

A background image of a world map, showing the outlines of continents and oceans. The map is rendered in a light, semi-transparent style, allowing the text to be clearly visible. A vertical red bar is on the left side of the slide.

WIPO Conference on IP Dispute Resolution in Life Science

# **IP Litigation in Life Sciences** **– Costs, Duration and Enforceability** **in Japan**

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# Agenda



- Court System for IP Litigation in Japan
- Cost
  - Official Litigation Fees
- Duration
  - Duration of IP Litigation
  - Judgment v. Settlement on IP Litigation in Japan
- Other Procedural Aspects of IP Litigation
- Enforceability of IP Rights in Japan
  - De fact Patent Linkage under Government Regulation
  - Patent Protection of Second Medical Use in Japan

# Court System for IP Litigation in Japan



## ➤ Exclusive Jurisdiction

- Exclusive jurisdiction of **Tokyo and Osaka District Courts** for the first instance of technology related cases (after April 2004).
- Establishment of **Intellectual Property High Court** (April 2005).

### Tokyo District Court

4 divisions

16 Judges

### Osaka District Court

2 divisions

5 Judges

## ➤ Intellectual Property High Court

- Exclusive jurisdiction for
  - (1) Litigations against appeal/trial decisions made by Japan Patent Office
  - (2) Appeals of all types of IP cases from Tokyo District Court and technological cases from Osaka District Court.
- 4 divisions, 16 Judges
- Chief Judge, Mr. Ryuichi Shitara (June 2014)

## ➤ The Supreme Court

- 14 Judges

# Official Litigation Fees in Japan - 1



## (A) Court fee for damage claim (District Courts)

If only damage is claimed, the Court fee is calculated based on the claimed damage amount according to an official calculating chart.

Claimed damage amount	100M JPY (830K USD)	1000M JPY (8.3M USD)	10,000M JPY (83M USD)
Court fee	320,000 JPY (2,667USD)	3,020,000 JPY (25,167 USD)	16,020,000 JPY (133,500 USD)

cf. Court fee in the U.S.

- e.g. \$400 in the Northern District of California or District of Delaware.

# CALCULATION OF COURT FEE



For example:

Annual loss of the infringed product is 100-oku JPY (about 83M USD)

Its profit ratio is 50%

Remaining patent life is 10 years

⇒ Jurisdictional amount is 62.5-oku JPY (= 100-oku x 50% x 10 x 1/8; \$52.1M)

⇒ Court fee is 12.27M JPY (about 102.25K USD)

<b>1. Litigation Value Portion &lt; \1M</b> <b>\1,000/each \100,000 of value</b>	$\1,000 \times 10 = \10,000$
<b>2. \5M &gt; Value &gt; \1M</b> <b>\1,000/each \200,000</b>	$\1,000 \times 20 = \20,000$
<b>3. \10M &gt; Value &gt; \5M</b> <b>\2,000/each \500,000</b>	$\2,000 \times 10 = \20,000$
<b>4. \1B &gt; Value &gt; \10M</b> <b>\3,000/each \1M</b>	$\3,000 \times (1,000M - 10M)/1M = \2,970,000$
<b>5. \5B &gt; Value &gt; \1B</b> <b>\10,000/each \5M</b>	$\10,000 \times (5,000M - 1,000M)/5M = \8,000,000$
<b>6. Value &gt; \5B</b> <b>\10,000/each \10M</b>	$\10,000 \times (6,250M - 5,000M)/10M = \1,250,000$
<b>SUM</b>	<b>\12,270,000</b>

# Official Litigation Fees in Japan - 2



## (B) Court fee for injunction (District Courts)

If only injunction is sought, the Court fee is calculated based on a jurisdictional amount which is calculated according to one of the following calculating formulae (the plaintiff can chose).

