

# Utilising IPR as a Weapon to Protect R&D Results

Sophia Antipolis - February 21, 2008



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## Outline

Outline  
Review  
Changes  
Strategy

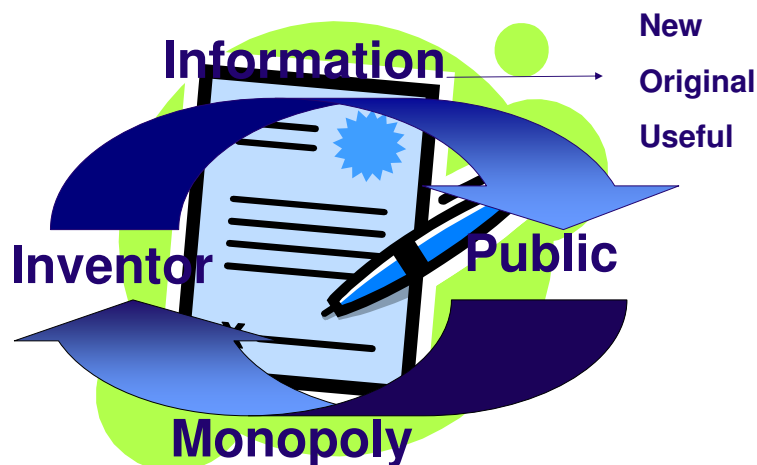
- Overall review of the European patent system
- Latest EPO changes, impact for the Life Science Industry
- Elements of strategy (balance of costs)



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## Principle

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## How to get a patent ?

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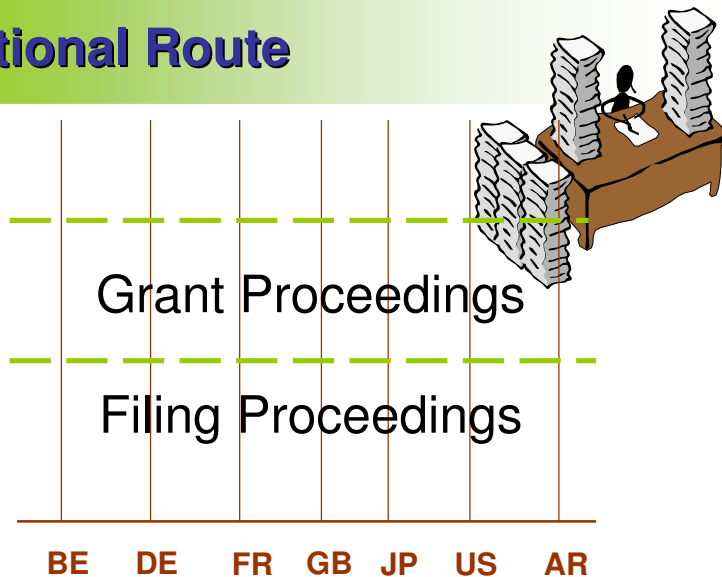
- National Route  
Individual filing in each countries
- Regional Route  
Single filing and single procedure within a given territory
- International Route  
Unique filing for the 138 contracting states of the PCT



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## National Route

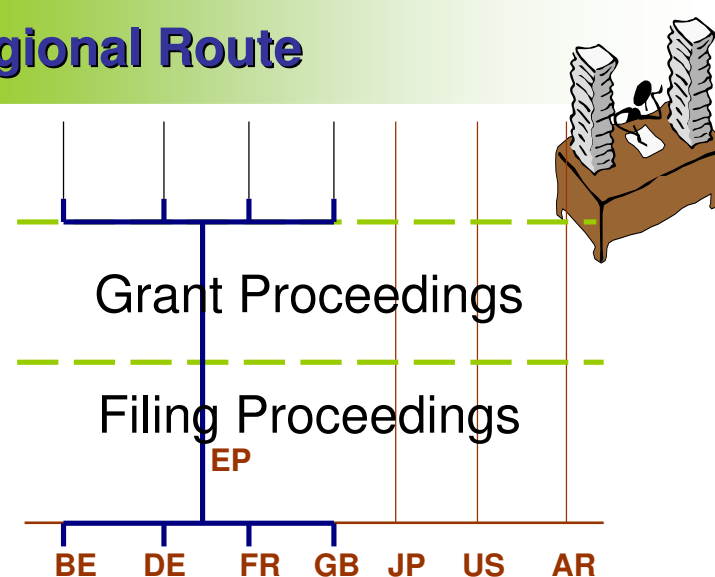
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## Regional Route

