






Inspired Thinking

From research result to patent application

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Summary of Presentation


- Value of patents
- Determining whether a patent is appropriate for your developments
- When to file a patent application
- What and who is involved in the process of obtaining a patent
- How to write a patent application
- Techniques to reduce money spent and time to grant

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Value of patents

Why patent?



- Patents are important
 - encourage investment to develop solutions to real-world problems
 - generate income to support research and education
- They are important to your employer
- They may benefit you


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Value of patents

- most inventions which are novel, inventive and can be used commercially can be patented
- claims define monopoly
 - e.g. “A peptide consisting of the sequence ACXDEFXGHIKXL, wherein X is M, N, P or Q.”
- others can not work commercially in claimed scope
- monopoly for 20 years from filing
- patent can only be enforced once granted

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Value of patents


A patent does not:

provide freedom to operate

- Patent only prevents others working within the claim scope
- Licence for a third party's patent may still be necessary
- Normal governmental regulations apply



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Value of patents

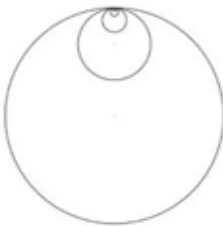
A patent does not:

prevent other patenting a development falling with the scope of the claim

A selection invention may be possible.

Granted patent:
 "A peptide consisting of the sequence ACXDEFXGHIKXL, wherein X is M, N, P or Q."

New patent:
 "A peptide consisting of the sequence ACMDEFNGHIKPL."



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Determining whether a patent is appropriate for your developments

- Can any aspects of your developments be commercialized?
- Is this form of IP protection the most appropriate?
- Is the subject matter patentable in principle?
- Has it already been disclosed or is it obvious?
- Is the term of protection from a patent appropriate?
- Would the patentable claim scope be beneficial?
- Would a trade secret be better?
- Are you ready to file the application?

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Examples:

Can any aspects of your developments be commercialized

- Development: Determination of the coordinates of a crystal.
- Commercial product or process?: Not without further development.

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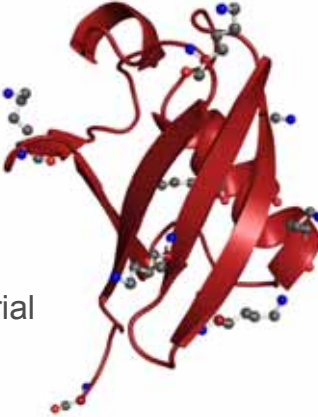
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Examples:

Is the subject matter patentable?

- Development: Identification of a protein or polynucleotide with no known function.
- Patentable?: No
- Why: No practical commercial application. (Fails for lack of industrial application.)




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Examples:

- Development: A genetically modified human or means for making the same.
- Patentable?: No
- Why : Statutory exclusion.





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Examples:

But these are all patentable:

Bacteria and cells 

Plants 

Transgenic animals 


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Examples:

Has it already been disclosed or is it obvious?

- Development: Determination of the underlying mechanism of action for a known medical treatment.
- Patentable?: No
- Why: No new technical effect. (Fails for lack of novelty.)



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Examples:

Would it be easy for a third party to design around your patent?

- Development: An array of probes on a platform which can be used to diagnose a disease.
- Patentable?: Yes
- Claim scope may be narrow.
- May be easy to design around using probes that bind to a different region of a target molecule.
- Can it be reverse engineered?

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Are you ready to file the application?



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When to file a patent application

Major considerations:

- File before public disclosure
- Data required to support the application
- IP strategy
- Funding

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When to file a patent application

File before public disclosure:

- Scientific article or conference reporting the work
- Third party publication
- Discussions with interested parties



Myth: I don't need to worry about my own disclosures before filing.

Reality: Any public disclosure, by anyone, oral or otherwise may affect patentability.

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When to file a patent application

Data required to support the application:

- Support required across the full scope of the claims.
- Medical indications require support at least at *in vitro*, preferably *in vivo* level.
- Difficult to treat conditions require particularly good evidence, e.g. cancer, HIV.
- Post-filing evidence only allowed in some countries.

When to file a patent application

Is the evidence sufficient to support the claims?



For example:

- a) evidence that a receptor is implicated in a disease and compound is receptor antagonist. (Unlikely to be sufficient)
- b) evidence that the antagonist has a relevant effect when tested *in vitro*. (Possibly sufficient)
- c) evidence that the inhibitor has a relevant effect when tested *in vivo*. (Sufficient)

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When to file a patent application

Balancing need to publish with avoiding prior disclosure

	0	12m	24m	36m
Developments	Multi – component mix antagonises target receptor implicated in disease	Active component identified	Antagonist effective in <i>in vitro</i> test relevant to disease	Antagonist effective <i>in vivo</i> to treat disease
Publishable results	↑	↑	↑	↑
Sufficient data for patent application			Maybe	Yes

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When to file a patent application

IP strategy:

- Application may be part of a larger filing series.
- Applications will publish and have prior art effect against one another.
- Strategic filing allows term to be extended to cover improvements.


