



# The PCT National Phase: One User's Perspective

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# National Phase Entry

- Who? – the applicant
- What?
- When?
- Where?
- How?

# What:

## National Phase Entry Filing Considerations

- Type of protection
- Preliminary amendment and argument
- Requesting examination
  - Regular examination request at entry
  - Accelerated examination (in some countries):
    - PCT-PPH pilot programs are in place in some countries if the appropriate ISA/IPEA is utilized
    - Some States have national procedures for accelerated examination:
      - EPO (PACE) – no reason necessary
      - GB – will accept request based on favorable PCT results
      - CA – accepts request based on a variety of reasons
      - Other States have accelerated programs – check local agent
  - Deferred examination (in some countries)

# When:

## Early National Phase Entry

- Applicant can enter the national phase at any time after filing up to the national deadline
- No country can require national phase entry before 30 months from priority
- Early national phase entry can be made in different Offices at different times
- Early national processing can only begin at the specific request of the applicant
- Once national phase entry has commenced in a country\*, the national phase application is not affected by:
  - withdrawal of the international application
  - withdrawal of the priority claim in the international application
- If early national phase entry is made before publication, applicant must arrange for a copy of the international application to be provided to the national Office(s) where early entry is being made

\* When national processing or examination has begun; standard varies by country.

# Where: Selecting Countries for Entry

- Four key factors:
  - Business/commercial need for exclusivity
  - Initial and long-term cost
  - Quality of IP protection and enforcement
  - Return on investment

## Business/Commercial Need for Exclusivity

- The single most important consideration in deciding where to file is the business/commercial need for exclusivity in the country under consideration
- Remember:
  - Any country you file should provide an adequate return on the money invested in IP protection
  - Any country you don't file, you will have no claim to exclusivity

# Some Questions to Consider in Determining the Business/Commercial Need for Exclusivity (1)

- What is your purpose – manufacturing/sales, licensing, selling the patent right, defensive?
- Where is the market for the invention – local, regional, global? Who is the customer for the invention? Who is the competition?
- Where will the claimed product be manufactured or the claimed process used? Where does the competition manufacture its products?
- Is the invention of interest or use to the competition? What patents do your competitors hold? What development direction are they taking?
- How easy (or difficult) would it be for competition to design around the claimed invention? How long and what resources would it take?

## Some Questions to Consider in Determining the Business/Commercial Need for Exclusivity (2)

- How easy (or difficult) would it be for a third party to copy the invention? Is there an incentive to copy your invention in “unprotected” countries?
- How costly would it be for a third party to copy and market the invention?
- What is the smallest market size that would economically justify a third party copying the invention?
- Is the market for your invention growing, declining or stagnant in the country?
- Is the invention on-point with your marketing strategy or is it defensive? Is it a break-through invention or a minor improvement?
- What are the consequences to your business if the invention is copied in some/all countries?