- a) Annual reduction of plaintiff's sales x profit ratio x remaining life of patent x 1/8*
- b) Defendant's expected sales x defendant's expected profit ratio x remaining life of patent x 1/8*
- c) (Annual royalty x remaining life of patent) – interim interest*

## (C) Court fee for a case including both damage claim and injunction

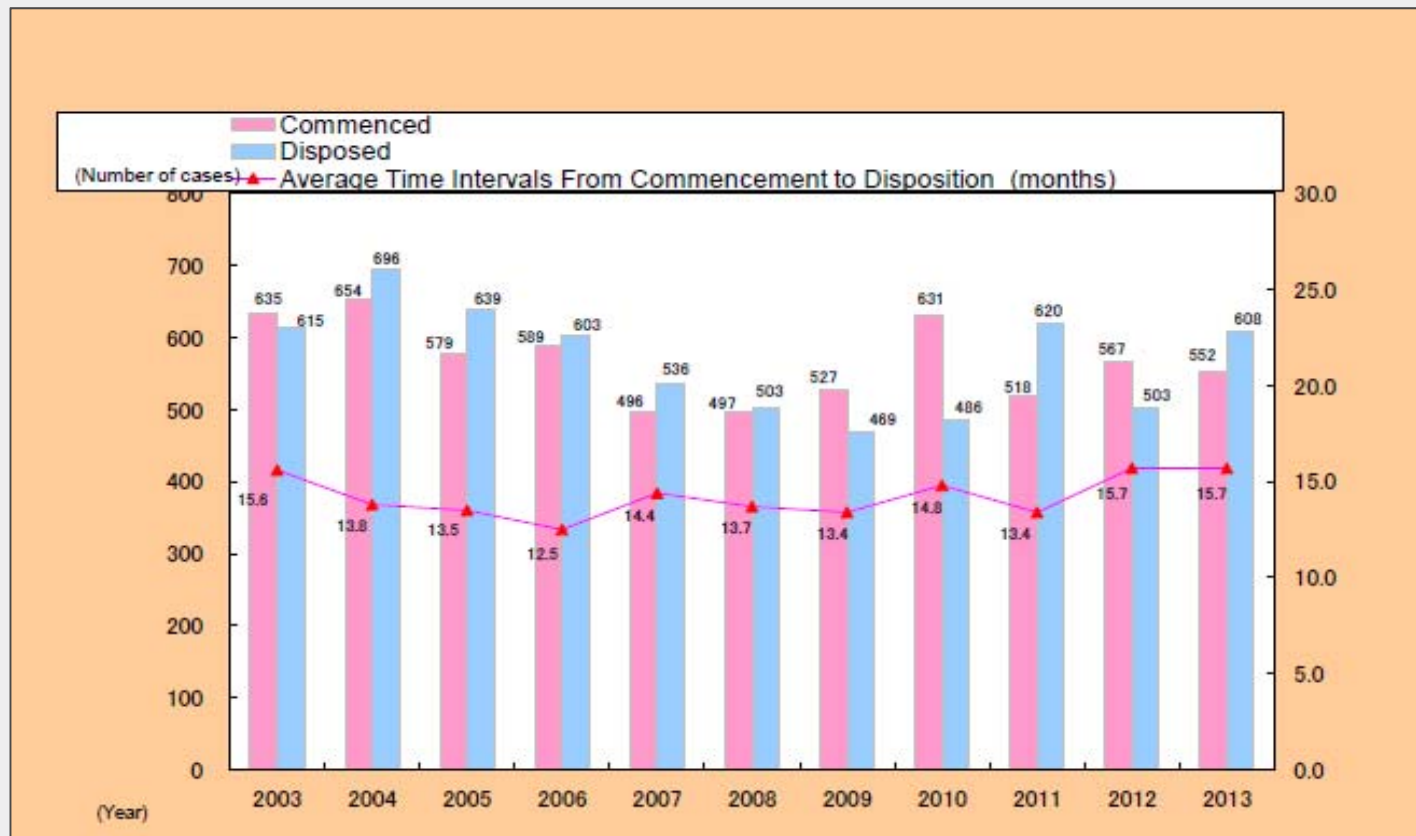
The sum of the above-mentioned (A) and (B).

