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Benefits of Japanese Patents from the Viewpoint of US Companies

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Overview

- Introduction
- Pro-Patent Decisions from Japanese Courts
- Why obtain patents in Japan?
- Real World Example

Introduction

- Many U.S. companies believe Japanese patents of limited value
 - Based on history no longer applicable
 - Situation prior to 2005
 - Invalidation trials at JPO
 - highly likely to find patents invalid
 - courts typically upheld JPO
 - Damages
 - Only minor damages available after finding infringement
 - No enhanced damages for willfulness
- By early 2000's, weakness of patents recognized as adversely affecting Japanese economy
 - Intellectual Property High Court founded 2005
 - Since 2005, both courts and JPO have taken more pro-patent positions

Doctrine of Equivalents in Japan

Background

Case number: H26(KE)10002



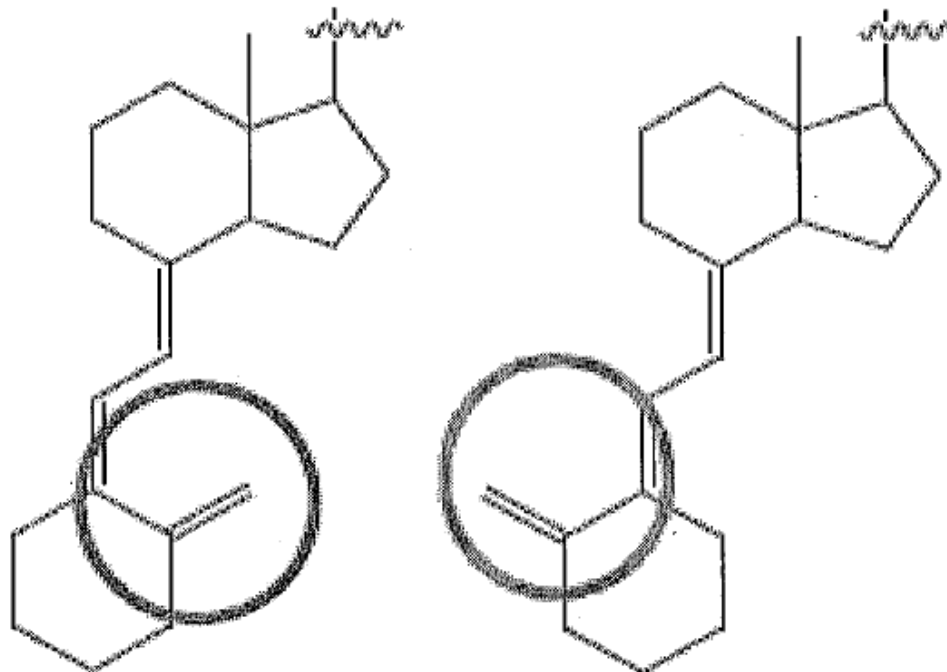
Sued for infringing
based on manufacturing
method



- Product: Oxarol ointment including Maxacalcitol for keratosis

Relationship between Patent and Manufacturing Method

- Accused method does not literally meet the claim limitation because the claim recites the cis-isomer while the accused infringers used trans-isomer



cis-isomer

trans-isomer

Supreme Court Decision

- Supreme Court concluded infringement occurred under doctrine of equivalents
 - The patentee could have easily conceived of the structure of the generic product.
 - The patentee did not intentionally exclude the trans-isomer from the patent claim during prosecution even if the trans-isomer did not fall into the patent claim.

