



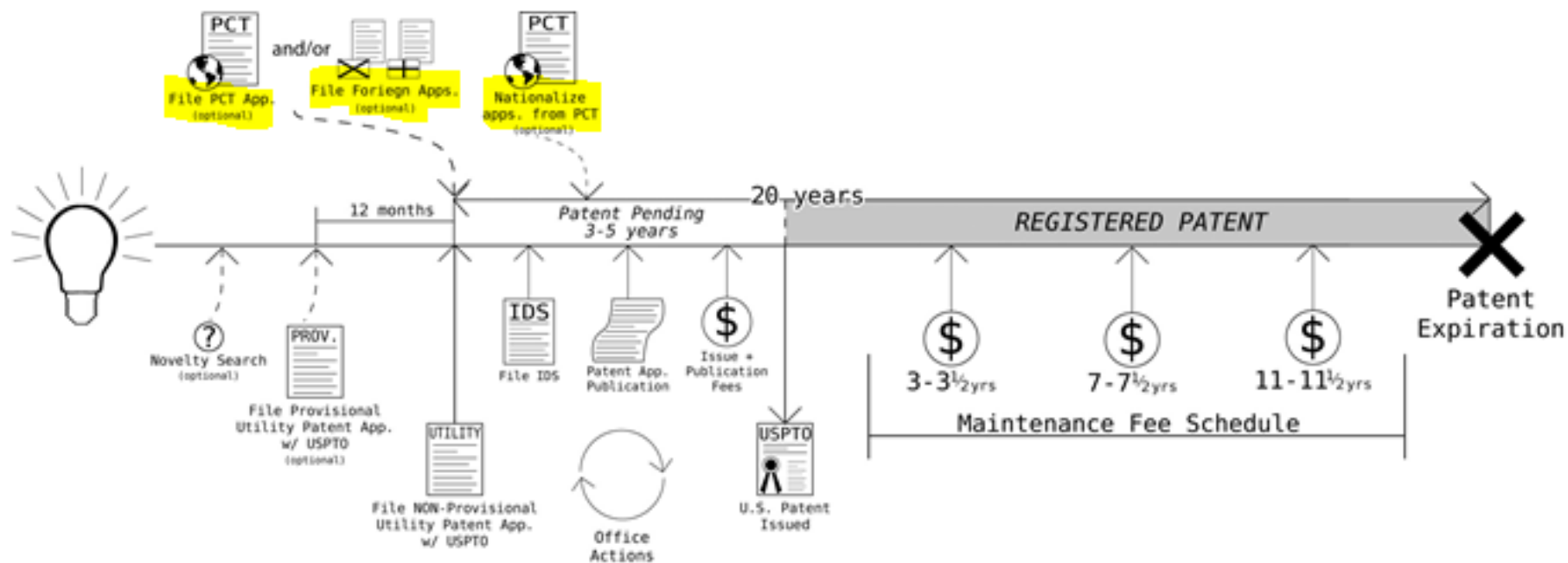
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Foreign Filing Strategies - Considerations in Protecting Your Patents Globally