# Duration of IP Litigation in Japan - 1



**Average time interval at the first instance has been stable as about 15 months**

Number of IP cases commenced and disposed, and average time intervals from commencement to disposition (Courts of First Instance : All District courts)

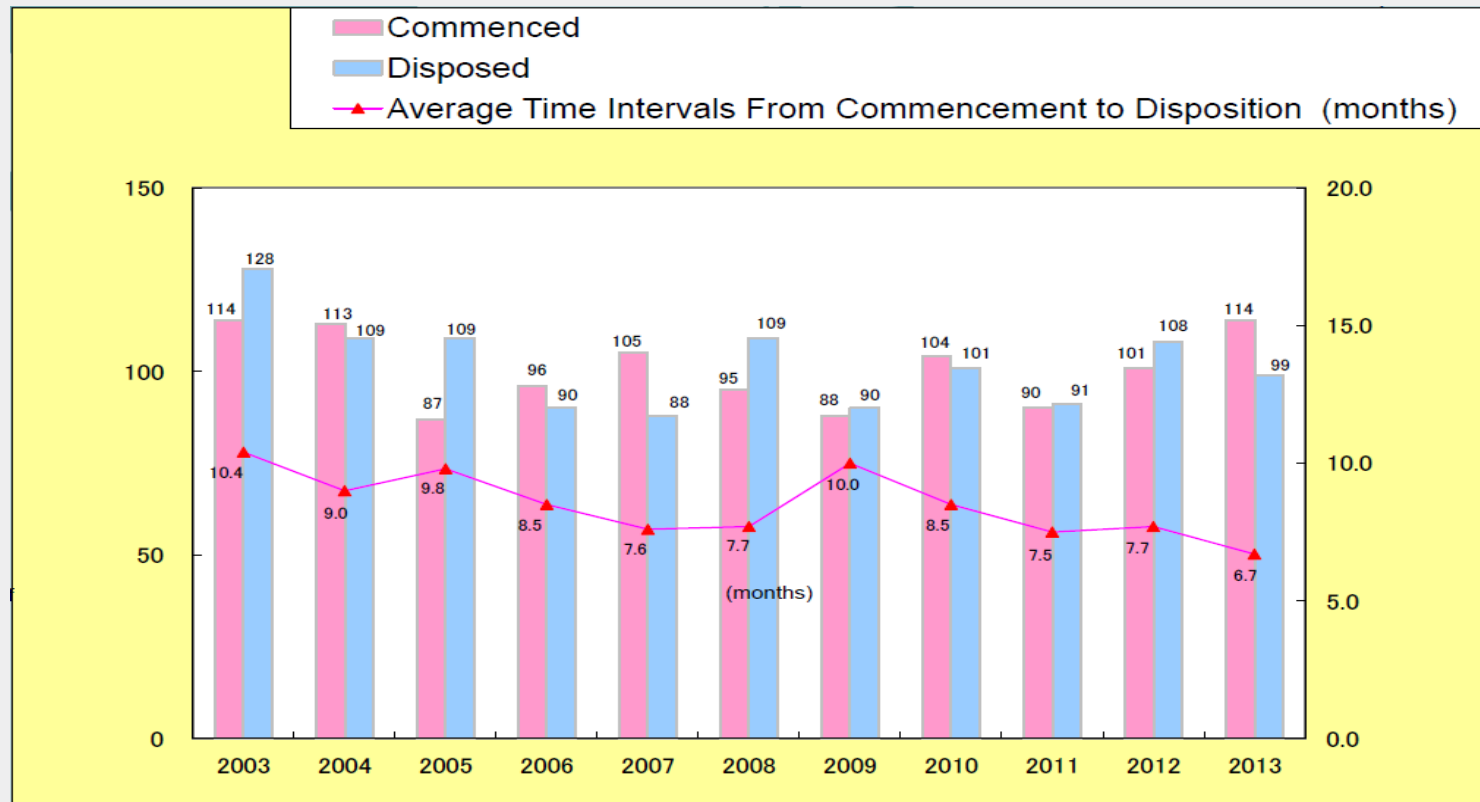


# Duration of IP Litigation in Japan - 2



Average time interval at the second instance has been getting shorter after the establishment of Japan IP High court

Number of IP Appeal Cases commenced and disposed, and average time intervals from commencement to disposition Court of Second Instance : Intellectual Property High Court (~ March 31 2005 Tokyo High Court)





# Summary of Duration and Total Cost



Average length	Total Cost including attorney fee **
District Court : 15.7 month IP High Court : 6.7 month Supreme Court : 12.5 month *	District Court : USD 100,000 - 1 million IP High Court : USD 50,000 – 100,000 Supreme Court : USD 50,000 – 100,000

\* As we could not find any data of average length of the Supreme Court cases, we use the average length of two Supreme court cases from life sciences patent infringement cases.

