



# National Phase Entry: A User's Perspective

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This presentation draws upon a wealth of practical filing experience and presents commercially successful filing strategies. They are not, however, necessarily the views of WIPO.

# National Phase Entry

One of the most challenging decisions a patent applicant must make is where in the world to file for patent protection consistent with the business goals and needs and budgetary constraints.

This presentation provides the reader with guidance on making these decisions.

There is no formula to give the reader a “turn-the-crank” answer to the question, “Where should I file/enter the national phase?” but this presentation may help.

# National Phase Entry

We will examine the ...

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

...of national phase entry.

# What: National Phase Entry Filing Considerations

- Type of protection – all types of protection, utility models, patents of addition, etc. are all available – the applicant must select the type of protection that best fits the business needs
- Preliminary amendment and argument – if there are unfavorable opinions in the IPRP or if the claims do not meet local formal requirements or will result in excessive filing fees, a preliminary amendment and/or preliminary argument will help move your application forward in the national phase
- Requesting examination – in deferred examination countries, a decision needs to be made regarding the best time to request examination. It can be done earlier if faster processing is desired, or it can be deferred to help delay costs.
  - Regular examination request at entry

# What: National Phase Entry Filing Considerations

- Accelerated examination (in some countries)
  - PCT/PPH 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
- Defer examination (in some countries)

# When: Early National Phase Entry

An applicant has complete freedom in deciding during the international phase to enter the national phase ...

- 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 processing has started in a country, the national phase application is not affected by:
  - Withdrawal of the international application
  - Withdrawal of priority claim in the international application
- If national phase entry is made before publication, applicant must arrange for a copy of the international application to be provided to the designated Office

# Where: Selecting countries

Perhaps the most challenging decision is where to enter the national phase.

- Four key factors should be considered
  - Business/commercial need for exclusivity
  - Initial and long-term cost
  - Status of patent systems 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 place you file should provide an adequate return on the money invested in IP protection
  - Any place you don't file, you will have no claim to exclusivity

The following list of questions provides a link between your business needs and goals, the commercial climate, the criticality of the claimed invention to your business and the IP posture of countries under consideration for filing.

This list is generic and should be supplemented by similar questions that relate directly to the area of technology and business in your field of endeavour.



# 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 competitor?
- 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 the competition to design around the claimed invention? How long and what resources would it take?
- 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?

## Some questions to consider in determining the business/commercial need for exclusivity (2)

- 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?

## Some questions to consider in determining the business/commercial need for exclusivity (3)

- What are the consequences to your business if the invention is copied in some/all countries?
- 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, prosecution 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

For each country under consideration for national phase entry the relevant questions in this list plus those directly related to your technology and business climate should be asked. If the commercial situation requires the exclusivity that comes from patent protection, then filing in a country with high costs and less than ideal examination and/or enforcement may well be worth the expense. If patent protection is not so critical based on the response to the questions, then the money for entry may be better spent on other filings or other business needs.