# Some Questions to Consider in Determining the Business/Commercial Need for Exclusivity (3)

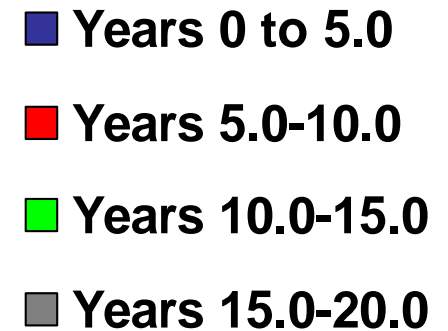
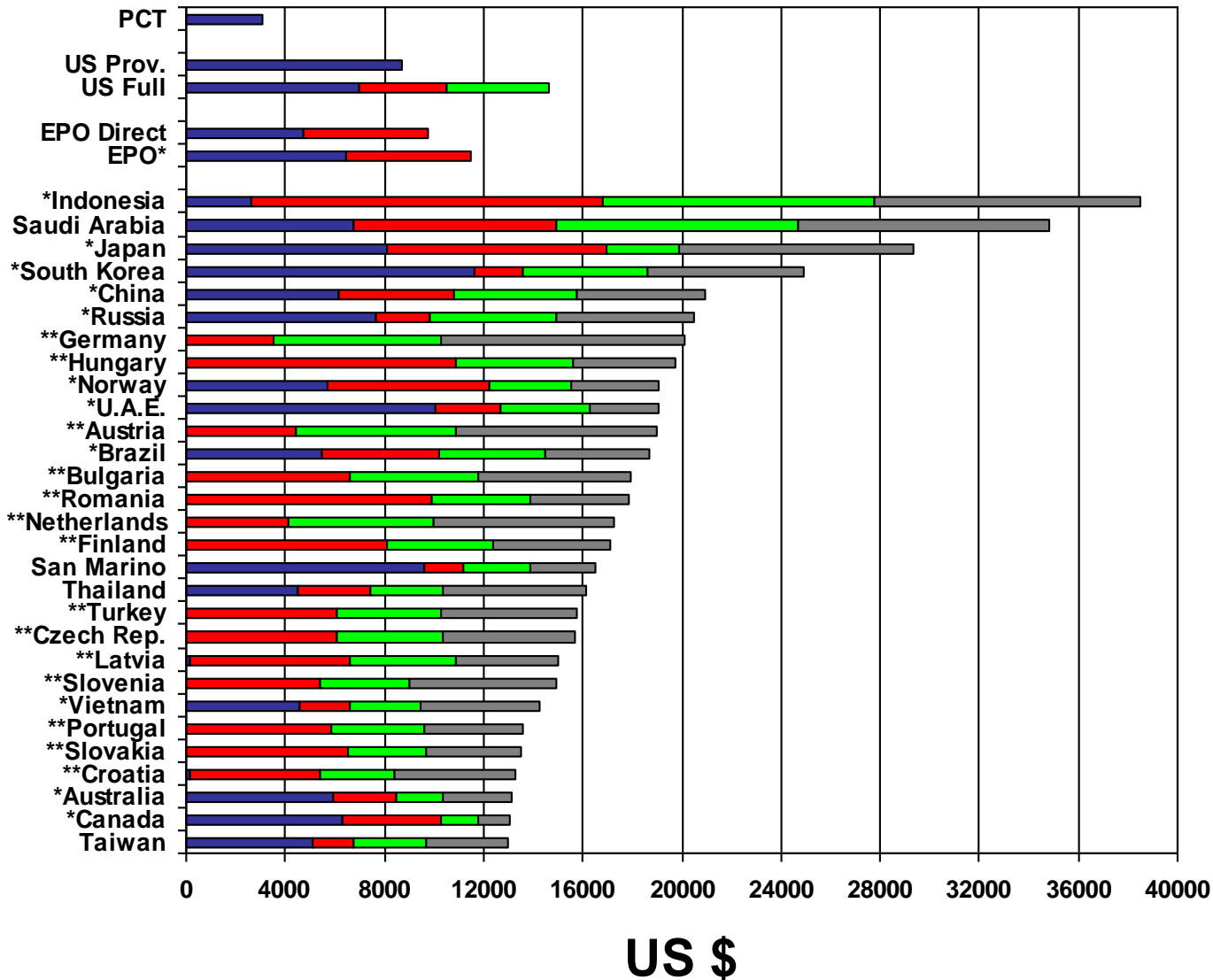
- By geographic area, what is critical? Is freedom-to-practice sufficient? Is exclusivity really needed?
- Is there licensing/cross-licensing value in the country?
- What portion of your total market is represented by the country under consideration for filing/maintenance?
- For what period of time and where is exclusivity commercially important? How long does it take to get a patent in these countries? What is the local law regarding provisional protection?
- What is your patenting budget? What other developments are competing for this budget money?
- What is the current state of the patent law, procurement and enforcement systems? Is it changing for the better? Worse?

## Initial and Long-term Cost

- The cost to file, prosecute, grant and maintain a patent varies widely by country
- Comparing the costs across different countries during various periods of time in a patent's life show the breadth of this variation

# Relative Cost to Obtain and Maintain A Patent

(Data from 2008/2009)

