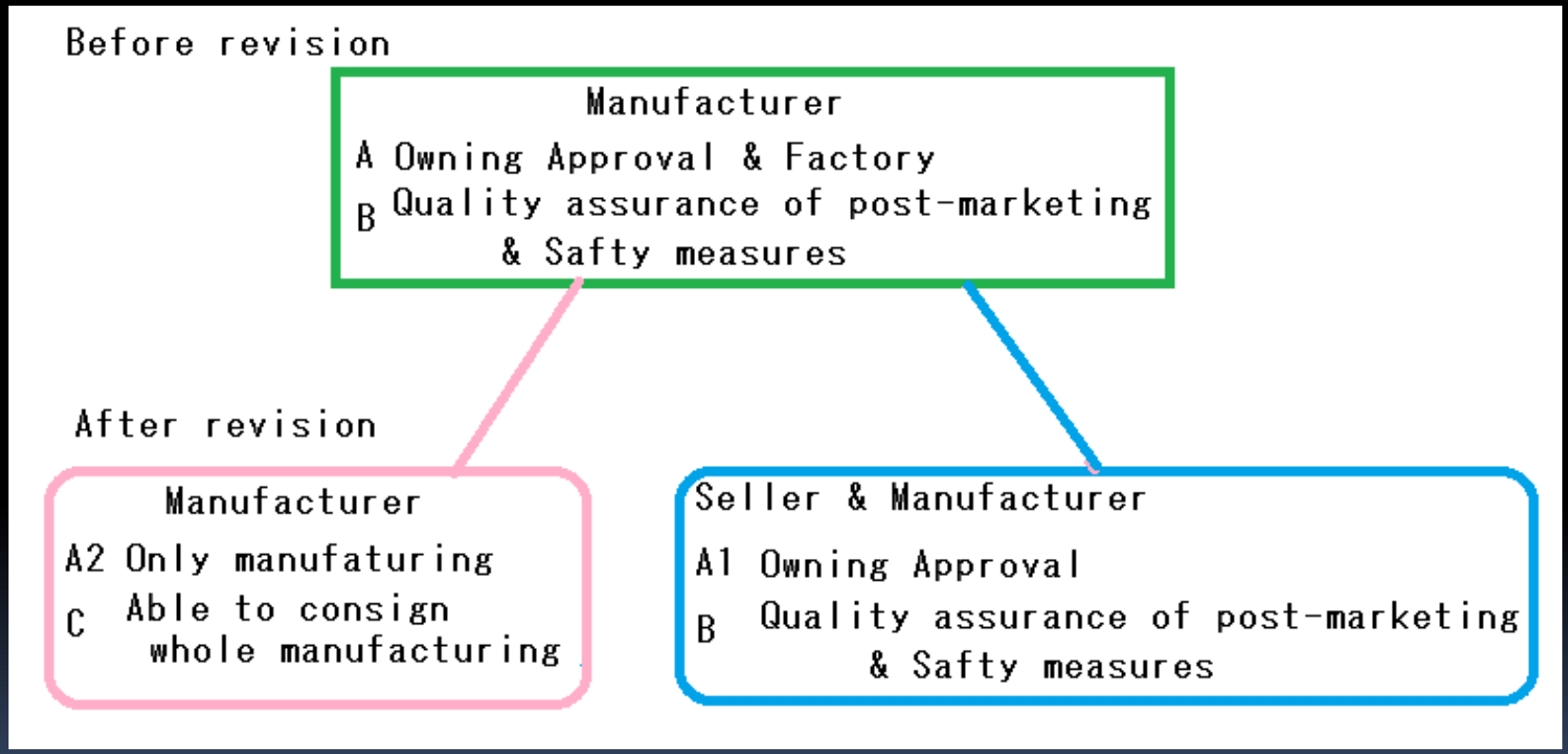
Patent Linkage

Revision of the Pharmaceutical Affairs Law in 2002

- Pharmaceutical Affairs law
  - Establishment in 1961
  - General Notification in 1967
    - Clarification of documents for application of approval
    - Separation of Ethics drug & OTC drug
  - Revision in 1979
    - Securing of safety & efficacy
    - Re-examination & re-evaluation system
- Revision in 2002, Enforcement in 2005
  - International harmonization
  - Separation of Manufacture & sales and Manufacture
    - Manufacture division can be divided
  - Reinforcement of safety of Post-marketing and medical devices