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When to file a patent application

Funding:

- File before seeking investment/collaboration
- Costs escalate rapidly on national phase entry



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What and who is involved in the process of obtaining a patent

- Inventor(s) - makes the invention (not always the authors of a scientific article).
- TTO – evaluates patentability and commercial potential.
- Patent attorney - writes the patent application and files it at the patent office.
- Patent Office Examiner - examines the patent application and ultimately refuses or grants the application.

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What and who is involved in the process of obtaining a patent

What does the Patent Office Examiner do?

- Search the application
- Examine whether the application meets patentability requirements

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Getting patents abroad

Individual countries

Initial Filing National Filing Publication Grant

Start 12 months 18 months 2+ years

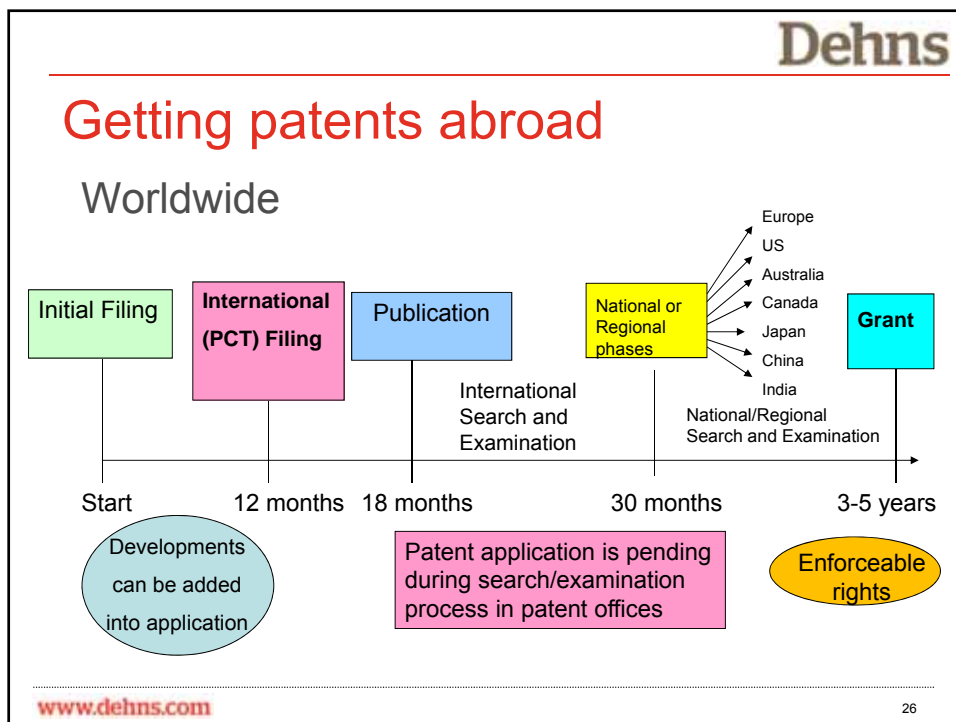
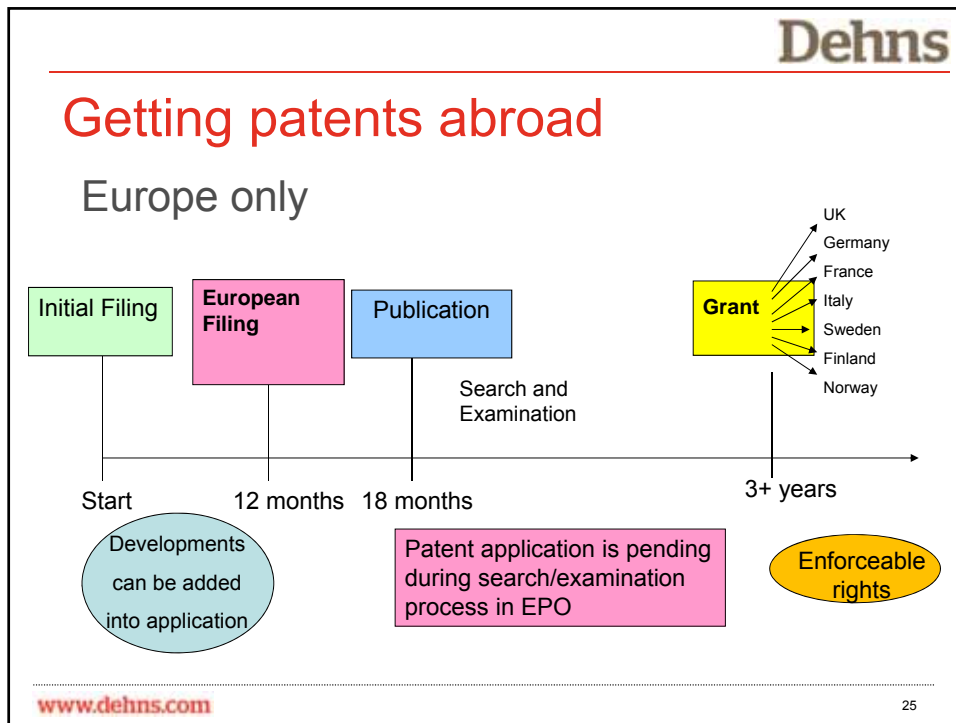
Search and Examination