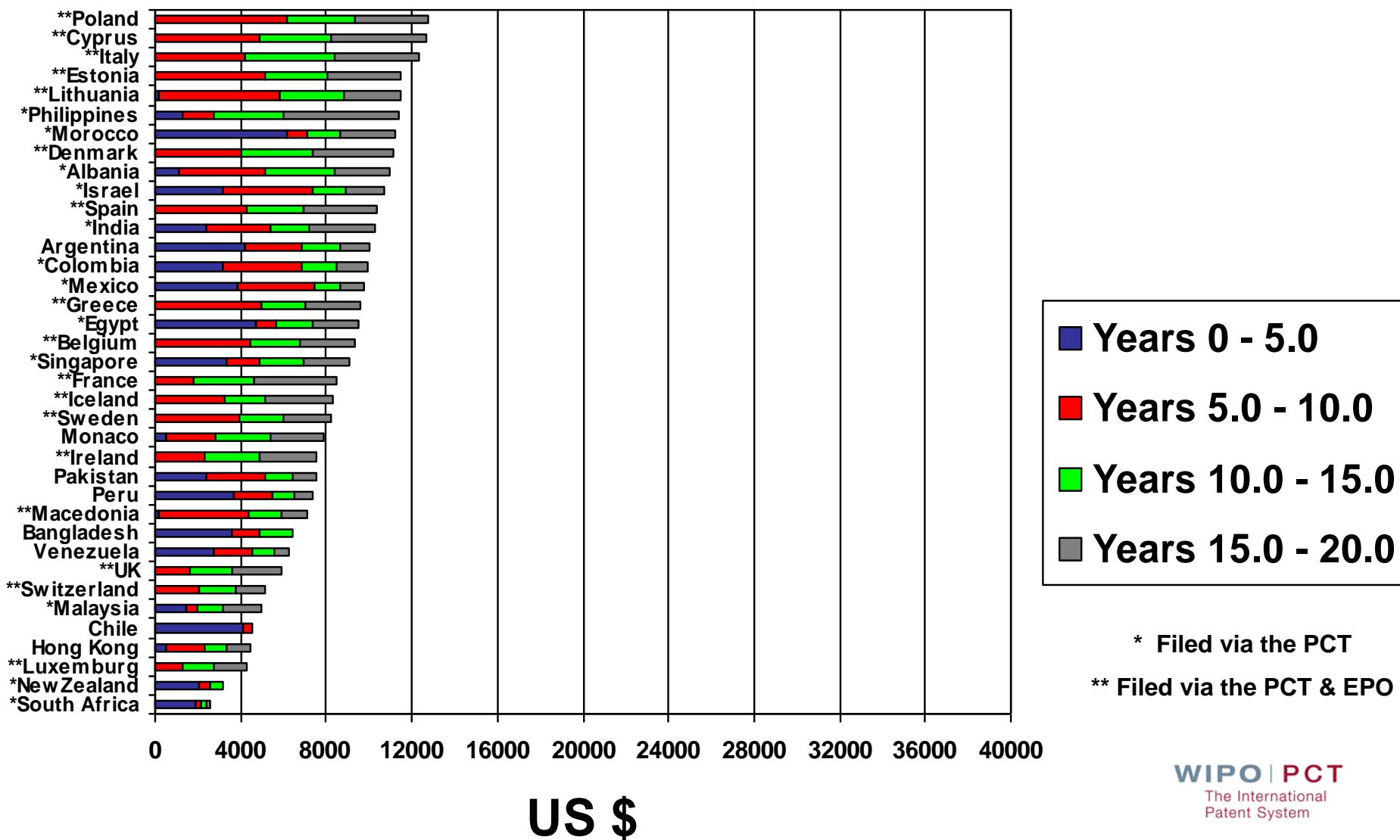


\* Filed via the PCT

\*\* Filed via the PCT & EPO

# Relative Cost to Obtain and Maintain A Patent

(Data from 2008/2009)



# Important Information Regarding Cost Data Charts

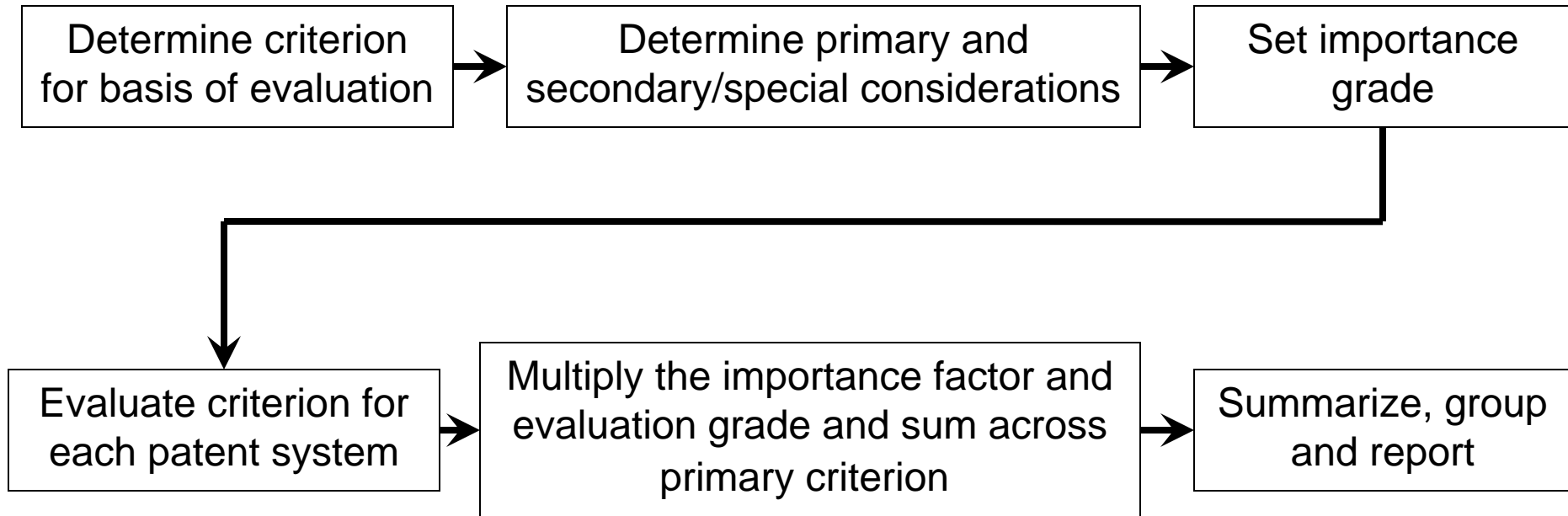
- Cost data is a compilation of actual charges billed to a company over a period of years coupled with current published annuity data
- The costs of company attorneys and agents are NOT included in the figures (EP, US and PCT costs are separated from the other data since the company acts as their own agents for those proceedings and consequently there are no local agent fees included in the listed costs as there are for all other countries)
- Data is current as of 2008/2009; official fees, exchange rates and professional costs change over time
- Data is based on applications filed in English. Translation costs included in the data are for required translations into non-English languages
- Costs are in US\$ using exchange rates applicable at the time the charges were received
- Data should be used for “order of magnitude” cross-country cost comparisons ONLY. Figures are historic and are not sufficiently accurate to project actual cost of a new filing