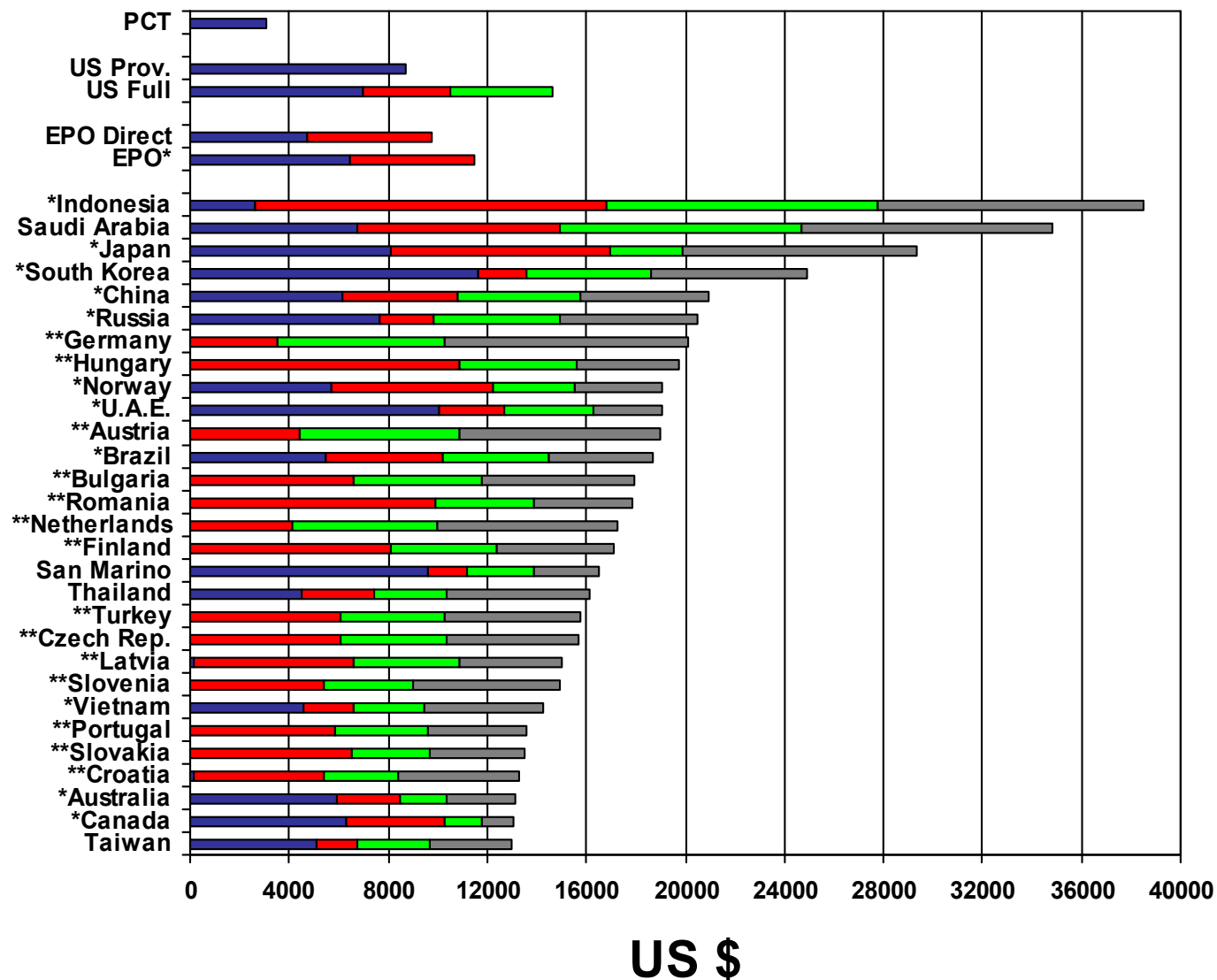
# Cost data

Second only to commercial need, the overall cost of obtaining and maintaining patents in the countries under consideration for filing needs to be factored into the final decision. Please note these *caveats* when looking at the data that follows

- 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 as the company acts as its own agent for those proceedings)
- Data is current as of 2008/2009; official fees and professional costs change over time and no adjustments have been made for these changes
- 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 conversions 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.

# Relative Cost to Obtain and Maintain A Patent

(Data from 2008/2009)