\*\* As we could not find any data of average total cost of life sciences patent infringement cases, we roughly estimate them based on our experience.

# Judgment v. Settlement on IP Litigation in Japan



➤ Number of all cases concluded all District Courts (FY2011)

Type of case	Total	Judgment	Settlement	Withdrawal
Total Number	212,490 (100%)	70,690 (33%)	68,857 (32%)	61,865 (29%)
Intellectual Property	585 (100%)	269 (46%)	174 (30%)	90 (15%)
Intellectual Property (w/ monetary claim)	409 (100%)	215 (53%)	102 (25%)	61 (15%)
Intellectual Property (w/o monetary claim)	176 (100%)	54 (31%)	72 (39%)	29 (16%)

- In general, cases conclude by settlement rather than by judgment, because "withdrawal" also includes out-of-court settlement.
- In IP-related cases, the ratio of ending by settlement or withdrawal is lower than the average of all types of cases.
- However, the trend is significantly different between IP-related cases *with* damage claim and the one *without* damage claim. IP-related cases *with* damage claim tend to conclude by judgment.

# Other Procedural Aspects of IP Litigation in Japan



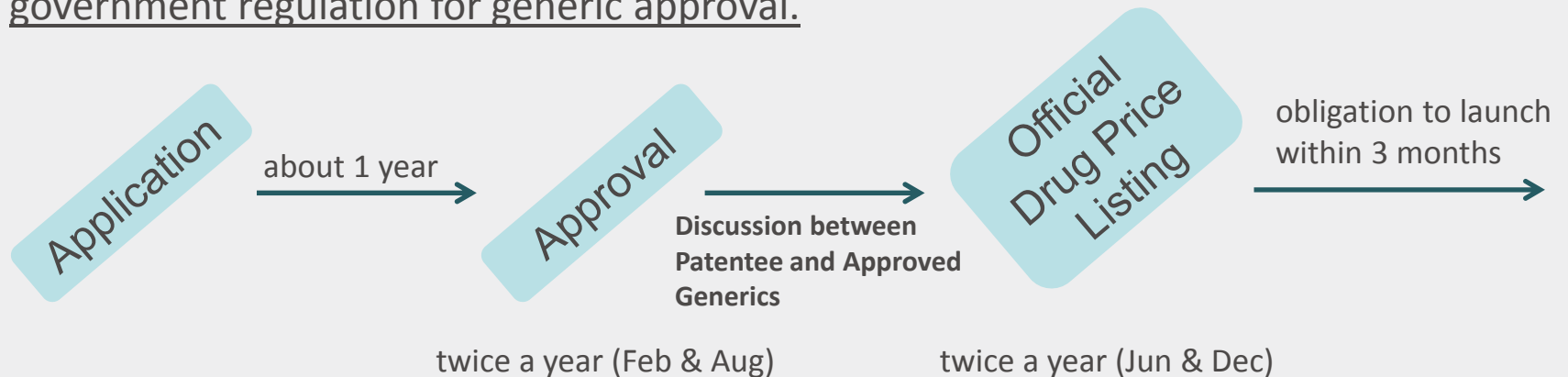
- Introduction of Protective Order in Japan
  - Protective order is a court order that prevents the disclosure of sensitive information (*e.g.* trade secret) except to certain necessary individuals (*e.g.* outside counsel) under certain conditions.
  - As there is no fact discovery in Japan, there had been no procedure like Protective Order in Japanese court system.
  - In 2005, in order to facilitate fact-finding in Civil Patent Infringement Lawsuit while strengthening protection of a trade secret, a procedure like Protective Order was introduced (Patent Act Article 105-4).
  - However, this procedure is not often utilized. It is said that this is because parties (or its outside counsel) are afraid of the possibility of criminal penalty due to an alleged breach of Protective Order (Patent Act Article 200-2).

# Enforceability of IP Rights in Japan – 1



## De fact Patent Linkage under Government Regulation (1)

- In order for patent infringement dispute against generics to be practically enforceable and workable, an immediate injunctive relief is necessary to prevent market erosion by generics. However, a preliminary injunction is rarely granted in Japan.
- Patent Linkage system can work as a kind of injunction to prevent generics from launching its product before patent expiration or dispute resolution. In Japan, there is no legitimate patent linkage, but there is a de fact patent linkage under a government regulation for generic approval.