# Quality of Patent and Ability to Enforce

- 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
  - considerations relating to obtaining an enforceable patent including costs, timing, quality of examination, etc.

are key to judging the quality of any patent system and the ability to successfully enforce a patent

# A Process for Evaluating the Quality of a Patent and Enforcement System



# Possible Key Criteria Relating to Obtaining a Patent (1)

- Cost and ease of filing and prosecution
- Competence and reasonableness of examiners
- Duration of examination
- Quality of examination
- Type, duration, cost and reasonableness of appeals
- Type, duration and cost of oppositions
- Announced/expected/contemplated changes in patent Office operations



# Possible Key Criteria Relating to Obtaining a Patent (2)

- Patentable and non-patentable subject matter:
  - pharmaceuticals, secondary uses, business methods, software,
  - methods of medical treatment, chemical compounds, etc.
- Novelty standards (for both publication and use)
- “Grace” periods following public exposure
- WTO/TRIPS compliance; Paris Convention/WTO membership
- PCT and/or regional Office membership
- Provisional protection following publication

# Possible Key Criteria Relating to Enforcing a Patent (1)

- Working requirements/consequences of non-working
- Parallel imports
- Prior user rights
- Border protection
- Technology transfer requirements/restrictions
- Other legal and regulatory requirements/laws
- Announced/expected/contemplated changes in the law
- 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.

# Possible Key Criteria Relating to Enforcing a Patent (2)

- 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- or anti- patent
  - neutral or pro- or anti- foreign patentee
- Announced/expected/contemplated changes in enforcement procedures/systems/timing/costs
- Changes in political/judicial attitudes towards patents

# Example of Selected Primary Criteria

## ■ Related to obtaining:

- time to get a patent
- quality of examination

## ■ Related to costs:

- cost to obtain
- cost to enforce

## ■ National IP culture:

- national posture toward IP rights of foreigners

## ■ Related to enforcement:

- patent experience of courts
- availability of preliminary relief
- adequacy of border protection
- adequacy of permanent relief and/or availability of damages
- ability to enforce court judgments
- timeliness of enforcement actions

# Example of Selected Secondary/Special Criteria

## ■ Related to patentable subject matter:

- methods of treatment patentable?
- secondary (medical) uses patentable?
- business methods patentable?
- software patentable?

## ■ Related to outside evaluations:

- USTR report status
- index of economic freedom
- corruption perception index

## ■ Others:

- data protection eg. clinical trial pharma. data
- ability to get acceptance by conforming claims to grant in another country
- acceptability/availability of alternative dispute resolution

## Setting the Importance Grade:

- Each criterion used for evaluation is assigned an importance grade indicating the weight each criterion will receive in the final evaluation:
  - 4 = very important
  - 3 = important
  - 2 = moderate importance
  - 1 = low importance

## Example Data Sources Utilized

- Surveys of foreign agents
- Surveys of multi-national agencies
- Personal experience
- USTR reports
- Experience of others
- Index of economic freedom
- Published reports
- IP matter management data
- WTO trade policy reviews

## Evaluate Criterion for Each Patent System

- Each patent system of interest is evaluated against each of the primary and secondary/special criteria selected using a scale like:

4 = excellent

3 = good

2 = fair

1 = poor

0 = unsatisfactory/non-existent



Patent System Overall Value Rating: JAPAN				
	Importance	Grade	Quality Points	Comments
	4 (high) to 1 (low)	4 (high) to 0	(Importance & Grade)	
<b>Filing &amp; Prosecution</b>				
Time to Get a Patent (Shorter is Better)	1	2	2	8.83 years
Quality of Examination of Local System	2	4	8	
<b>Enforcement</b>				
Patent Experience of Forum/Courts	4	4	16	average of 500-600 per year; have specialized court;
Availability of Preliminary Relief (Injunctions/Seizures)	3	4	12	available, easy to obtain, enforce
Adequacy/Availability of Border Protection	3	4	12	***
Availability/Adequacy of Permanent Relief (Injunctions/Damages)	4	4	16	max award 80MM; no obstacles to enforcement - smoothly executed;
Speed of Enforcement Actions	3	4	12	possible, including prelim injunction; no special procedure for speedy trial; ave 13 mo
Ability to Enforce Court/Forum Decisions	4	4	16	relatively easy;
<b>Costs</b>				
Cost to Obtain (Filing/Prosecution/Maintenance)	2	1	2	23M
Cost to Enforce (Cost of Litigation/Arbitration)	1	3	3	~250M
<b>National Attitude</b>				
National/Governmental Posture Toward IP Rights Owned by Foreigner	2	1	2	
<b>TOTAL POINTS (Maximum 110)</b>			<b>101</b>	
<b>Special Considerations</b>				
Are treatments for humans allowed?	1	0	0	
Are secondary uses allowed? (backup if no treatments allowed)	1	0	0	
Are business methods allowed?	1	2	2	
On USTR Watch List	1	0	0	
Restricted Re-Use of Rx data (springboarding)	1	0	0	
Economic Freedom Category (2007 Index of Economic Freedom*)	1	1	1	Japan's economy is 73.6 percent free, according to our 2007 assessment, which makes it the world's 18th freest economy. Its overall score is 1 percentage point lower than last year, partially reflecting new methodological detail. Japan is ranked 5th out of 30 countries in the Asia-Pacific region, and its overall score is much higher than the regional average. Japan enjoys high levels of trade freedom, property rights, business freedom, freedom from corruption, fiscal freedom, labor freedom, and monetary freedom. The average tariff rate is low, and business regulation is efficient. Virtually all commercial operations are simple and transparent. A very modest, stable deflation in prices has been occurring. Taxes are fairly high, and overall tax revenue is moderate as a percentage of GDP. Contracts in Japan are often imprecise, which can impede smooth judicial handling of commercial disputes. Despite the confusion, contract agreements are highly respected by the judiciary. There is very little corruption in the civil service. Japan is weaker in freedom from government and financial freedom. T
Property Rights (2006 Index of Economic Freedom*)	1	4	4	70% free - Property rights are generally secure in Japan. The courts do not discriminate against foreign investors but are not well suited to litigation of investment and business disputes. Japanese businesses tend to write their contracts in general terms, but despite this lack of precision, contracts are highly respected.
Does the PTO officially allow conformance to EPO or US?	1	0	0	
Corruption Perceptions Index 2006 (www.transparency.org)	1	1	1	7.6
A global settlement may not be honored in countries where there is no				
Ability for P&G to get a successful outcome in an infringement dispute				
<b>SubTotal Special Considerations</b>			<b>8</b>	
<b>Grand Total</b>			<b>109</b>	

# Final Thoughts Regarding Patent and Enforcement Systems

- The life of a patent is 20 years from filing
- The evaluation of the patent and enforcement systems is made before this 20-year period begins
- Patent laws and court systems can and do change with time. Today's poor system may well be tomorrow's good system
- Every applicant and practitioner should keep up-to-date on the patent and enforcement systems of interest - factoring current trends and expected future patent system improvements

## Return on Investment (ROI) (1)

- Considering patents, it should not be a surprise that seeking protection in a broad range of countries can prove to be very expensive
- The cost over the 20-year life of a broadly filed patent can be USD 750,000 or USD 1,000,000 or more
- Obtaining an adequate return on the investment made in filing, obtaining and maintaining patent applications is important to your business
- A patent is a business tool and must “pay its own way.” If it does not, the patent is a drain on business assets and (most likely) should either not have been filed or maintained

## Return on Investment (ROI) (2)

- For applicants who license or sell their patents, an actual ROI can be determined from the investment and the revenue from the patent sale or license
- For applicants manufacturing and/or selling a product, learning the actual ROI may be impossible – you will never really know if the absence of a filed patent would have affected your commercial success, or *vice versa*
- When a patent (or application) no longer provides an adequate ROI, it should be dropped
- To help insure a proper ROI, a rigorous program of portfolio management is needed