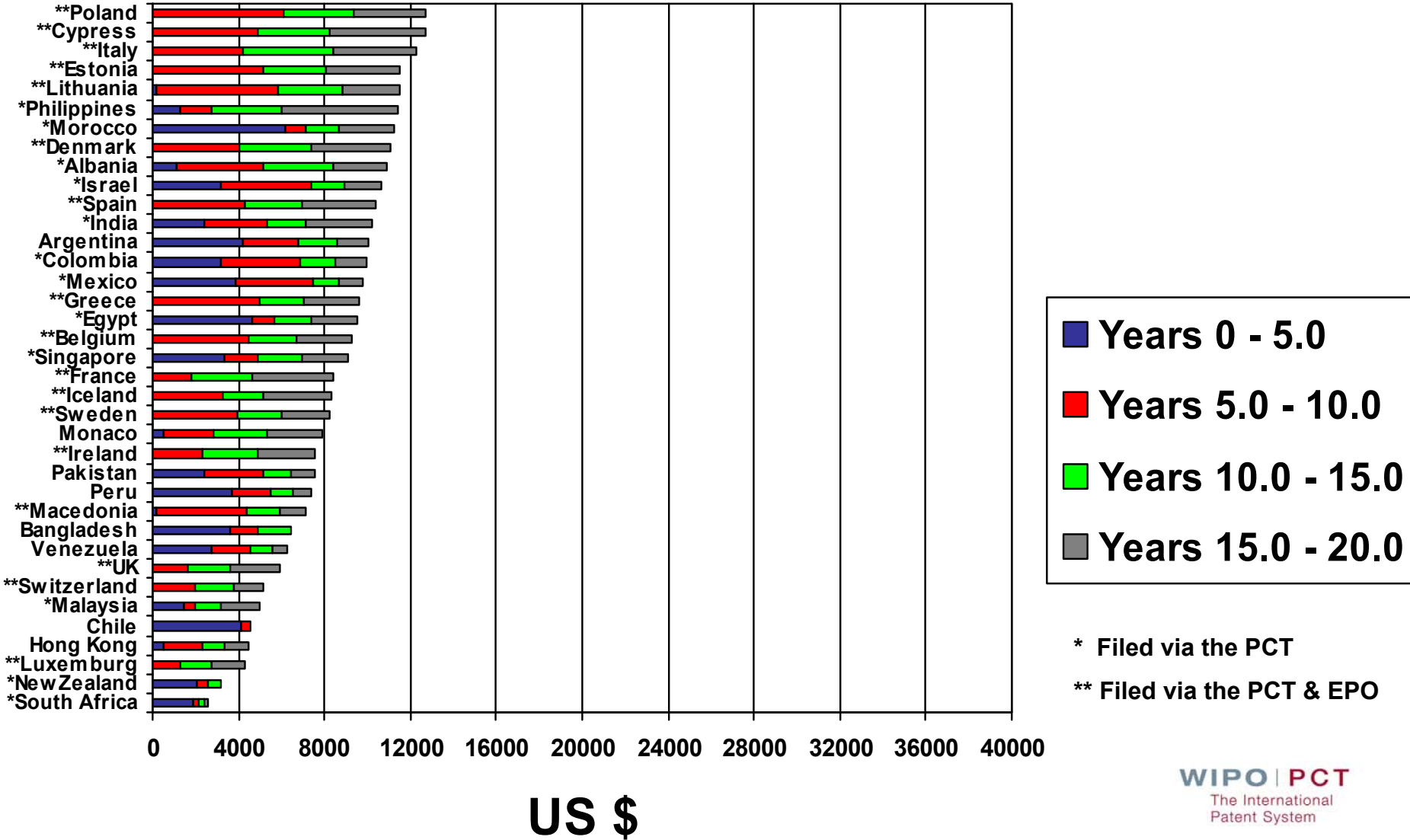


\* Filed via the PCT

\*\* Filed via the PCT & EPO

# Relative Cost to Obtain and Maintain A Patent

(Data from 2008/2009)