Osaka High Court Decision under Doctrine of Equivalents

Background

Case number: H28-1242

Genentech



Sued for infringing
based on biological
product

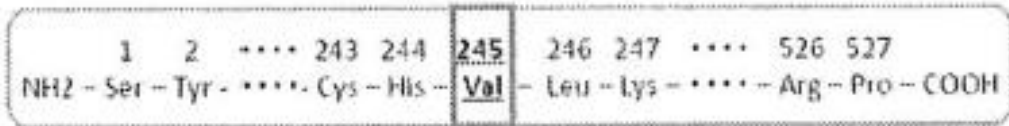


- Product: Plasminogen activator (t-PA)

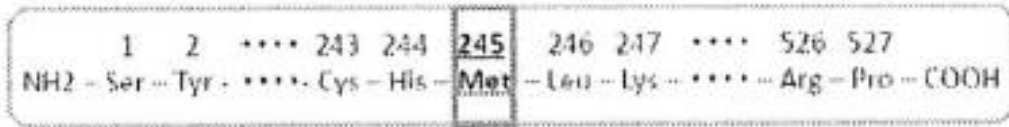
Relationship between Patent and Manufacturing Method

- t-PA in accused product has methionine (Met) at position 245
- Patent claim recited valine (Val) at position 245
- No other differences between accused t-PA and patent.

Patent's t-PA



Sumitomo's t-PA



Osaka High Court Decision

- Osaka high court affirmed infringement under doctrine of equivalents.
 - Met at position 245 from N-terminal has same characteristic as Val
 - Accused t-PA has same effect as patent's t-PA
 - Replacement of one amino acid for another under these conditions meets requirement for equivalent replacement under Japanese law.

IP High Court Decision Regarding validity of Patent

Background

Case number: H26(KE)10045

- JPO had invalidated Novartis patent for use of Zoledronic acid (Zoledronate)

Claim of JP Patent Application No. 2001-585739:

“A treatment agent containing [Zoledronate], wherein 4 mg of Zoledronate is to be administered intravenously over a period of 15 minutes to a patient.”

Relationship between Patent and Prior Art

- Claim has three main limitations:
 - (A) 4 mg of Zoledronate
 - (B) IV administration
 - (C) 15 minute administration period
- D1
 - Discloses (A) and (B)
 - Discloses 5 minute administration period
- D2
 - Discloses range of 5-30 minute administration period, with an example of a 20 minute administration period
- D3
 - Discloses slow administration is preferred

IP High Court Decision

- JP patent office had concluded “15 minutes” was obvious over D1 in view of D2 and D3 under Japanese law.
- IP high court concluded that there was no motivation to specifically identify a time of “15 minutes” based on “5 minutes” of D1 even in view of D2 and D3 under Japanese law.
- IP high court rescinded the JP patent office’s decision.

Why obtain patents in Japan?

Law Favors Patent Holders

- Foregoing decisions may have gone against patentee in USA
 - Cis-isomer is the opposite of trans-isomer and therefore might be considered not equivalent
 - Some cases in US have held that single amino acid change is not an equivalent
 - A showing of criticality generally required to support nonobviousness of specific numeric criteria
- The examples are from pharma, but similar results in other fields

Japanese Economy Remains Vibrant

- Japan remains third largest economy in the world
 - Behind only USA and China
 - China remains much more difficult to do business
- ~50 of Fortune Global 500 are Japanese companies
- Population of >125,000,000
 - Not growing, but sophisticated consumers
 - Slow GDP growth yields moderate GDP per capita growth