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Fish & Richardson Patent Webinar Series
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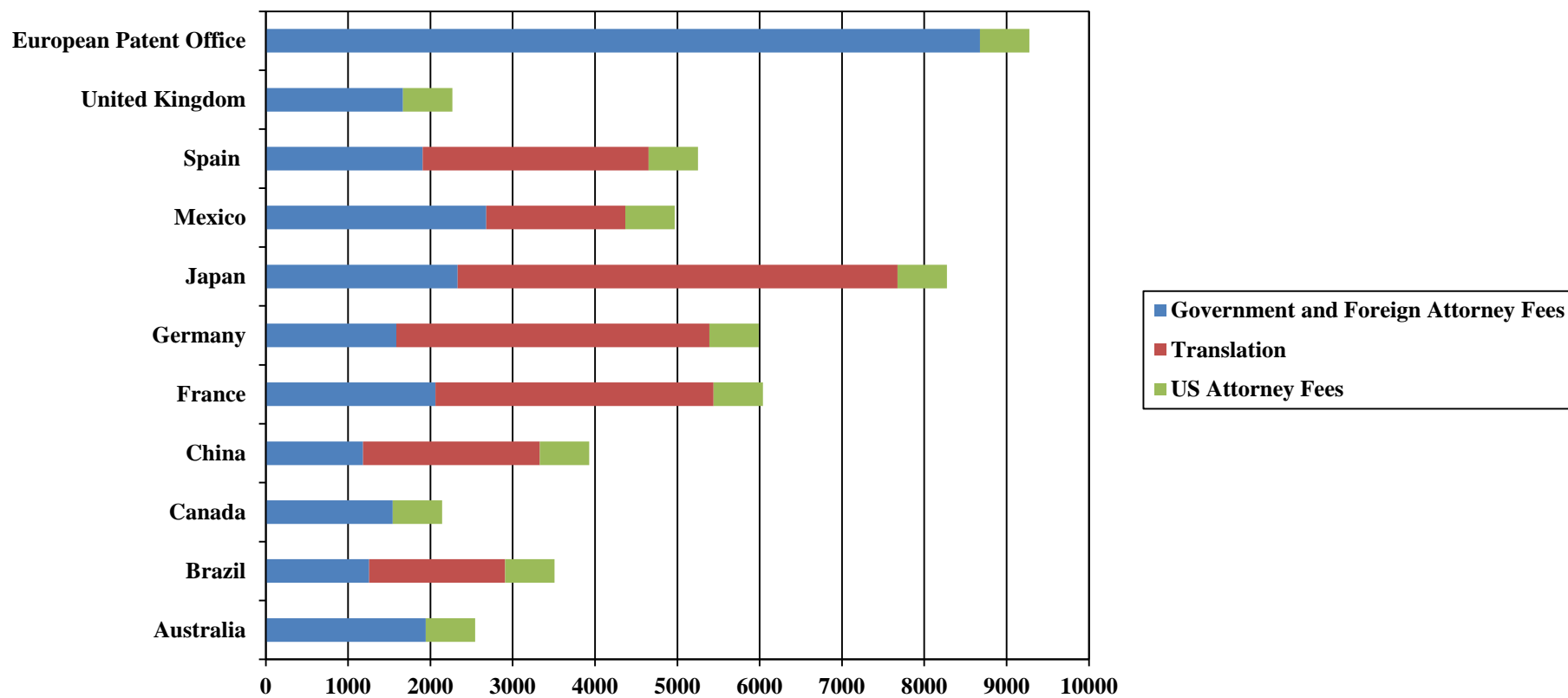