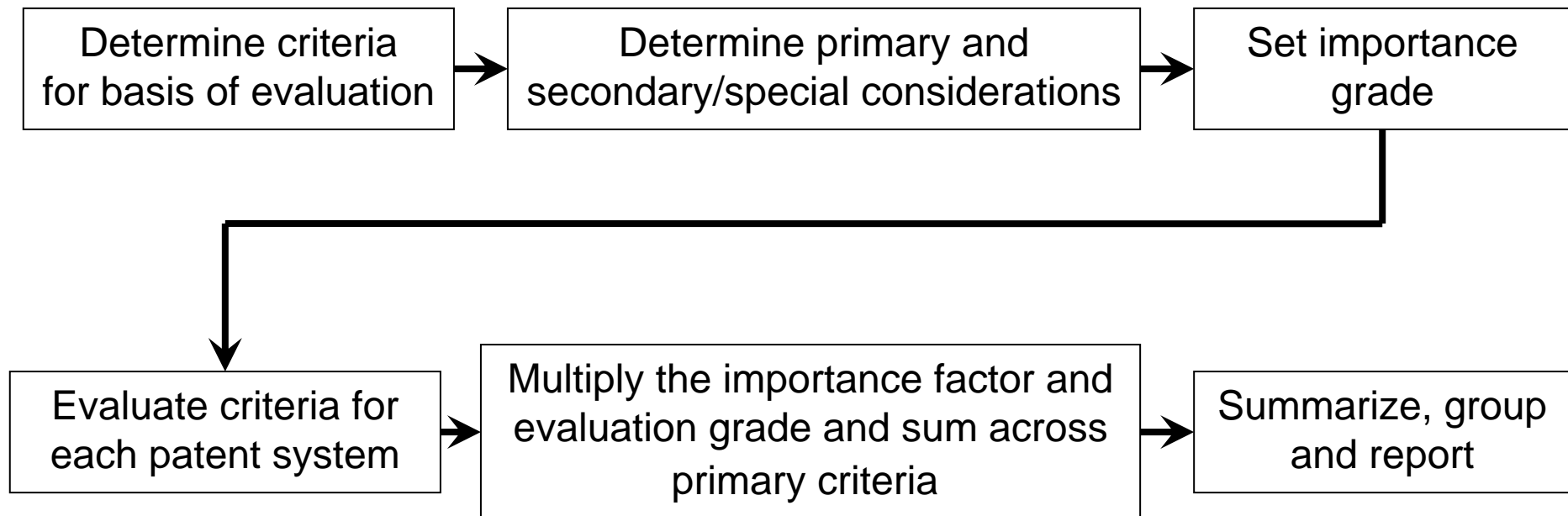
# Status of patent systems and enforcement

- The extent to which a patent and legal system meet the needs of the applicant and the applicant's business 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 value of any patent system and the ability to enforce a patent versus what the applicant seeks from their "ideal patent system"

In an effort to assess each patent and enforcement system versus the applicant's needs and expectations, the following process has proved useful...



# Assessment of a patent and enforcement system



# Possible key criteria relating to obtaining a patent (1)

The first step is to determine the basis on which the evaluation will be made. There are many criteria on which to make a judgment. Each applicant must decide for himself “what is important.”

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

# 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 public use)
- “Grace” periods following public exposure
- GATT/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
- Changes in political/judicial attitudes towards patents
- Announced/expected/contemplated changes in enforcement procedures/systems/timing/costs

# Primary criteria

Once the list of criteria is formulated, setting the stage for the evaluation, those which are considered primary, i.e., significant criteria for every patent to be filed, should be separated from those that are secondary, i.e., not so important or only applicable to a subset of applications.

- 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

# 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 perceptions index
- Others:
  - Data protection eg. clinical trial pharma data
  - Option of conforming claims to facilitate acceptance in another country
  - Acceptability/availability of alternative dispute resolution
  - Availability of PCT-PPH

# Setting the importance grade:

Realizing that even among the primary criteria, some are more important than others, a “weight” is assigned to each criterion indicating the relative importance of the specific criterion to the business decision.

- 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 = moderately important

1 = not very important



# Data sources

In order to make the evaluation as data-based as possible, data must be gathered from whatever sources are available to the applicant. Keeping the evaluation as data-based as possible is important so that the final decisions based on the individual evaluations are sound and minimally influenced by emotions, “old tapes,” etc. Some good sources and methods to gather relevant data are:

- 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 system data (docketing system)

# Evaluate criteria for each patent system

With the data in hand, the applicant must evaluate each patent system of commercial interest against the criterion set earlier. As much as possible the evaluation grade should be data-based, allowing other factors to influence the grade as little as possible. In this example, a simple four-point grading system was utilized.