Patent Linkage

Revision of the Pharmaceutical Affairs Law in 2002



Patent Linkage

With Regulation – Recent changes

- ELD/PFSB Notification No. 060514, EAD/HPB Notification No. 065001, dated June 5 2009
  - Whether related patent exists is determined at the time of approval
    - Approval: February and August
  - In case API cannot be manufactured due to the existence of the patent for innovator API, generic cannot be approved
    - E.g., substance patent
  - In case there is no patent for some of the indications, generic can be approved for them
    - Carving out indications can be permitted

Patent Linkage

With Regulation – Recent changes

- ELD/PFSB Notification No. 0616-1, dated June 16 2011
  - Conventionally
    - different polymorphs from innovator drug were not actually approved as the API of generic drugs
  - Different polymorph can be approved as API of generic drug
    - 16th Revised Japanese Pharmacopeia
      - Confirmation test for recrystallized different polymorph
    - Stability test is required

PATENT LCM OF INNOVATOR COMPANIES

Patent LCM of Innovator comp.

Establishment of basic and peripheral patents

- Basic patents from R&D activities
  - Substance and Use (first approved) patents
  - Process and formulation patents
- Additional peripheral patents from LCM
  - Additional use, process and formulation patents
  - Analog (e.g. polymorph) Storage, device patent
  - Dosage & administration patent
- Patent term extension
  - Filing within three (3) months form the date of disposition

Patent LCM of Innovator comp.

Exclusivity & Patent Linkage of Innovator drug

- Application of an approval of new drug
  - Situation of the patent
- Approval
  - Approval: March, June, September, and December
  - NHI listing: February, May, August, and November
  - Patent term extension: within 3 months
- Re-examination period
  - Novel substance drug – 8 years (6 years: until 2007)
  - Orphan drug – 10 years
  - Known substance/ Novel use – 6 years
  - Known substance & use/ Novel route – 4 years

Patent LCM of Innovator comp.

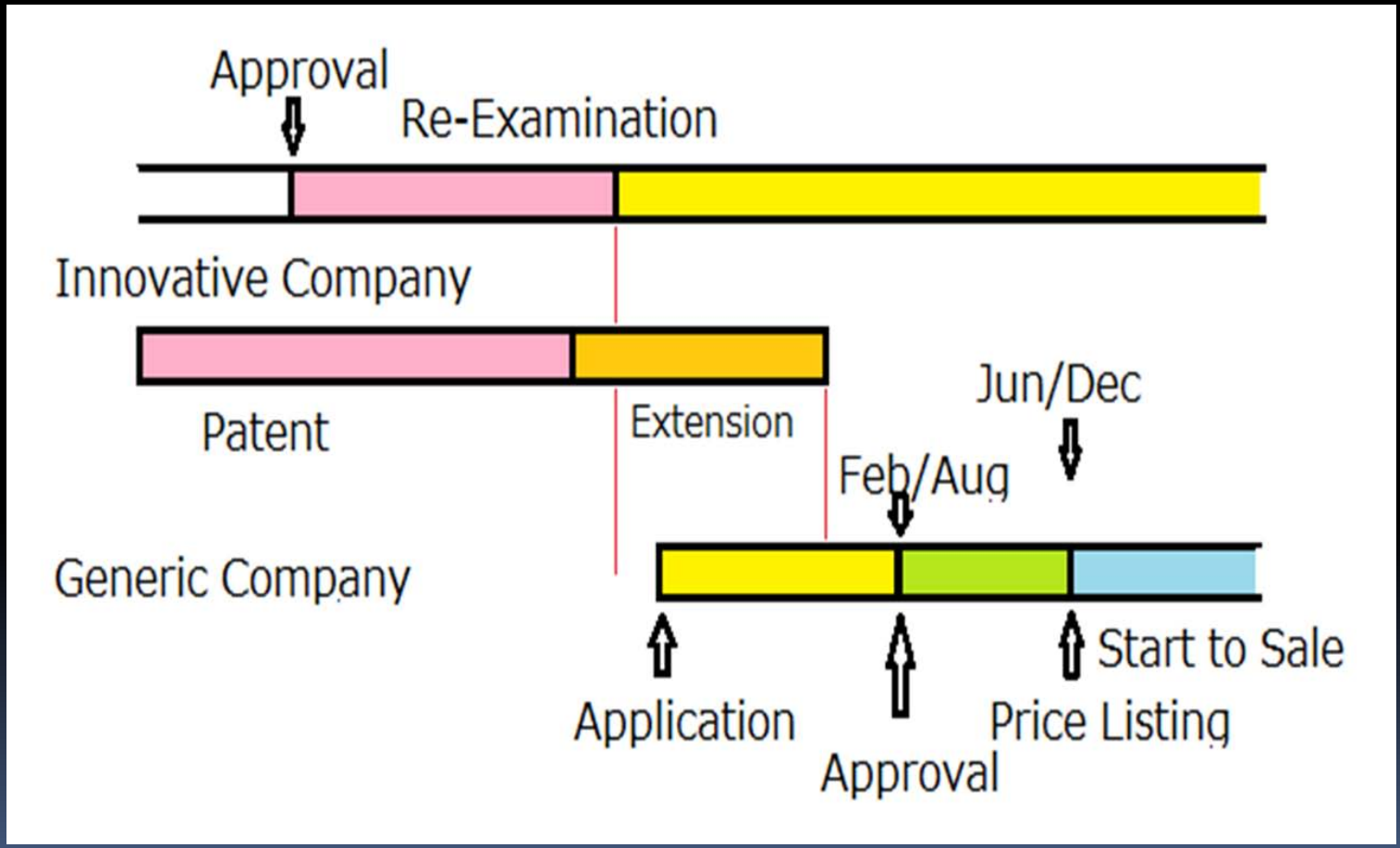
Protection from the entry of generic drugs