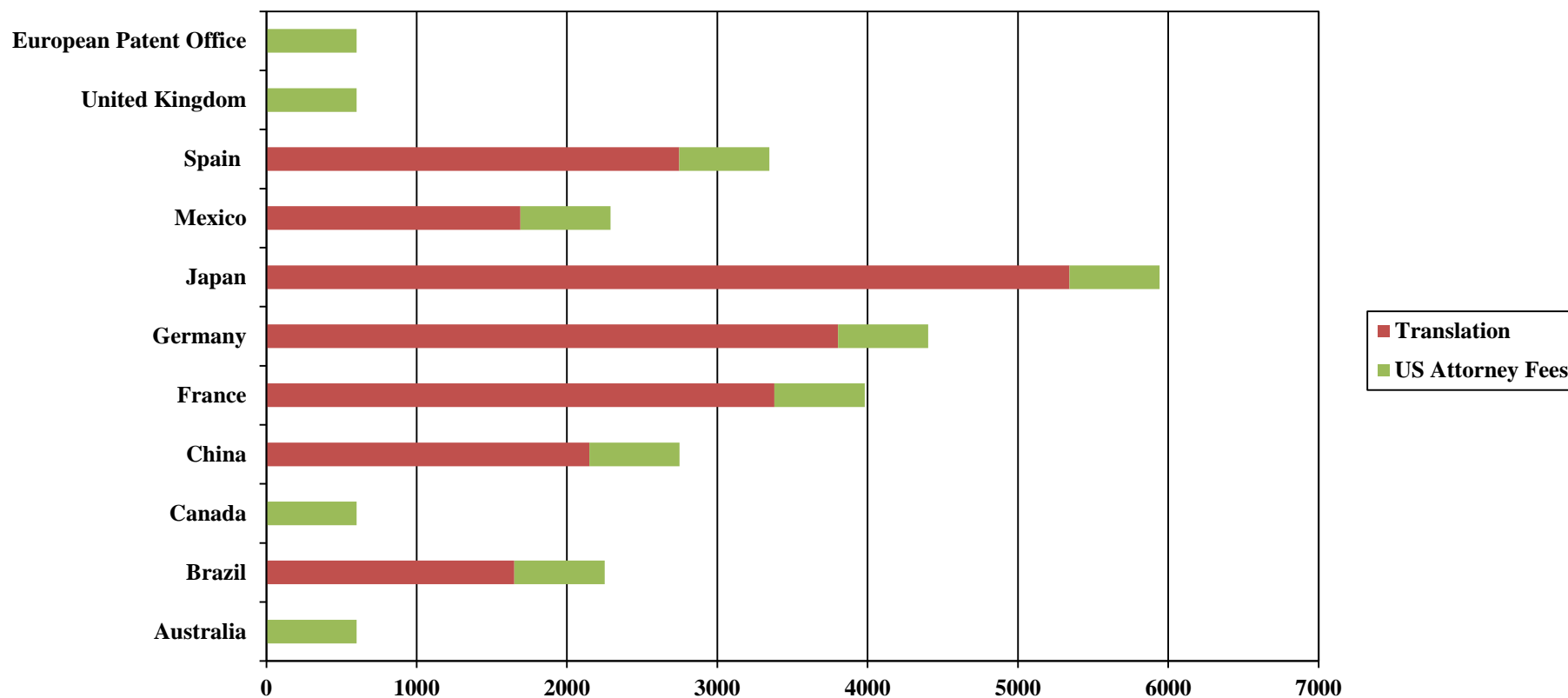
- Foreign filing
- Considerations
- Where **Not** to File
- Where to File
- Decision-making process
- Ongoing survey relating