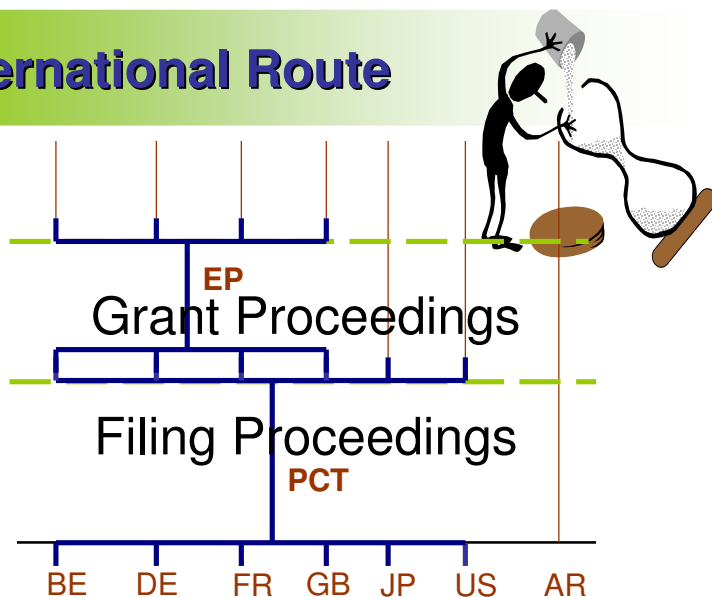
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## International Route

Outline  
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Strategy



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## The European patent system

Outline  
Review  
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Strategy

### • History

- **1949** First proposal: Longchambon Plan;
- **1962** Haertel's proposal:
  - Unitary patent for the EEC (6 members)
- **1969** Split of Haertel's proposal;
- **1973** Munich Convention
- **1977** **Entry into Force**
- **2007** Entry into force of the EPC2000 reform



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## The European patent system

Outline  
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- Contracting states (34)
- Austria, Belgium, Bulgaria, **Switzerland**, Cyprus, Czech Republic, Germany, Denmark, Estonia, Spain, Finland, France, United Kingdom, Greece, **Croatia**, Hungary, Ireland, **Iceland**, Italy, **Liechtenstein**, Lithuania, Luxembourg, Latvia, **Monaco**, Malta, Netherlands, **Norway**, Poland, Portugal, Romania, Sweden, Slovenia, Slovakia, **Turkey**



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## The European patent system

Outline  
Review  
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Strategy

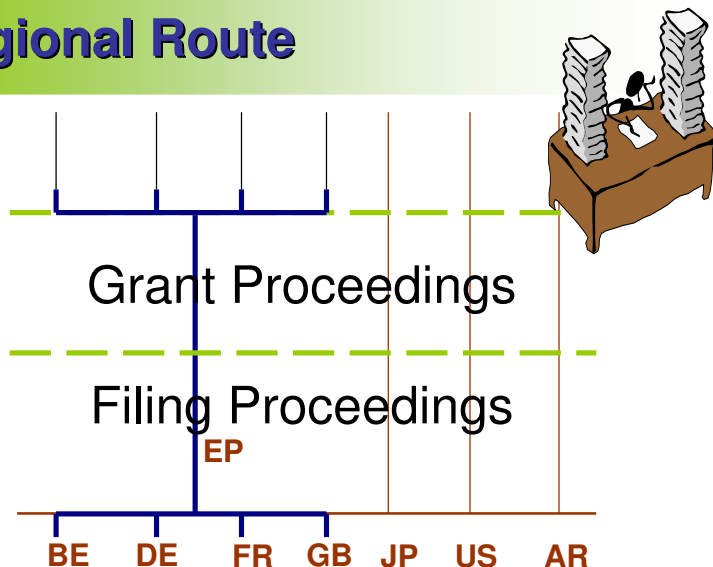
- Extension states (4)  
(Non-member states which recognise the European patent) :
- **Albania, Bosnia and Herzegovina, the former Yugoslav Republic of Macedonia and Serbia**



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## Regional Route

Outline  
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Changes  
Strategy



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## The European patent system

Outline  
Review  
Changes  
Strategy

- Filing
  - Description, drawings, claims filed only once in one of the official languages (German, English or French)
  - Filing fee paid only once
  - Designation fees (maximum of 7)



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# The European patent system