- 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

# Results

The final evaluation grade is obtained by multiplying the evaluation grade by the importance factor for each criterion. The final overall evaluation grade is the sum of the products of the individual grades and the importance factors. Separate totals factoring in secondary criterion can be made for those decisions where the secondary criterion are relevant.

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

4 = excellent

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# Sample country data sheet

<b>Patent System Overall Value Rating: Country "A"</b>				
	<b>Importance</b>	<b>Grade</b>	<b>Quality Points</b>	<b>Comments</b>
	4 (high) to 1 (low)	4 (high) to 0	(Importance & Grade)	
<b>Filing &amp; Prosecution</b>				
Time to Get a Patent (Shorter is Better)				
Quality of Examination of Local System				
<b>Enforcement</b>				
Patent Experience of Forum/Courts				
Availability of Preliminary Relief (Injunctions/Seizures)				
Adequacy/Availability of Border Protection				
Availability/Adequacy of Permanent Relief (Injunctions/Damages)				
Speed of Enforcement Actions				
Ability to Enforce Court/Forum Decisions				
<b>Costs</b>				
Cost to Obtain (Filing/Prosecution/Maintenance)				
Cost to Enforce (Cost of Litigation/Arbitration)				
<b>National Attitude</b>				
National/Governmental Posture Toward IP Rights Owned by Foreigners				
<b>TOTAL POINTS (Maximum 110)</b>				
<b>Special Considerations</b>				
Are treatments for humans allowed?				
Are secondary uses allowed?				
Are business methods allowed?				
On USTR Watch List				
Restricted Re-Use of Rx data (springboarding)				
Economic Freedom Category (Index of Economic Freedom)				
Property Rights (Index of Economic Freedom)				



# Sample reporting sheet

For ease of use, the final data can be reported in any convenient manner, for this example, the countries were divided into quartiles from the highest grade to the lowest

Arranging countries by quartiles based on Quality Point totals							
	Quality Points		Quality Points		Quality Points		Quality Points
Group 1	86 - 101	Group 2	71 - 85	Group 3	55 - 70	Group 4	39 - 54
Country 11	###	Country 21	##	Country 31	##	Country 41	##
Country 12	###	Country 22	##	Country 32	##	Country 42	##
Country 13	##	Country 23	##	Country 33	##	Country 43	##
Country 14	##	Country 24	##	Country 34	##	Country 44	##
Country 15	##	Country 25	##	Country 35	##	Country 45	##
Country 16	##	Country 26	##	Country 36	##	Country 46	##
Country 17	##	Country 27	##	Country 37	##	Country 47	##
Country 18	##	Country 28	##	Country 38	##	Country 48	##
Country 19	##	Country 29	##	Country 39	##	Country 49	##
etc.		etc.		etc.		etc.	

When making decisions on where to enter the national phase, the “value” of each patent prosecution and enforcement system under consideration is very helpful in making the final decision in conjunction with the other considerations of commercial need, cost and return on investment.

# Final thoughts on this process

This evaluation system takes some time to initially set up, however it is fairly easy to maintain. The individual country data sheets and the summary sheets can be put into a spreadsheet program and linked so that a change in the evaluation grade or importance grade for any country automatically updates all related pages.

It is critical that for each country and each evaluation there are detailed explanations notes of why certain grades were assigned to certain criteria. Situations in countries evolve and as systems improve, change or deteriorate, it is important that the original basis for the evaluation is clear so that appropriate modifications in the grades can be made.

# 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 and *vice versa*
- Every applicant and practitioner should keep up-to-date on developments in patent and enforcement systems



# Return on investment (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 run to \$750,000 or \$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 (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 return on investment, it should be dropped
- To help insure a proper return on investment, a rigorous program of portfolio management is needed – a suggested system follows...