to foreign filing strategies



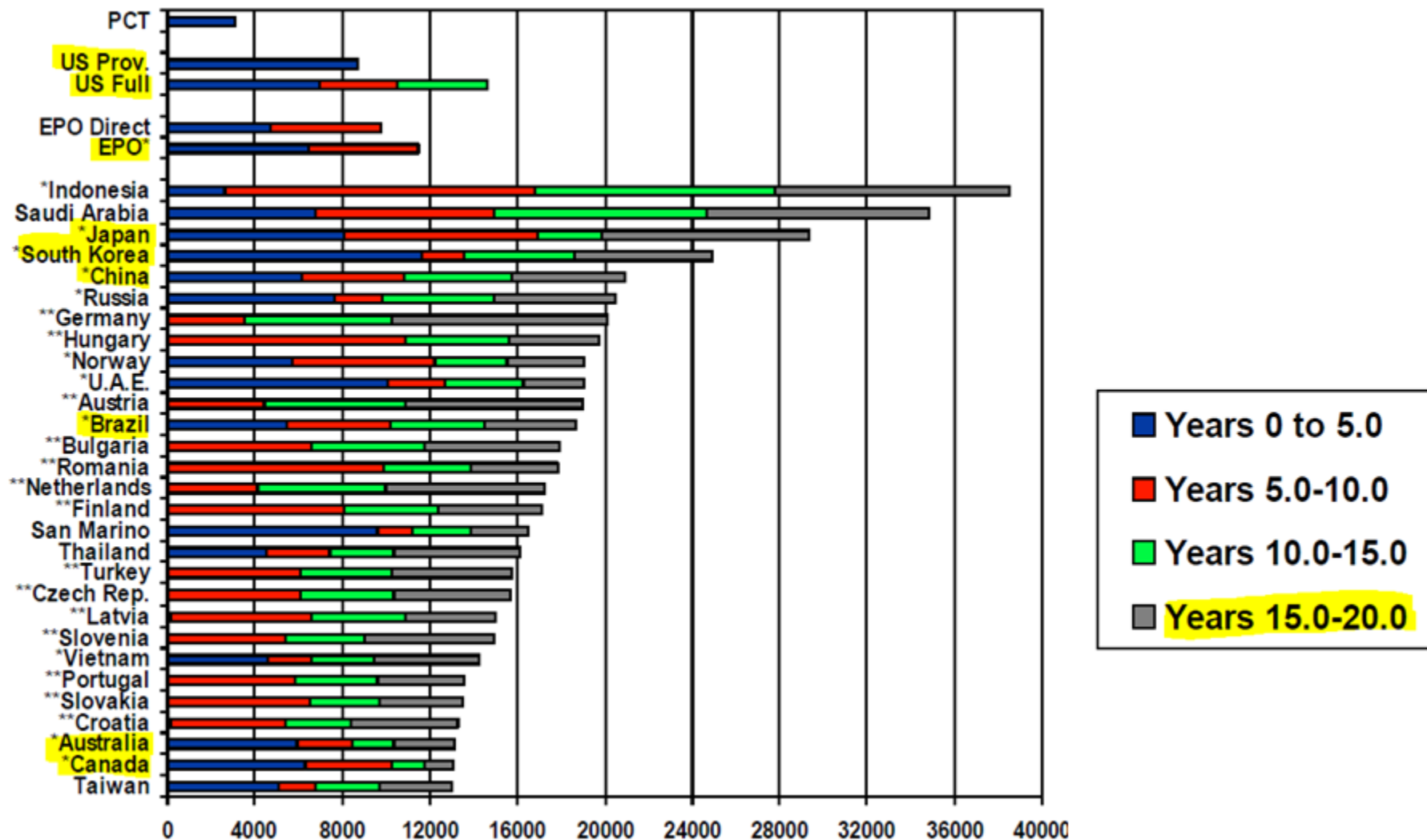
- Company's goals
- Company's profile
- Company's resources to be devoted to patent protection