- Patent LCM
  - Basic & peripheral patents, patent term extension
- At the time of ANDA approval etc.
  - Warning (Newspaper, magazine)
  - Preliminary negotiation
    - Approval
    - NHI price listing
- Disputes against generic companies
  - Court & Customs office
  - Against Invalidation trials

EARLY ENTRY STRATEGY OF GENERIC COMPANIES

Early Entry Strategy of GE comp.

Exclusivity, Patent term, and Approval system of GE



Early Entry Strategy of GE comp.

Pre-approval of a generic drug

- Conventional strategy for Patent Clearance
  - Investigation of patents & patent term extension
  - Investigation of basic & peripheral patents
  - Entry after expiries of patents
- Positive strategy for Early Entry
  - Invalidation trial
    - Patent
    - patent term extension: LEVOFLOXACIN case (2009)
  - Action for the declaration of non-existence
    - Right to demand an injunction: LIVACXT case (2005)

Early Entry Strategy of GE comp.

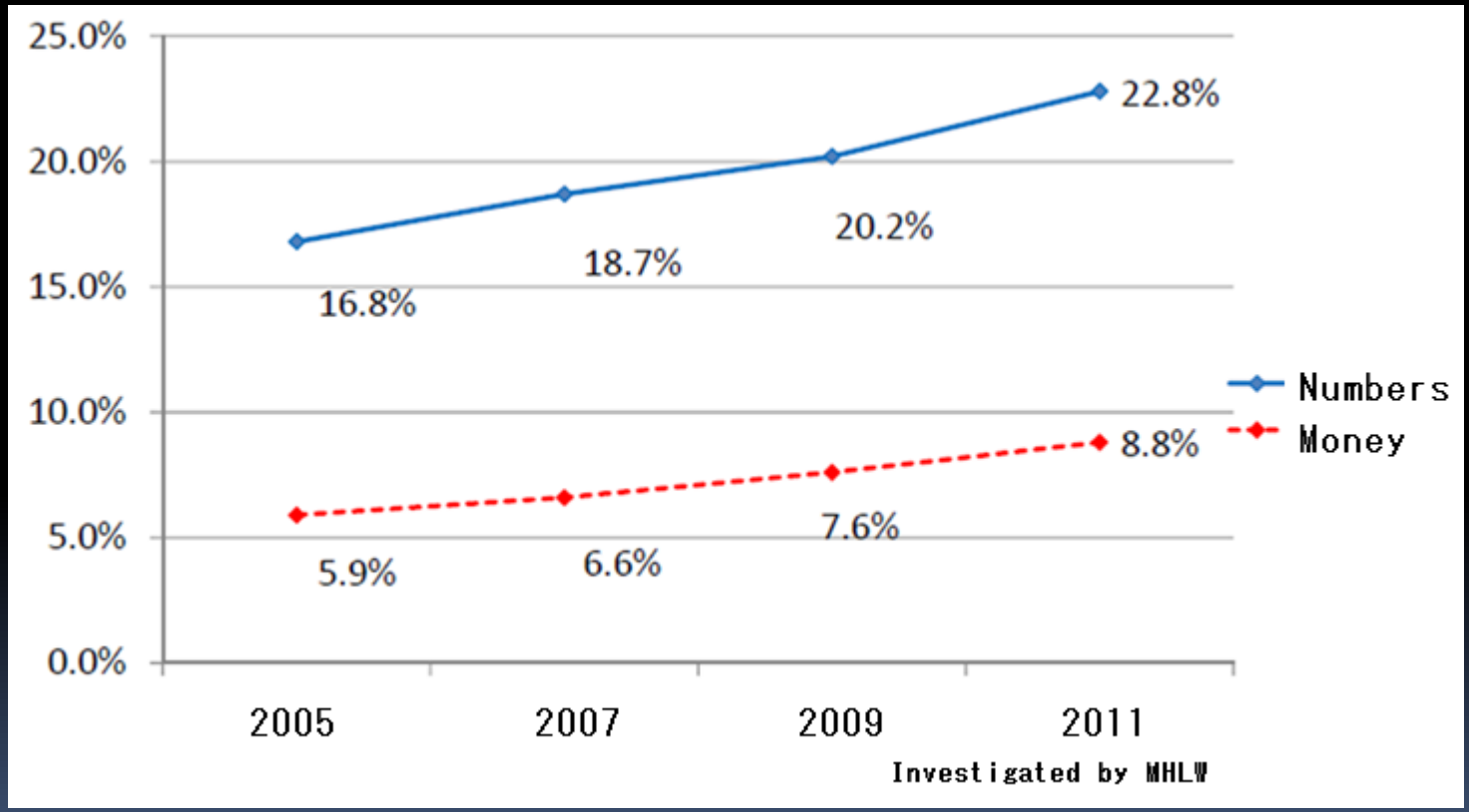
On & Post-approval of a generic drug

- Preliminary negotiation
  - Approval
  - NHI price listing
- Disputes against innovator companies
  - Defense in Court & Customs office
  - Invalidation trials against infringement case