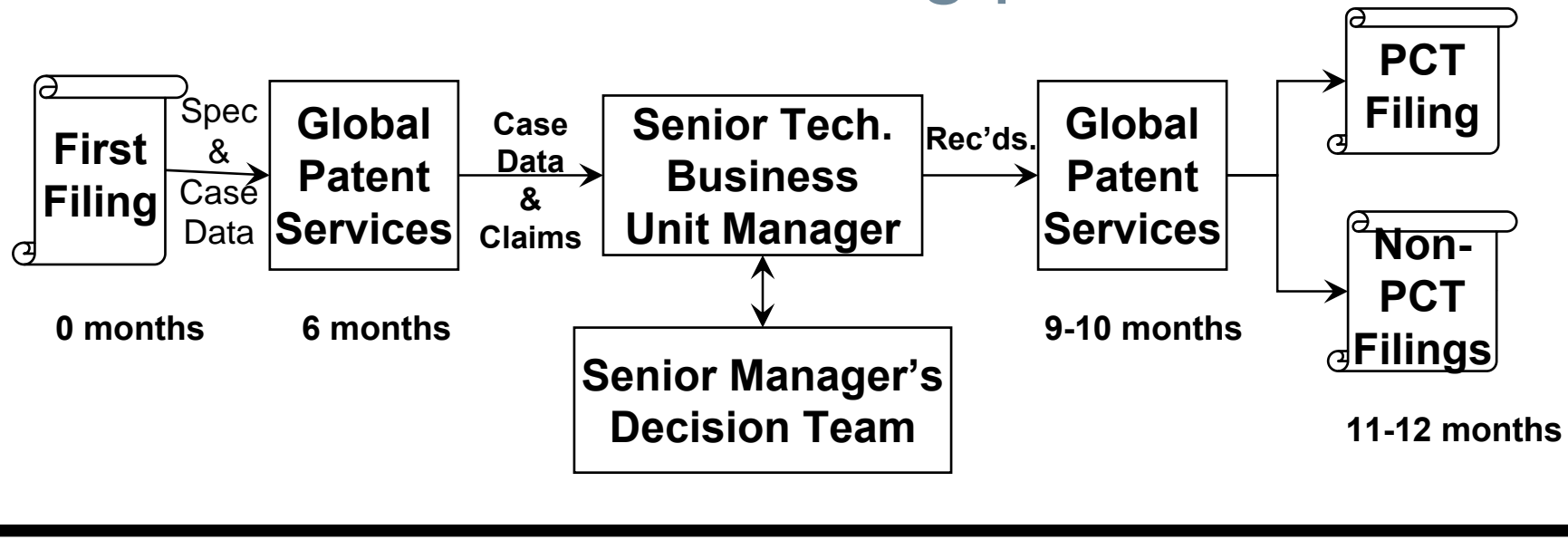
Discussions on measuring the return on investment are beyond the scope of this presentation, but I am sure there are experts in the field that can help make such a determination. The key is that the patent holder must determine that an acceptable return is being received. If it is not, the money should be invested elsewhere.

# 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 logical decision point is towards 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 is made. These instructions are passed back to the central group who executes the filings.

# How: 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 for a product

<b><u>Tier Level</u></b> ►	<b>Tier 1</b>			<b>Tier 2</b>			<b>Tier 3</b>		
<b><u>Commercial Interest</u></b> ►	<b>High</b>			<b>Moderate</b>			<b>Low</b>		
<b><u>Countries To be Filed</u></b>  (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>	AR	<i>FI</i>			<i>US</i>		
	<i>EG</i>	<i>PL</i>	SA	<i>ID</i>	AR				
	<i>EP</i>	<i>RU</i>	TW	<i>IN</i>	TW				
	<i>FI</i>	<i>SG</i>		<i>JP</i>					
	<i>IN</i>	<i>SK</i>		<i>KR</i>					