Resources (Filing fees)



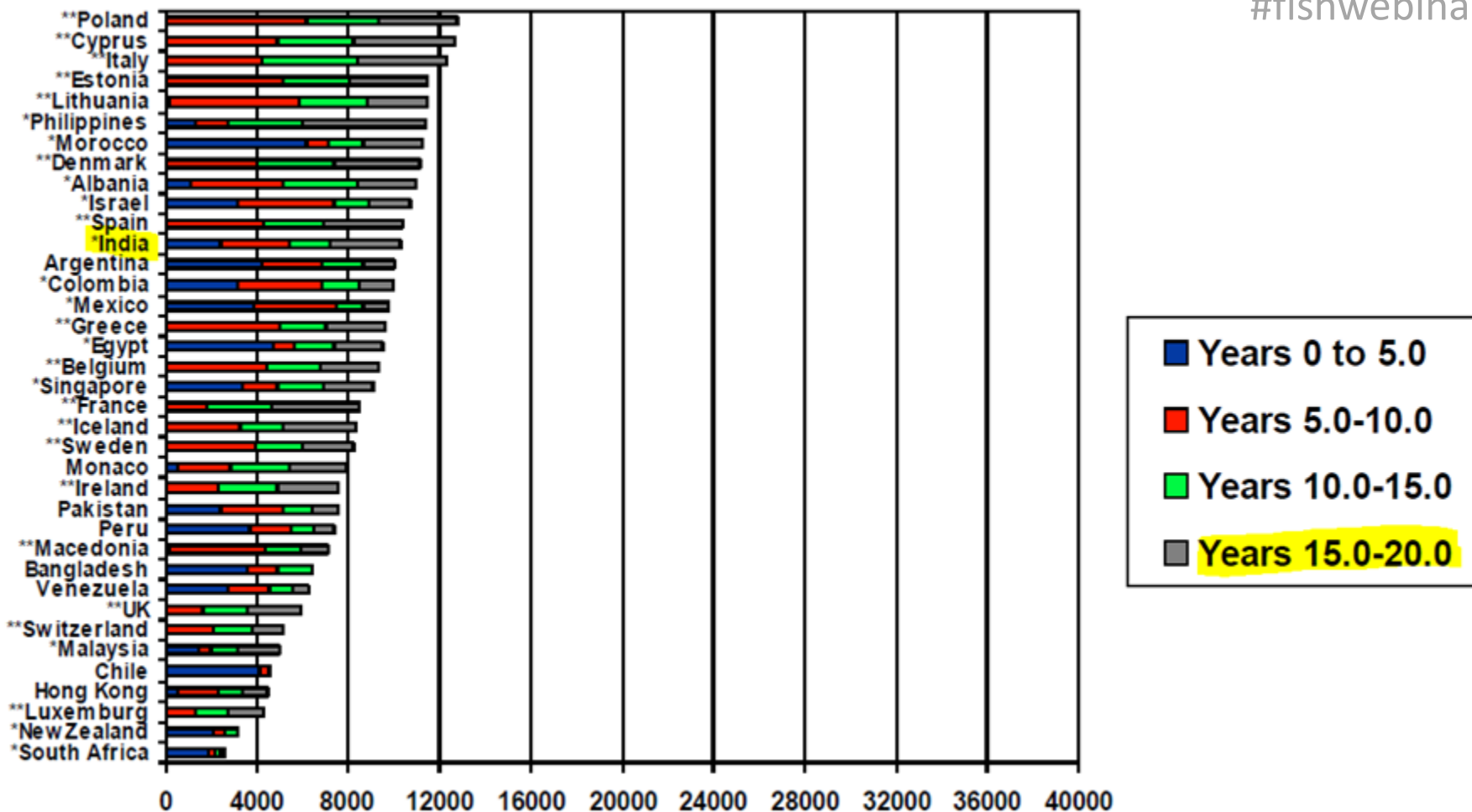


Resources (life of patent)



Resources (life of patent)

#fishwebinar



1. Patent system in each country

- The “adequacy” of the patent and legal systems including:
 - considerations relating to enforcing the patent right, including costs, timing, immediate remedies, long-term remedies, availability/size of damage awards, etc.
 - the current and expected future state of the patent law relevant to enforcement of the patent

1a. Procurement of patent

- Costs and relative ease/difficulty of filing and prosecution
- Availability of delayed examination and accelerated examination
- Length of examination period
- Grace periods following public disclosure v. absolute novelty
- Quality of examination
- Patentable and non-patentable subject matter:
 - Pharmaceuticals, methods of medical treatment, etc.
 - Cloned genes, transgenics
 - Software
 - Business methods

1b. Enforcement of patent

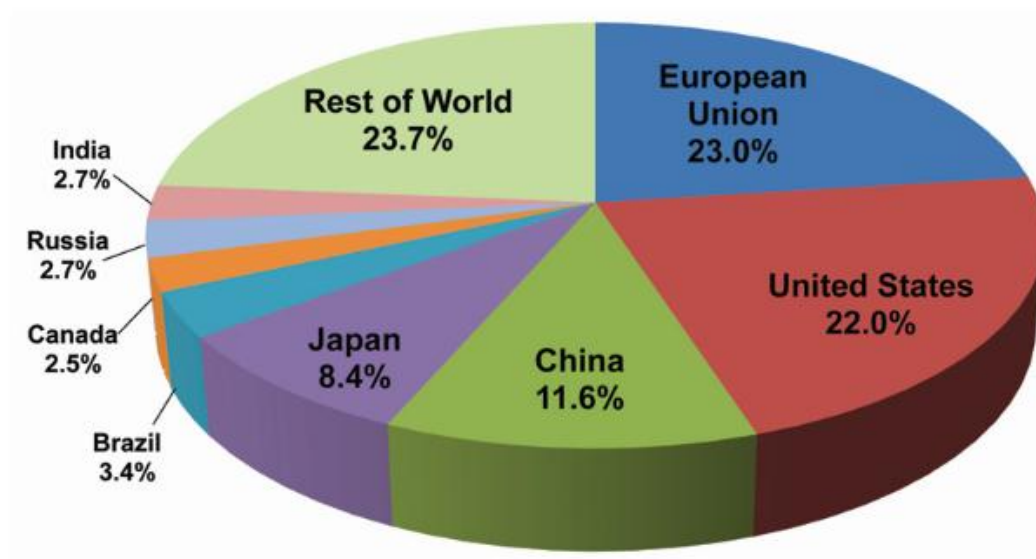
- Border Protection (customs?)
- Available remedies for infringement under local law:
 - Preliminary/permanent injunctions, seizure actions, border actions, availability of and amounts of/limits on damage awards, criminal/civil penalties, etc.
- System(s) for dispute resolution
 - Civil courts, patent courts, patent office proceedings, criminal courts, separate validity and infringement proceedings, mediation, arbitration, etc.
- How long for resolution? How expensive?
- Availability of and rules of discovery
- Technical competence of courts
- Historical level and direction of any court bias
- Political/judicial climate:
 - neutral or pro- versus anti- patent
 - neutral or pro- versus anti- foreign patentee