TREND OF PHARMACEUTICAL BUSINESS AND IP STRATEGY

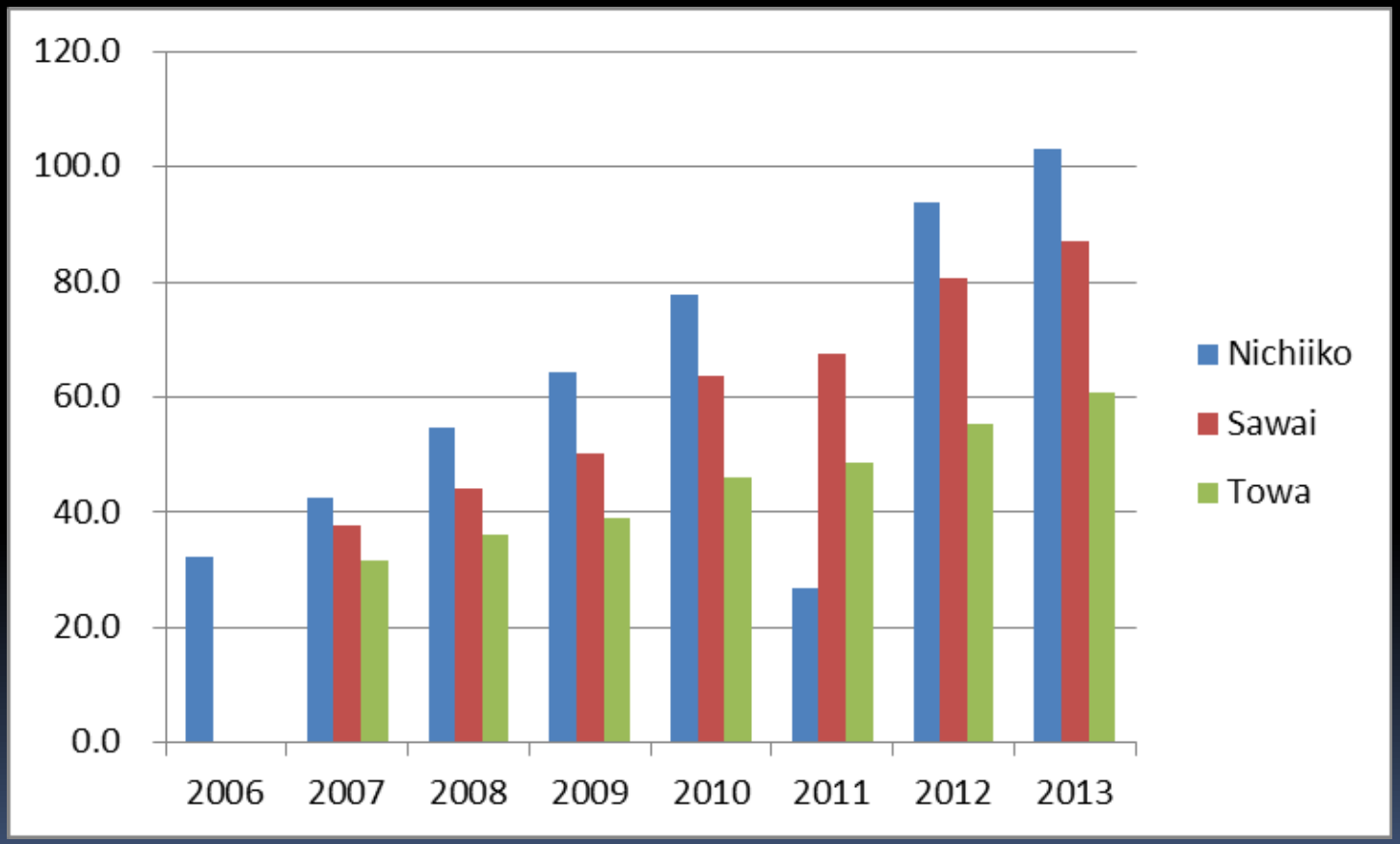
Growth of generic Business

Change of the sale of Generic drugs (2005 – 2011)



Growth of generic Business

Change of the Sales of Generic-professional comp.