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

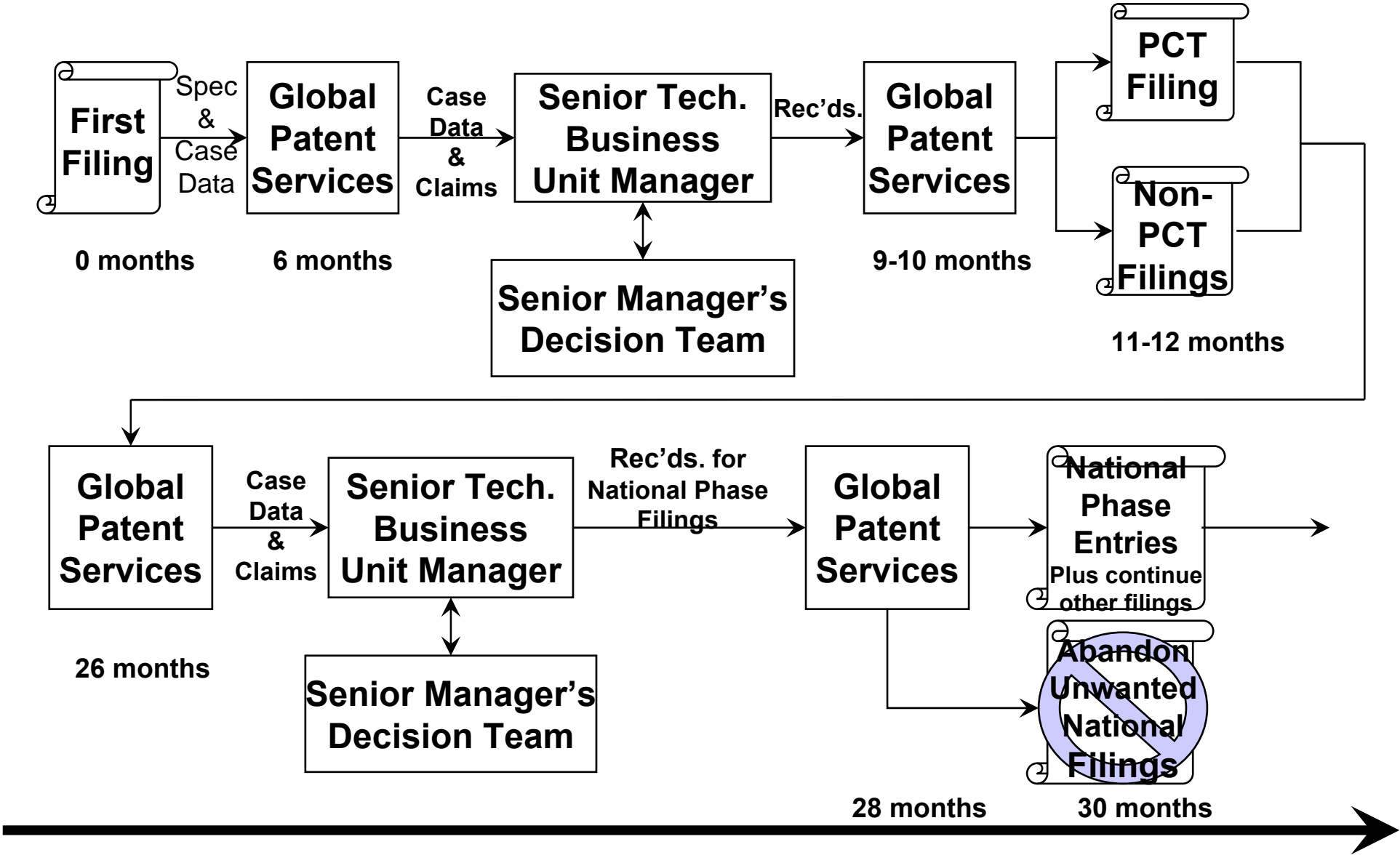
# How: A decision making process

- The second filing decision point occurs at 30 months from priority when the PCT application 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.