Outline  
Review  
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Strategy

- **Search**
  - Extended search report
- **Examination**
  - Examination fee
  - Office actions
  - Grant
- **Opposition**



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# The European patent system

Outline  
Review  
Changes  
Strategy

- **Validation**
  - Translation of the specification (German, English or French) into a prescribed language in all the contracting states



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# Upcoming Changes



Outline  
Review  
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Strategy

- **London Protocol**
  - Just ratified by France
  - Will enter into force on May 1, 2008
  - Cost attractive post-grant translation regime
  - Parties to the Agreement undertake to waive, entirely or largely, the requirement for translations of European patents to be filed in their national language
  - **Croatia, Denmark, Latvia, Netherlands, France, Liechtenstein, Slovenia, Germany, Luxembourg, Switzerland, Iceland, Monaco and United Kingdom**



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# Upcoming Changes



Outline  
Review  
Changes  
Strategy

- **EPC2000 reform**
  - Already entered into force (Dec. 13, 2007)
  - **Little change in terms of substantive patent law**
  - Applications can be filed in any language
  - All EPC contracting states are designated
  - Requirements for obtaining an official filing date have been simplified significantly
  - Patentees have the right to limit their patent
  - Further processing is now standard legal remedy where a time limit is not observed.
  - Possibility to have **decisions** of boards of appeal reviewed.



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## Upcoming Changes

Outline  
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Changes  
Strategy



- EPC2000 reform
- Exceptions to patentability
  - Art. 53 b) (**Unchanged**)  
Plant or animal varieties or essentially biological processes for the production of plants or animals; this provision shall not apply to microbiological processes or the products thereof.



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## Upcoming Changes

Outline  
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- EPC2000 reform
- Exceptions to patentability
  - Art. 53 c) (**New**)  
Methods for the treatment of the human or animal body by surgery or therapy and diagnostic methods practised on the human or animal body; **this provision shall not apply to products, in particular substances or compositions, for use in any of these methods.**



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## Upcoming Changes

Outline  
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Strategy



- EPC2000 reform
- Novelty
  - Art. 54 (4) (**Unchanged**)  
Paragraphs 2 and 3 shall not exclude the patentability of any substance or composition, comprised in the state of the art, for use in a method referred to in Article 53(c), provided that its use **for any such method** is not comprised in the state of the art.



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## Upcoming Changes

Outline  
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Strategy



- EPC2000 reform
- Novelty
  - Art. 54 (4) **First medical use**
  - Examples:
    - Compound X for use as medicament
    - Composition X for curing disease Z
    - Compound X as antibacterial agent
  - But not
    - ~~Use of compound X as a medicament~~
    - ~~Method for the treatment of disease Z comprising administering composition X~~



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## Upcoming Changes

Outline  
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Strategy



- EPC2000 reform
- Novelty

– Art. 54 (5) (**New**)

Paragraphs 2 and 3 shall also not exclude the patentability of any substance or composition referred to in paragraph 4 for any **specific use** in a method referred to in Article 53(c), provided that **such use** is not comprised in the state of the art.



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## Upcoming Changes

Outline  
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Strategy



- EPC2000 reform
- Novelty

– Art. 54 (5)

**Second medical use**

– Examples:

- Use of compound X for the manufacture of a medicament for the treatment of disease Z
- Use of compound X for the treatment of disease Z



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## Upcoming Changes

Outline  
Review  
Changes  
Strategy



- EPC2000 reform
- Sequence Listing (EPC2000)

– **New remedy:** Introduction of **late furnishing fee € 200**

– **Explanatory remarks:** The late furnishing of sequence listings causes significant extra effort and delay in preparation of the European search report



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## Upcoming Changes



- New Fee regime
- Due to enter into force April 1, 2008

– Annuities

- Fine for late payment increases from 10-50% of the overdue annuity

– Claims fees

- Currently 45 EUR from the 11<sup>th</sup>
- From April 1, 2008 200 EUR from the 16<sup>th</sup>
- From April 1, 2009 500 EUR from the 51<sup>st</sup>

– "Length" fee

- From April 1, 2009 12 EUR / page from the 36<sup>th</sup>

– Designation fees

- Currently 80 EUR/ country (max. 560 EUR)
- From April 1, 2009 Flat fee of 500 EUR



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## Upcoming Changes



Outline  
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Strategy

- **Case Law of the EPO Boards of Appeal**
  - **Diagnostic methods vs. Surgical Method**
  - **Stem Cells**
  - **Essentially Biological Processes**