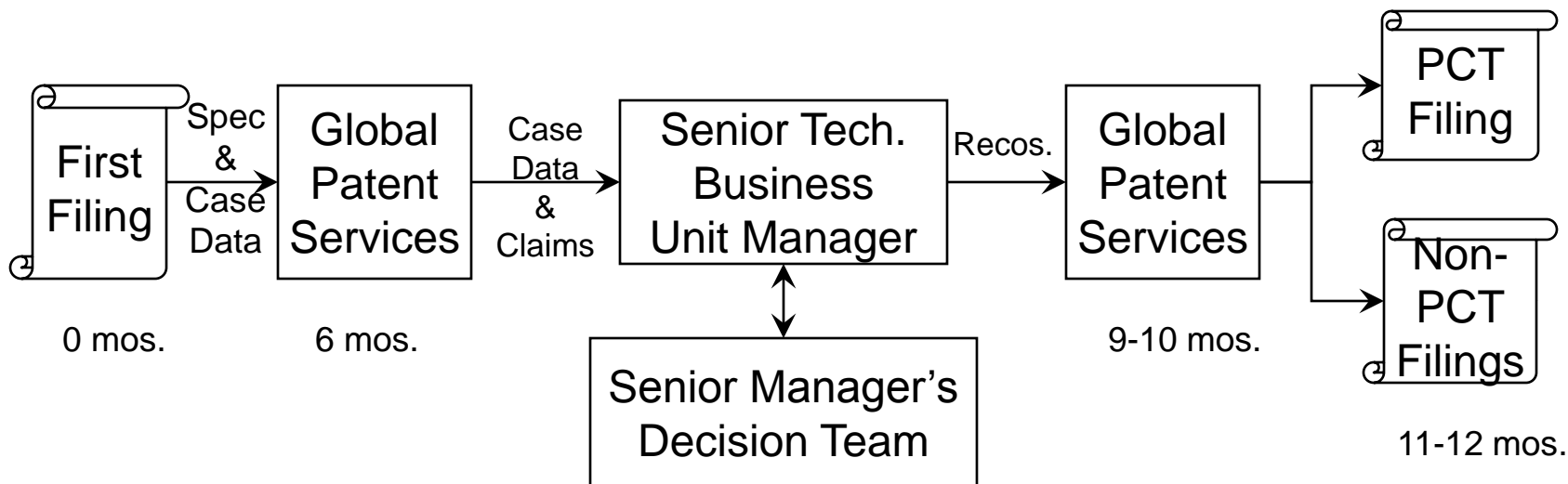
# How:

## A Decision-Making Process

- The initial filing decision is just the first step in a necessary program of rigorous patent portfolio management
- One scheme for portfolio management is detailed in the following slides

Following the initial decision to file the first application, the next decision logical decision point is toward the end of the priority year. In the following flow chart, the case is prepared for the decision-makers by a central group (Global Patent Services) and is forwarded to the decision making team. This team is comprised of senior managers and their staff and is responsible in their area of technology for making the decisions where each case should be filed. The team gathers input on the invention from several sectors – technical, marketing, licensing, etc. At the 12-month decision point, a decision to file a PCT application designating all PCT Member States, as well as individual decisions on non-PCT States are made. These instructions are passed back to the central group who executes the filings.

# A Decision-Making Process



- Each decision-maker has full technical, commercial and cost information available when making the filing decisions.
- At the end of the priority year, the filing decision is generally, “PCT – yes or no” plus decisions on non-PCT countries.
- Decision-maker has full flexibility when selecting countries for filing.
- Most decision-makers utilize a system of technology-specific “tiers” or “categories” when making the country selections.

# Sample Tier Structure

<u>Tier Level</u> ►	<b>Tier 1</b>			<b>Tier 2</b>			<b>Tier 3</b>		
<u>Commercial Interest</u> ►	<b>High</b>			<b>Moderate</b>			<b>Low</b>		
<u>Countries To be Filed</u>  (PCT Member States shown in <i>bold Italics</i> )	<i>AU</i>	<i>JP</i>	<i>US</i>	<i>AU</i>	<i>MX</i>		<i>CA</i>		
	<i>BR</i>	<i>KR</i>	<i>VN</i>	<i>BR</i>	<i>RU</i>		<i>CN</i>		
	<i>CA</i>	<i>MR</i>	<i>ZA</i>	<i>CA</i>	<i>SG</i>		<i>EP</i>		
	<i>CN</i>	<i>MX</i>		<i>CN</i>	<i>US</i>		<i>JP</i>		
	<i>CO</i>	<i>NZ</i>		<i>EP</i>	<i>VN</i>		<i>MX</i>		
	<i>CZ</i>	<i>PH</i>		<i>FI</i>			<i>US</i>		
	<i>EG</i>	<i>PL</i>	AR	<i>ID</i>	AR				
	<i>EP</i>	<i>RU</i>	TW	<i>IN</i>	TW				
	<i>FI</i>	<i>SA</i>		<i>JP</i>					
	<i>IN</i>	<i>SG</i>		<i>KR</i>					
		<i>SK</i>							