Japanese Culture Respects Patents

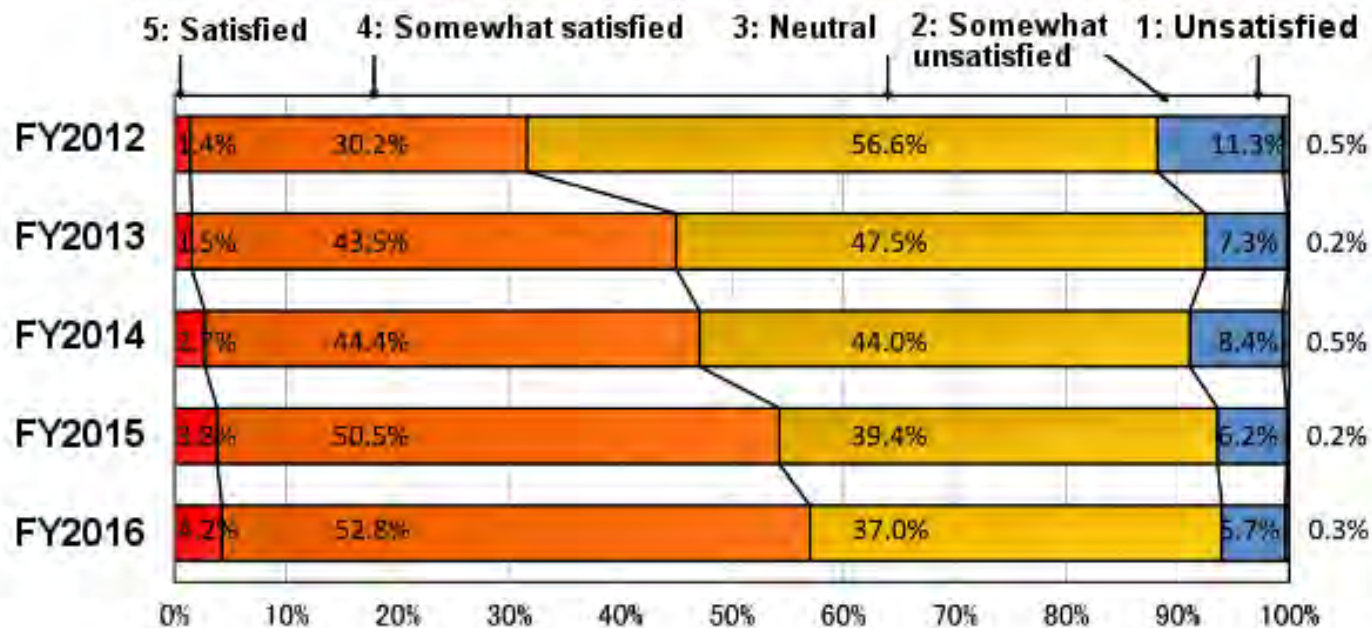
- Relatively few patent cases are filed
 - Companies typically settle patent disputes without need for lawsuit
 - Culturally-sensitive approach required
 - US-style cease & desist letter not taken well
 - Both legal and business representatives recommended
- In many Asian countries, patents seen as foreign concept
 - Patent system much more developed in Japan
 - Rudimentary patent system introduced in Japan in 1871
 - More robust patent system introduced in Japan in 1885
 - Many decades for cultural sense to develop in Japan that inventions should not be stolen

When litigation is necessary

- Costs much lower than US
 - Very limited discovery
- Attorney-client privilege available
- Injunctive relief readily available
- Damage awards have increased since IP High Court introduced
 - Still much lower than US
 - Record award is about US\$74,000,000
 - At least ten cases with awards above US\$2,000,000
 - Awards above US\$1,000,000 remain relatively rare, but increasing