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## Upcoming Changes



Outline  
Review  
Changes  
Strategy

- **Diagnostic methods**
  - Clarified by decision G1/04 (OJ EPO 2006, 334)
  - Definition:
    - i) the examination phase involving the collection of data,
    - ii) the comparison of these data with standard values,
    - iii) the finding of any significant deviation, i.e. a symptom, during the comparison, and
    - iv) the attribution of the deviation to a particular clinical picture, i.e. the deductive medical or veterinary decision phase,
  - wherein **the steps of a technical nature** belonging to steps i) to iii) must satisfy the criterion "practised on the human or animal body" (see G 1/04; point 6.4.1 of the Reasons for the opinion).



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## Upcoming Changes



Outline  
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Strategy

- **Diagnostic methods**
  - **No specific type and intensity of interaction with the human or animal body**
  - **A preceding step of a technical nature thus satisfies the criterion "practised on the human or animal body" if its performance implies any interaction with the human or animal body, necessitating the presence of the latter".**



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## Upcoming Changes



Outline  
Review  
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Strategy

- **Diagnostic methods**
  - **If one of the steps i) to iv) is missing, the method would no longer fall under the "diagnostic methods" definition and would not be excluded from patentability.**



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## Upcoming Changes



Outline  
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Strategy

### • Diagnostic methods

– New Case

1. A method for MRI the pulmonary and/or cardiac vasculature using dissolved-phase polarized  $^{129}\text{Xe}$ , comprising the steps of:
  - positioning a patient in an MRI apparatus having a magnetic field associated therewith;
  - **delivering** polarized  $^{129}\text{Xe}$  gas to a predetermined region of the patient's body, the polarized gas having a dissolved imaging phase associated therewith;
  - exciting a predetermined region of the patient's body, having a portion of the dissolved phase polarized gas therein with at least one large flip angle RF excitation pulse; and
  - acquiring at least one MR image associated with the dissolved phase polarized gas after said exciting step."



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## Upcoming Changes



Outline  
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Strategy

### • Diagnostic methods

- As is immediately apparent, this claim relates only to the first step of a diagnostic method (i.e. the collection of data) and, as such, is not excluded from the patentability pursuant to Art. 53 c).
- Nevertheless, the step of delivering the  $^{129}\text{Xe}$  gas is questionable
- Is this a surgical treatment ?
- Need for a proper definition of "Surgical treatment"
- Referral to the Enlarged Board Of Appeal (**Case G 1/07; pending**)



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## Upcoming Changes



Outline  
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Strategy

### • Stem Cells

### • WARF case

1. A cell culture comprising **primate embryonic stem cells** which (i) are capable of proliferation in vitro culture for over one year, (ii) maintain a karyotype in which all chromosomes normally characteristic of the primate species are present and are not noticeably altered through culture for over one year, (iii) maintain the potential to differentiate to derivatives of endoderm, mesoderm, and ectoderm tissues throughout the culture, and (iv) are prevented from differentiating when cultured on a fibroblast feeder layer."



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## Upcoming Changes



Outline  
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Strategy

### • Stem Cells

- In the application as filed, the use of embryos as starting material was described as essential to obtain the **stem cells** (the method as such was not claimed).
- I.e. disclosure (but not claiming) of the use of embryos (including human embryos) for industrial purpose.
- Rule 23d (Now Rule 28 EPC 2000)
  - Under Article 53(a), European patents shall not be granted in respect of biotechnological inventions which, in particular, concern the following:
    - ...
    - (c) uses of human embryos for industrial or commercial purposes;



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## Upcoming Changes



### • Stem Cells

- Questions pending before the Enlarged Board of Appeal (G2/07)
  - 1. ...
  - 2. If the answer to question 1 is yes, does Rule 23d(c) EPC forbid the patenting of claims directed to products (here: human embryonic stem cell cultures) which - as described in the application - at the filing date could be prepared **exclusively** by a method which necessarily involved the destruction of the human embryos from which the said products are derived, if the said method is not part of the claims?
  - 3. Does Article 53(a) EPC forbid patenting such claims?
  - 4. In the context of questions 2 and 3, is it of relevance that after the filing date the same products could be obtained without having to recur to a method necessarily involving the destruction of human embryos (here: eg derivation from available human embryonic cell lines)?