- Tier definitions are reviewed frequently and modified as needed to reflect the current needs and long-term business plans

# A Decision-Making Process

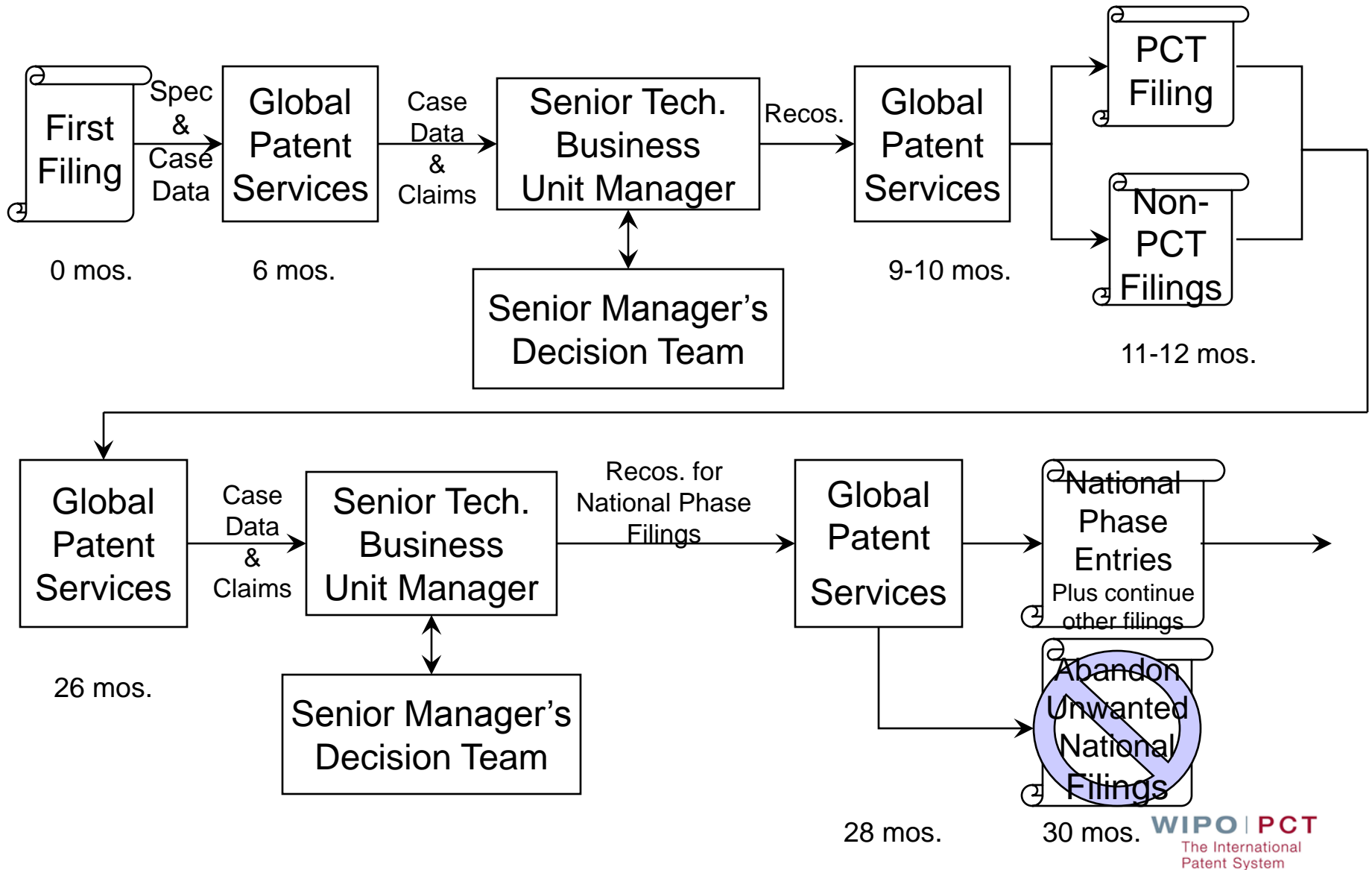
- The second filing decision point occurs at 30 months from priority when the PCT filing will be entering the national phase.

At 30 months the process is essentially the same as at the 12-month decision point *except* the decision-makers have a lot more information about the commercial value of the invention, how it fits into the overall product and marketing strategy and a better grasp on the chances of obtaining meaningful patent protection based on the information gained through the PCT international phase.

One key feature of this scheme is that a decision is not only made on where to enter the national phase, but the filings in the non-PCT States made at 12 months are also reviewed. If the commercial situation has changed and any of these filings are judged to be no longer of interest, they are abandoned to avoid continued spending on applications of no further interest.