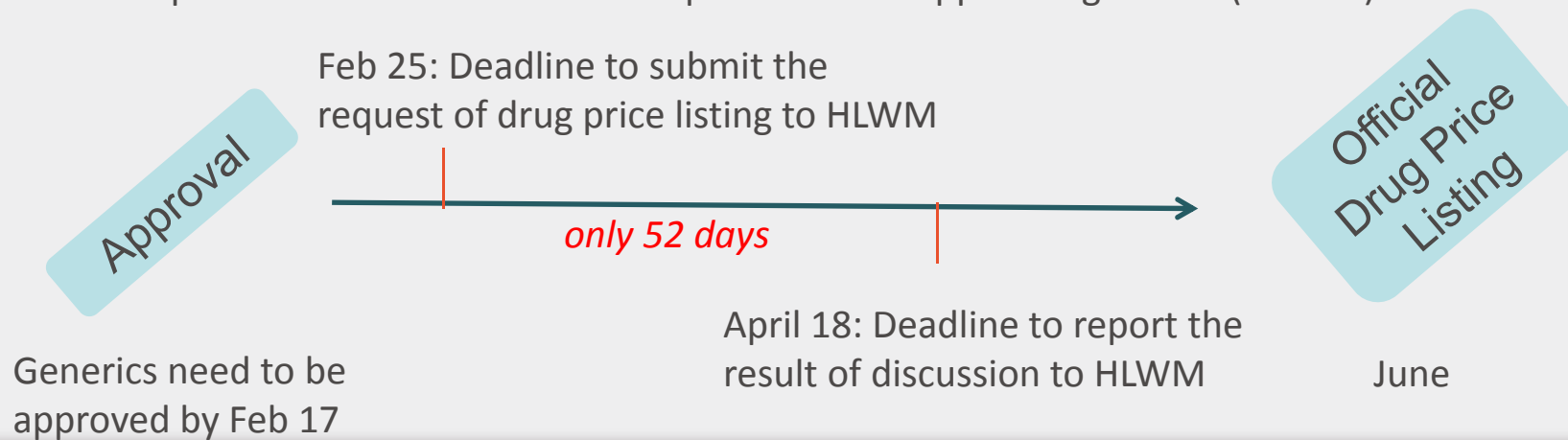
- **Before expiration of a substance (molecule/compound/NCE) or a second medical use patent, Japan Health, Labour and Welfare Ministry (HLWM) does not approve generic products which could infringe these patents from the viewpoint of stable supply of approved products.**

# Enforceability of IP Rights in Japan – 1



## De fact Patent Linkage under Government Regulation (2)

- Japan Health, Labour and Welfare Ministry (HLWM) does NOT take into consideration other types of patents (pharmaceutical formulation, method of manufacturing *etc.*).
  - Before official price listing of approved generic products, a discussion between patentees and generics are guided under a government regulation (not by law).
  - Because of lack of automatic stay of generic approval like Hatch-Waxman statute in the US and the very limited time period for the discussion, the discussion between patentees and generics often ends inconclusively, which results in generic erosion.
- The process of discussion between patentee and approved generics (FY2015)



# Enforceability of IP Rights in Japan – 2

## Patent Protection of Second Medical Use in Japan (1)



- Second medical use is an invention which is based on a discovery of a new medical usage of a known compound. It constitutes an important part of life-science innovation.
- An innovation needs to be properly protected under the Patent Law at the beginning.
- However, **a medical use invention basically needs to be claimed as an invention of "a product" in Japan.** It cannot be claimed as a method of treating patients by the medicine. Therefore, a patent right on the second medical use invention cannot be granted in a straightforward manner, though being a method is an essential aspect of the invention.

US Patent 5965584	JP Patent 3973280
<p>Claim 6: <b><u>A method for treating diabetes</u></b> in a mammal in need thereof, which comprises administering to such mammal a therapeutically effective amount of an insulin sensitivity enhancer in combination with a biguanide, wherein the insulin sensitivity enhancer is selected from the group consisting of: ... (3) pioglitazone or its pharmacologically acceptable salt, ...</p>	<p>Claim 1: <b><u>A medicament for treating or preventing diabetes or diabetic complications,</u></b> which comprises pioglitazone or its pharmacologically acceptable salt in combination with at least one of biguanides or statins.</p>



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