## Upcoming Changes



### • Essentially Biological Processes • PLANT BIOSCIENCE case

"1. A method for the production of *Brassica oleracea* with elevated levels of glucosinolates, which comprises:  
a) crossing wild *Brassica oleracea* species selected from the group consisting of *Brassica villosa* and *Brassica drepanensis* with broccoli double haploid breeding lines;  
b) selecting hybrids with levels of glucosinolates elevated above that initially found in broccoli double haploid breeding lines;  
c) backcrossing and selecting plants with the genetic combination encoding the expression of elevated levels of glucosinolates; and  
d) selecting a broccoli line with elevated levels of glucosinolates, capable of causing a strong induction of phase II enzymes,

wherein molecular markers are used in steps (b) and (c) to select hybrids with genetic combination encoding expression of elevated levels of glucosinolates capable of causing a strong induction of phase II enzymes."



## Upcoming Changes

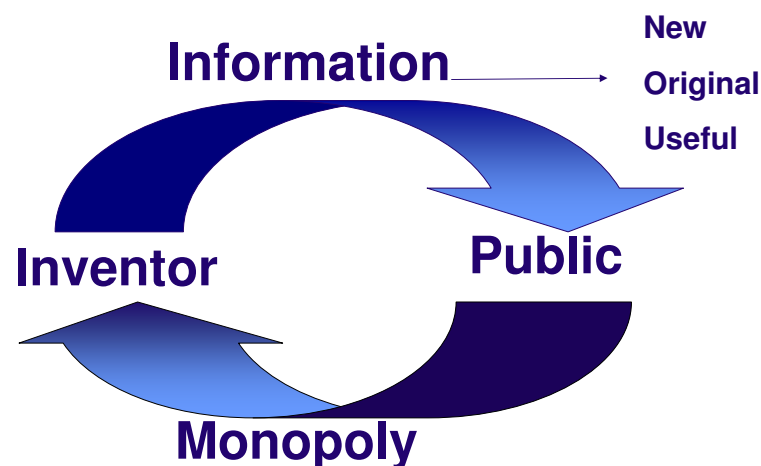


### • Essentially Biological Processes

- Questions pending before the Enlarged Board of Appeal (G2/06)
  1. Does a non-microbiological process for the production of plants which contains the steps of crossing and selecting plants escape the exclusion of Article 53(b) EPC merely because it contains, as a further step or as part of any of the steps of crossing and selection, an additional feature of a technical nature?
  2. If question 1 is answered in the negative, what are the relevant criteria for distinguishing non-microbiological plant production processes excluded from patent protection under Article 53(b) EPC from non-excluded ones? In particular, is it relevant where the essence of the claimed invention lies and/or whether the additional feature of a technical nature contributes something to the claimed invention beyond a trivial level?



## Elements of Strategy



# Elements of Strategy



Outline  
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## • 1) Identify your needs

- Why do you need a patent ?
  - To protect
  - To negotiate
  - To exploit
- Do you really need a patent ?
  - Would not confidentiality be enough ?
- Where do you need patent protection ?
- For how long ?



# Elements of Strategy



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## • 2) Choice

- National Application
- Regional Application (EP)
- International Application



# Elements of Strategy



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## • 3) Mind the costs

- Example



# Cost structure



Outline  
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- Drafting application (prior art search, interview with inventors, etc.)
  - FEE
  - TAX
- Filing EP patent application
  - FEE
- Analysis of search report
  - External FEE
- Foreign filings (MY, TW, AR, VE, ...)
  - TAX
- PCT filing
  - FEE
- Paperwork on filing
  - FEE
  - TAX
- International procedure (Preliminary Examination)
  - External FEE
  - FEE
  - TAX
- NPE/RPE PCT
  - External FEE
  - FEE
  - TAX
- Examination, grant, opposition procedures
  - External FEE
  - FEE
  - TAX
- Validation of EP
  - External FEE
  - FEE
  - TAX
- Maintenance
  - FEE



## Definitions



Outline  
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### TAX

official taxes paid directly to patent offices (EPO, WIPO, ...)

### External FEE

Fees of the foreign patent attorneys

### FEE

Internal costs / costs of the patent attorney in charge of the file



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## Definitions



Outline  
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### Analysis of SR

A SR is prepared by the EPO on the basis of the application. Generally requires amending the text.

Constitutes a go/no go point.

### Foreign filings

Only for those countries which are not part to the PCT (Patent Cooperation Treaty); requires appointing a local attorney and filing a translation.