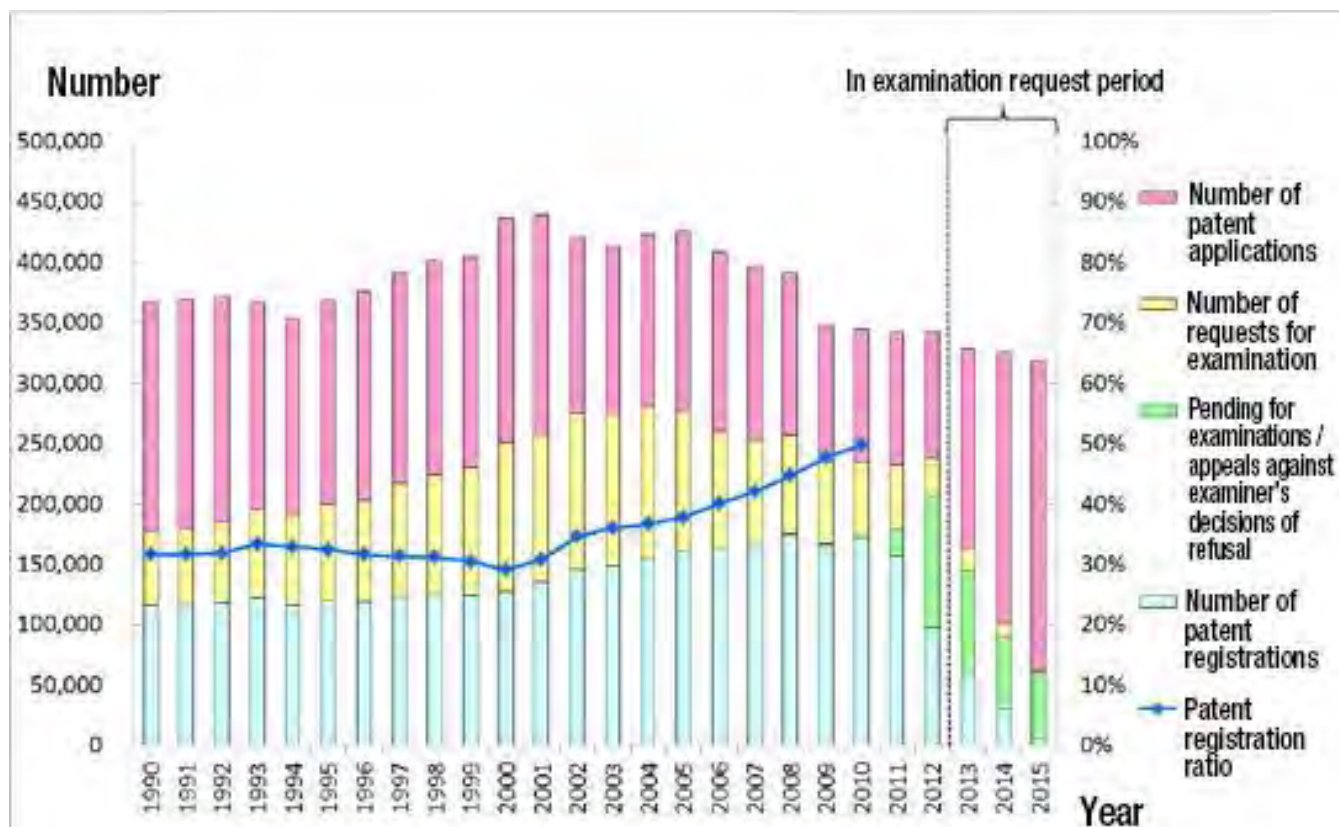
JPO becoming user friendly

Satisfaction with examination at JPO is increasing rapidly



Survey of “users” of JPO, i.e. attorneys and applicants

Decreasing Applications yield benefits to Applicants

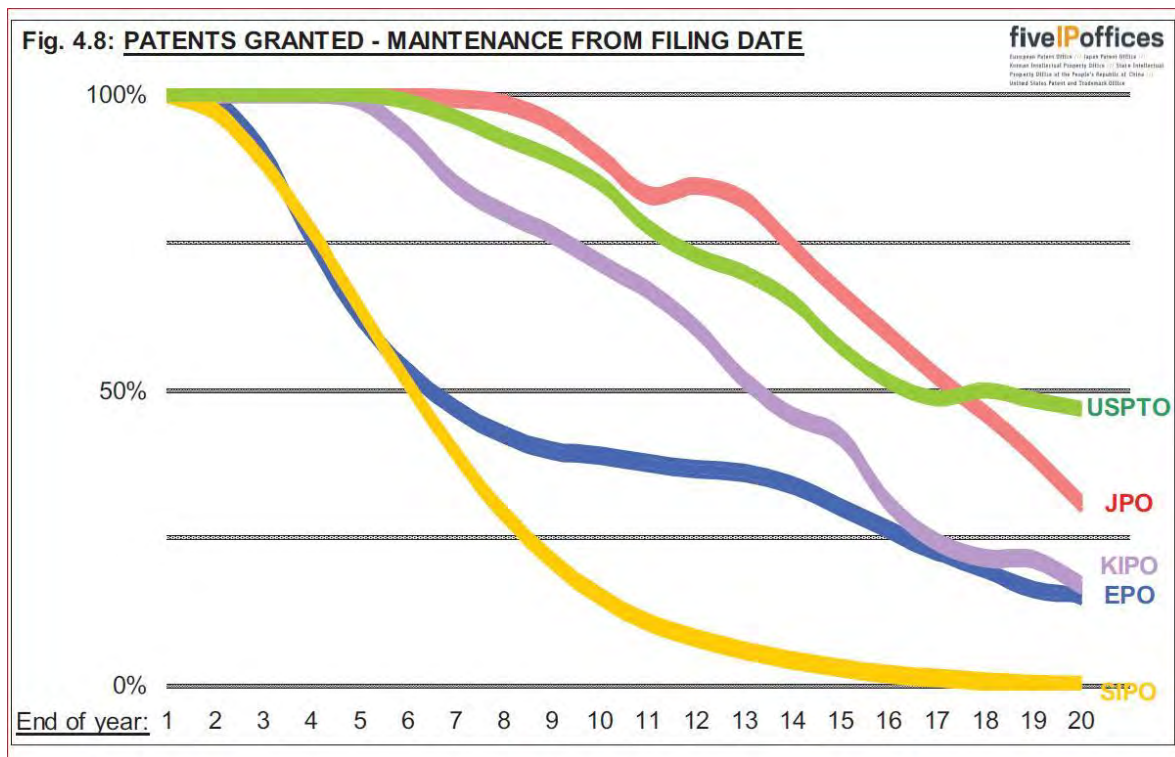


Increasing allowance rate (blue line)

Decreasing Applications Yield Benefits to Applicants

- Time to first action at JPO is now targeted at 11 months
- Time to grant is now targeted at 14 months
 - Compare to targets at other Global 5 Patent Offices
 - USPTO: 20 months
 - EPO: 27 months
 - SIPO: 22 months
 - KIPO: 16 months

Relatively Inexpensive Patent Maintenance Fees



- No maintenance fees prior to grant
- Fees low in first ten years after grant
- Higher percentage of patents maintained

Real World Example

Client with pharmaceutical invention

- Client had licensed invention to European pharma company
 - Not particularly good deal for client
 - Client received one-time flat fee of \$1,000,000, while EP pharma company made 100 times that amount every year
 - License covered only US, Canada and Europe

Client with pharmaceutical invention (cont'd)

- Client made improvement to invention
 - Pursuant to license agreement, EP pharma company obtained royalty-free license in US, Canada and Europe
 - However, client free to pursue other licenses in other countries
 - Pharma company obtained patent for improvement in US, Canada and Europe
 - Client obtained patent in China and Japan
 - Rights to improvement in Japan licensed to Japanese pharma company

Client with pharmaceutical invention (cont'd)

- Japanese pharma company willing to pay substantially more than EP pharma company
 - Commercial value of invention already proven
 - Paid client up-front fee, milestone payments and ongoing royalty

Other technologies

- Japan particularly suitable for pharma and medical inventions due to aging population
- But, Japan also major market for electronics and consumer goods
- Success can be achieved in Japan in all fields

Thank you!
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Orange County



Los Angeles



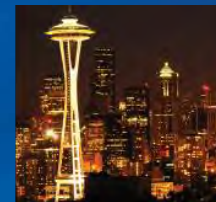
New York



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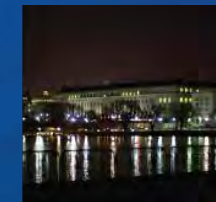
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Silicon Valley



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