# A Decision-Making Process



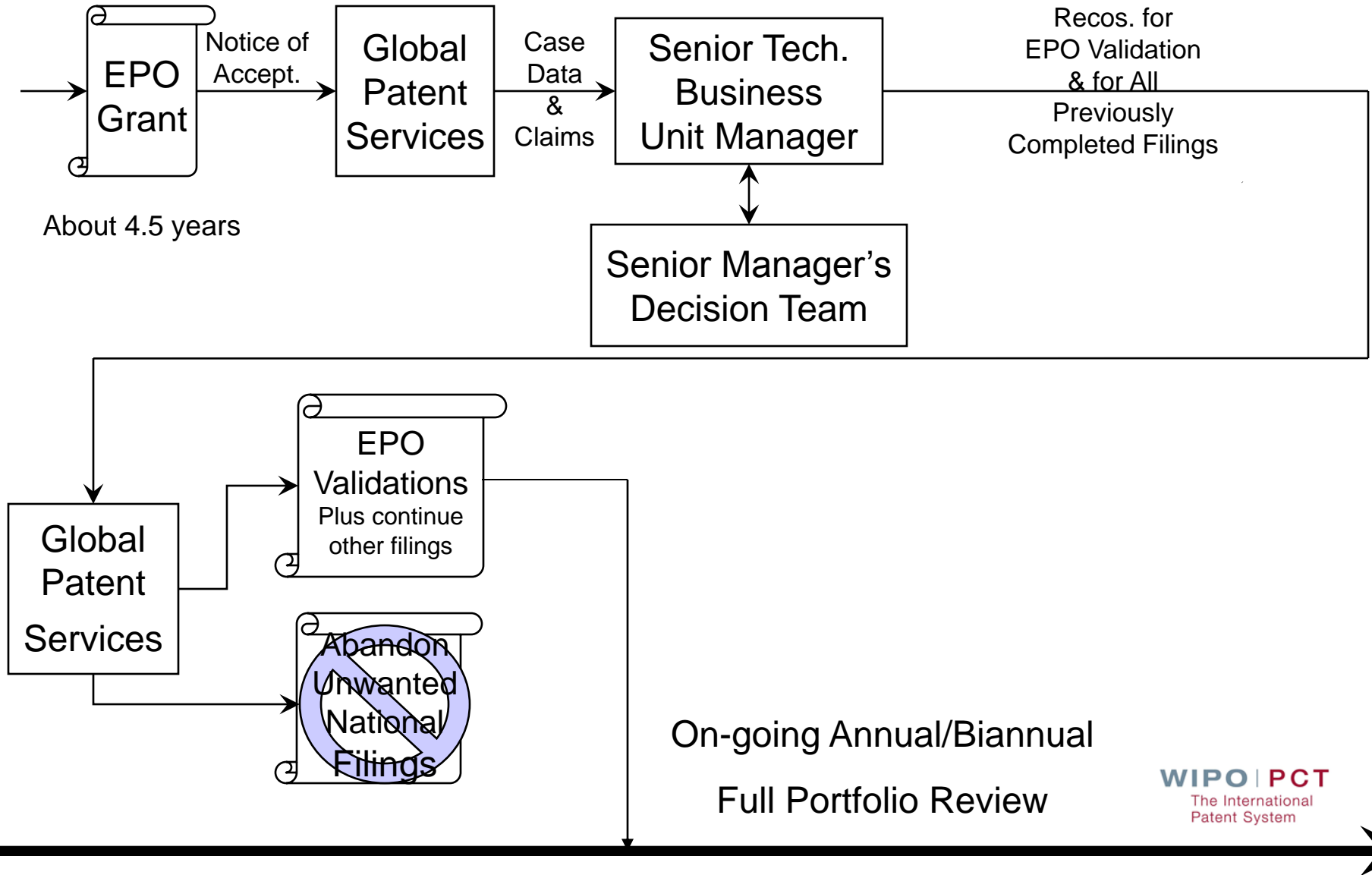
# A Decision-Making Process

- The third filing decision point occurs about 4.5 years from priority when any EPO filing is accepted and must be validated in the designated EP States of interest.

EPO validation provides another point when decisions must be made and the used process is essentially the same as at the 12- and 30-month decision points.

As at the 30-month point, this review of the case to decide where to validate in Europe also provides another good opportunity to review what has gone before. Once again, each filing and national entry made during the life of the case is examined and if the filings made at past decision points are no longer of value, they are abandoned.

# A Decision-Making Process



# A Decision-Making Process

- On-going yearly/biannual full portfolio reviews round out the process to insure only applications and granted patents of continued commercial value are maintained.

The periodic portfolio reviews help ensure that the system remains efficient and helps ensure the applications and patents, that have passed through the process detailed above, continue to justify further prosecution costs and/or and maintenance fees.



**Thank You**