# How - A decision making process



# How: A decision making process

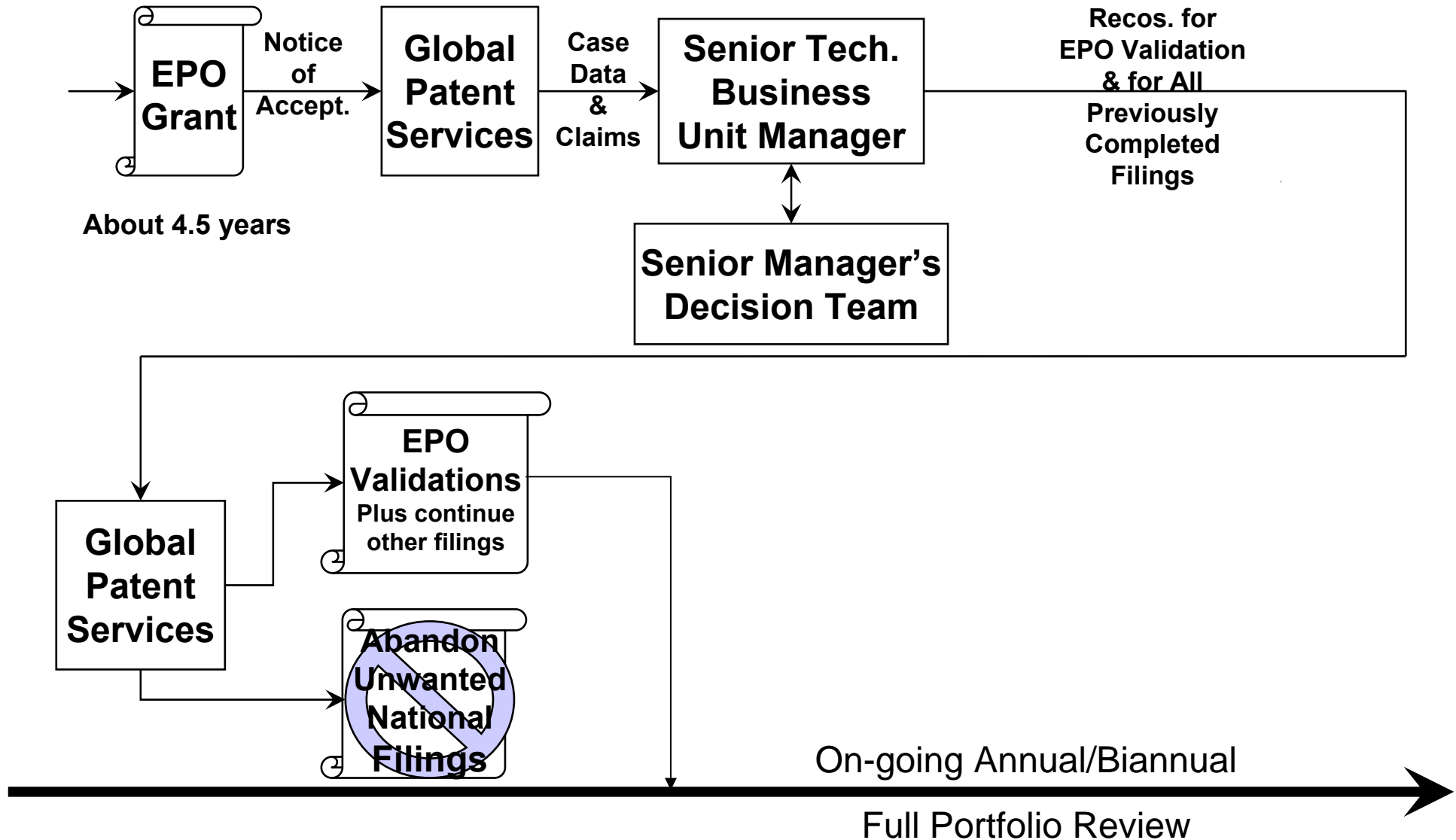
- The third filing decision point occurs about 4.5 years from priority when any EPO patent is granted is accepted and must be validated in the designated EP states of interest

EPO validation provides another point when decisions must be made and the 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. It also provides another good opportunity to review earlier decisions. 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



# How: A decision making process

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

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