### PCT Filing

International application covering about 140 countries (selection is made later; no translation necessary at this stage; no external agent required)



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## Definitions



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### Intl Procedure

The IPRP is prepared during the International phase; this examination permits to cure almost all defects in the application before entering NP/RP (which means less work/costs in the different countries).

Constitutes a go/no go point.

### NPE/RPE PCT

At the end of the International phase, it is necessary to initiate the national procedures in the selected countries (translation, appointment of agent, etc.)

### Examination, ...

The applications are examined country by country (a positive IPRP helps a lot).  
Constitutes a go/no go point.



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## Definitions



Outline  
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### Validation EP

Once the European patent is granted, it is necessary to file a translation of the European patent as granted in the relevant countries (to be selected among the 32 contracting states)

### Maintenance

Once the patent is granted (even before grant in certain jurisdiction), it is necessary to pay taxes periodically (generally annually) to keep the patent (application) alive.



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## Timing



T <sub>0</sub>	• Drafting application (prior art search, interview with inventors, etc.)	FEE
	• Filing EP patent application	TAX
T <sub>0</sub> + 12 m.	• Analysis of search report	FEE
	• Foreign filings (MY, TW, AR, VE, ...)	External FEE
	• PCT filing	TAX
T <sub>0</sub> + 31 m.	• Paperwork on filing	FEE
	• International procedure (Preliminary Examination)	FEE TAX
3y. < T < 8y.	• NPE/RPE PCT	External FEE FEE TAX
	• Examination, grant, opposition procedures	External FEE FEE TAX
5y. < T > 7y.	• Validation of EP	External FEE FEE TAX
	• Maintenance	FEE
Up to 20 y.		



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## Estimate



T <sub>0</sub>	• Drafting application (prior art search, interview with inventors, etc.)	FEE
	• Filing EP patent application	1100 €
T <sub>0</sub> + 12 m.	• Analysis of search report	FEE
	• Foreign filings (MY, TW, AR, VE, ...)	External FEE
	• PCT filing	2655 €
T <sub>0</sub> + 31 m.	• Paperwork on filing	FEE
	• International procedure (Preliminary Examination)	FEE 1720 €
3y. < T < 8y.	• NPE/RPE PCT	External FEE FEE 2050 €
	• Examination, grant, opposition procedures	External FEE FEE 715 €
5y. < T > 7y.	• Validation of EP	External FEE FEE Variable
	• Maintenance	Variable
Up to 20 y.		



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## Estimate TAX



Total taxes for the whole life of the patent

**7230 €**

+ validation taxes  
+ maintenance taxes  
(depend upon the No. of countries;  
can evolve by dropping patents in  
certain countries)

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## Estimate External Fee



Depends largely upon the number of countries:

Rough estimate:

Filing fee about 1000 €/ country

NPE/RPE

for the most industrialized countries (US, IN, JP, MX, CA, KR, CN, AU, ...)  
about 20000 €

Validation of EP

for the most important countries about  
10000 €

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## Internal attorney fee



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- Hidden in salary of patent attorneys / administrative staff
- For the sake of comparison  
External attorney fee:  
about 100-400 €/hour

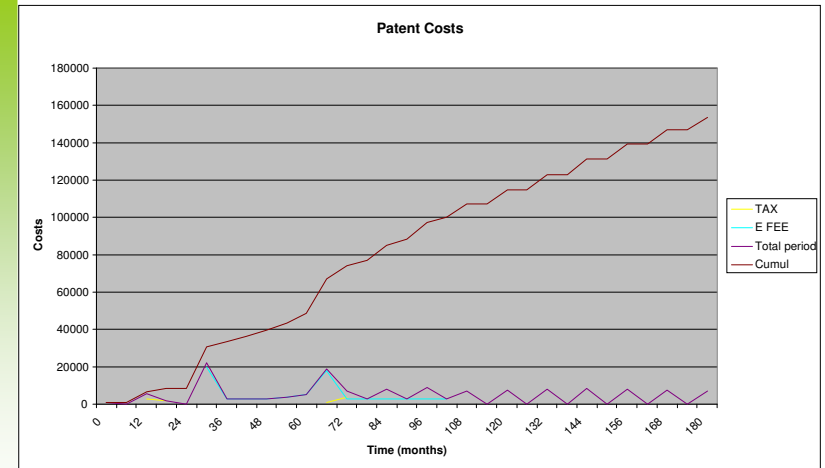


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## Cumulative Costs



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Thank you for your  
attention !



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