Miscellaneous

- Others types of protection (data protection -- clinical trial data for pharma)
- Availability of patent term extensions
- Ability to get acceptance by conforming claims to those granted in another country
- What do my investors/shareholders want?
- Useful for licensing purposes?
- Are there compulsory licenses?
- What will the country/market look like in 5, 10, 15 years
- **Return on Investment**

General questions to ask

- Where and how big are my markets for the invention? Who is the customer? Who is my competition? Where are my business partners located?
- Where will the product be manufactured? Where will product be used? Where would my competition manufacture its product?







- Fee for patentability examination – went from \$260 to \$ 43.692,64 (up to \$100,000?)
- Annuities – final year fee went from \$570 to over \$20,500
- Long pendency - patent examination may take up to seven years
- Very low allowance rate -- 8 to 10%.
- Various patent fees have increased by about 3600% -
 - BUT – there is a potential discount (up to 90%) on all rates and maintenance procedure to MSMEs, universities legally recognized in the country, independent inventors, public institutions, small and medium farmers, Companies with Popular and Solidarity Economy.
- Ecuadorian Government's current policy is to favor those companies which invest in Ecuador by assigning their patents to local national companies or companies domiciled and producing in Ecuador

General, technology neutral strategy:

- EPO (almost always)
- Huge markets and economies (China, Japan, and India)
- Large markets and economies (South Korea, Brazil, Russia (Eurasian Patent Office?), and Mexico)
- “No translation required” markets (Canada, Australia, and South Africa)
- “Proximity to the US” markets (Canada and Mexico)

Medical device filings

- Almost always file in the EPO
- Japan, China, Korea, Canada, Mexico and Australia



“Tech” patents

- Almost always file in the EPO
- Korea, Japan, Taiwan, India and China
- Canada, Brazil and Australia



NY CLE Code: 586

Pharma/biotech patents

- High commercial significance: Australia; Brazil; Canada; China; Colombia; EPO; Israel; India; Indonesia; Japan; Mexico; Malaysia; New Zealand; Philippines; Russia; South Korea; Singapore; Thailand; Ukraine; Vietnam; and South Africa.
- Medium commercial significance : Australia; Brazil; Canada; China; EPO; Israel; India; Indonesia; Japan; Mexico; New Zealand; Philippines; Russia; Korea; and Singapore.
- Low commercial significance: Canada; China; EPO; Japan; and Mexico.



- Taiwan – expensive translations but patents typically enforceable
- Argentina –examination very slow, no real procedures for accelerating exam; enforcement questionable
- Venezuela - examination very slow; enforcement questionable especially for US held patents

- Initial decision to file the priority application
- At 12 month date, decision to file a PCT application designating all PCT Member States -- as well as individual non-PCT States.
- At 30 months, decision as to where to nationalize (for PCT Member States); also revisit the previous decisions made regarding non-PCT filings.
- During subsequent prosecution, any change in circumstance
- At grant
- At deadlines for payment of maintenance fees/annuities




Ongoing study regarding life sciences companies' foreign filing strategies

- "Where to File: A Framework for Pharmaceutical and Biotechnology Companies to Develop an International Patent Filing Strategy."
- Professor Randy Berholtz and team of IP Fellows at Thomas Jefferson School of Law
- <http://edu.surveymzmo.com/s3/1465783/WHERE-TO-FILE-A-Framework-for-Biotechnology-and-Pharmaceutical-Companies-to-Develop-an-International-Patent-Filing-Strategy>.



Thank You!

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