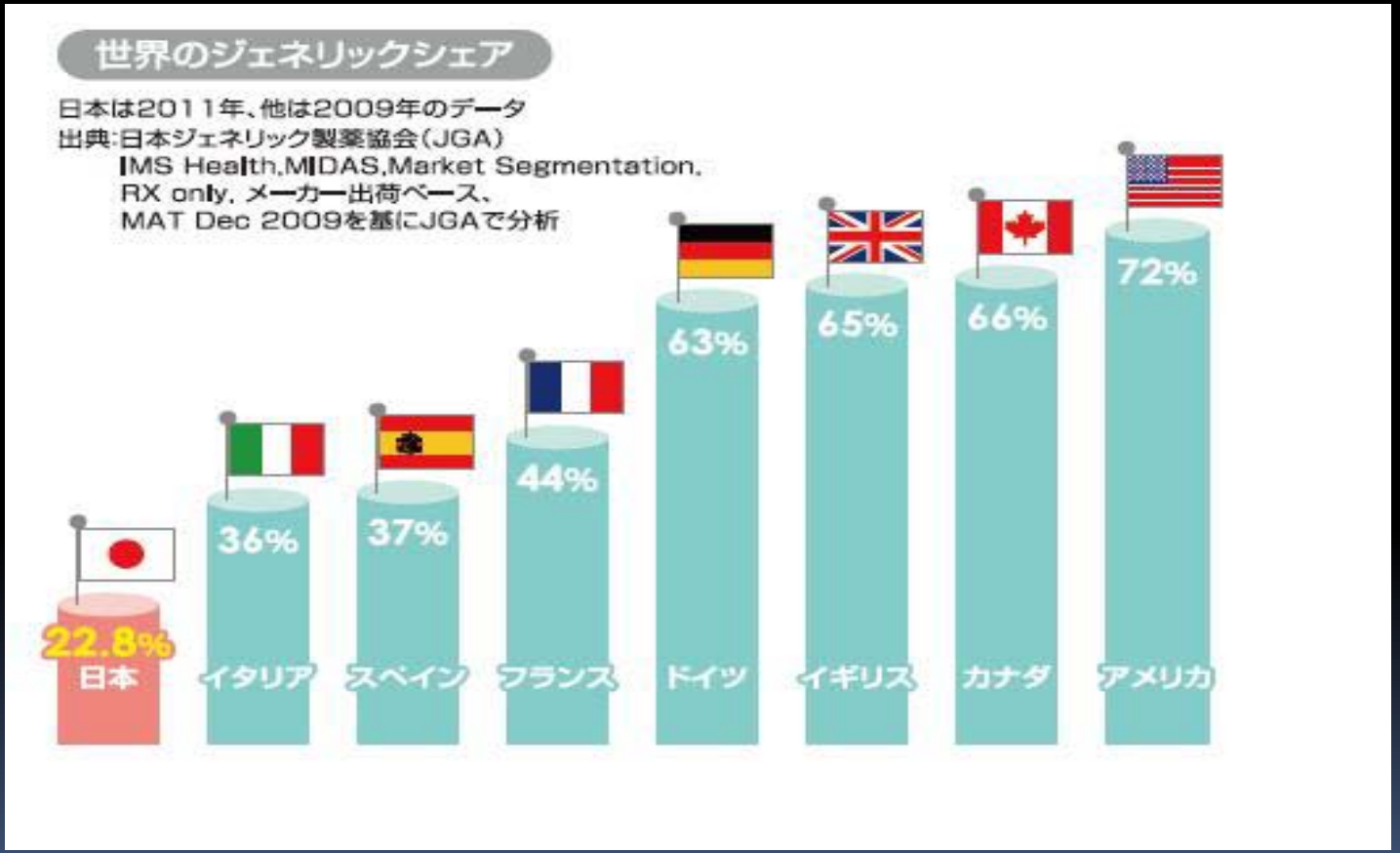


Vertical axis: Billion Yen

Growth of generic Business

Still Low-ratio sales of Generic drugs in Japan

Generic Share of the world Market



Japan Italy Spain France Germ-any UK Canada US

Keen Competition in GE Business

Many Companies Joining with M & A

- Generic-professional companies
  - Nichiiko, Sawai, Towa, etc.
- Foreign generic companies
  - Teva, Milan, Sandoz, Zydus, Lupin, etc.
- Innovator companies
  - Takeda, Pfizer, Daiichi-Sankyo, Tanabe-Mitsubishi,
- Other industry companies
  - Meiji, Fuji Film, etc.

Patent Problems

The Pharmaceutical Business into Chaos

- 2010 Problem
  - Many Blockbusters' patents expired
  - Contribution to the growth of generic business
- 2015 Problem
  - Patents of biological substance begins to expire
  - Alliance having capacity for Bio-similar
- 2017 Problem
  - Fewer Expiring of innovator drugs' patents
  - Keen competition & New direction

IP Strategy in the Future

On & Post-approval of a generic drug

- Fusion of Innovator and GE company
  - conventionally inconsistence businesses
- No border in the business
  - Joining of foreign companies
- New business of Outsiders
  - Other business companies
- Multiple IP strategies for one company
  - Inconsistent strategies, etc.

Summary

1. Features of Medicinal Patents in Japan
2. Patent LCM Strategy of Innovator Companies
3. Early Entry Strategy of Generic Companies
4. Trend of Pharmaceutical business & the IP Strategy

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THANK YOU FOR YOUR ATTENTION!