Developments can be added into application

Patent application is pending during search/examination process in patent office

Enforceable rights

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How to write a patent application

Anatomy of a Patent

Front page	Bibliographic information, abstract, drawing
Description	What is the invention about? Background to the invention Statements of invention, preferred features Examples of the invention
Claims	Define the scope of the invention in words
Drawings	Illustrations of examples of the invention

How to write a patent application

The priority application

- ≤12 months before national/international application
- Not essential
- File in any Paris Convention country
- Provides priority only for disclosed, enabled subject matter
- Frequently used as a filing before all data is ready but must be used with caution
- Will not always protect against relevant disclosure between priority and filing date

How to write a patent application

The priority application

Myth: Once I've filed my priority application I can freely disclose its content.

Reality: If a later filed application is not fully entitled to priority intermediate disclosures may affect patentability.

- priority application : "A peptide consisting of the sequence ACXDEFXGHIKXL, wherein X is any amino acid."
- final application claiming priority: "A peptide consisting of the sequence ACXDEFXGHIKXL, wherein X is M, N, P or Q."
- intermediate prior art: Peptide ACPDEFPGHIKPL (i.e. X = P)

How to write a patent application

Claims

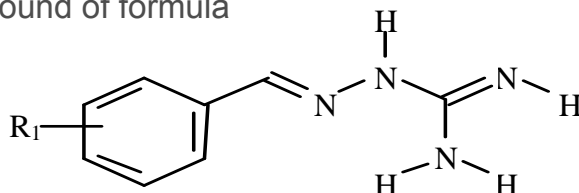
What types of claims are possible:

- Product - e.g. A DNA molecule, a protein, an apparatus.
- Method - e.g. A method of making a product, a method of screening.
- Use – e.g. Use of a product as a herbicide.
- Use limited product – e.g. Compound for use in treating a disease.

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Medicines

A compound of formula



wherein R₁ is C₁₋₂₀ alkyl or amino,
or a pharmaceutically acceptable salt
thereof.



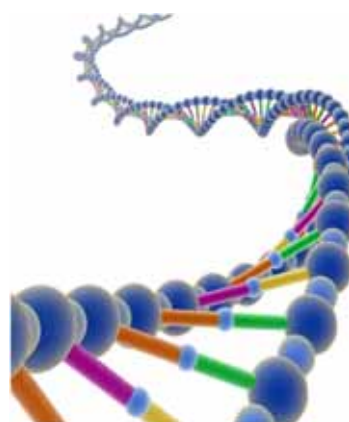
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Biological molecules

1. An **isolated nucleic acid molecule** comprising the nucleotide sequence shown in SEQ ID NO: 1.
2. A **purified polypeptide** comprising the amino acid sequence shown in SEQ ID NO: 2.



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Biological Molecules – Other Claims

3. A **vector** which comprises a nucleic acid molecule as claimed in claim 1.
4. A **host cell** comprising a vector as claimed in claim 3.
5. An **antibody** which specifically recognises a polypeptide as claimed in claim 2 but which does not recognise a polypeptide having the sequence of SEQ ID NO: 5.
6. A **pharmaceutical composition** comprising a polypeptide as claimed in claim 2, optionally together with one or more carriers, adjuvants or excipients.
7. A **vaccine** comprising a **polypeptide** as claimed in claim 2, optionally together with one or more adjuvants.

Chemical compounds

1. A compound of Formula X... (or a salt thereof, or ester prodrug etc)
2. A compound of Formula Y... (intermediate compounds)
3. A composition comprising the compound of Formula X (e.g. a pharmaceutical composition)

Methods and Processes

Standard method and process claims

- A process for producing a polypeptide of formula ... comprising the steps ...
- An *in vitro* method of assaying for the presence of *Staphylococcus* bacteria comprising ...
- Use of a nucleotide primer of SEQ ID NO: 1 for determining ...
- A method of producing a transgenic plant comprising ...
- A process for making a compound of Formula X comprising...
- A compound of Formula X for use in treating disease Y
- Use of compound Y for doing....

How to write a patent application

Points to consider when drafting claims:

- What actions need to be taken and products used to put the invention into effect?
- Which actions or products would be performed or made commercially?
- What variants could be used?

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How to write a patent application

Claim scope

- Claim language must be clear and concise
- Take prior art into account
- Claims should be unified
- Provide fall-backs
- Include only essential features
- Cover embodiments for which data is presented
- Cover reasonable variants

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How to write a patent application

Claim Scope

A, B, C = proteins with >80% sequence identity
 D = known protein

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Example

Invention - A new protein has been identified which treats a disease X.

Possible claims:

1. A polypeptide comprising an amino acid sequence as set forth in SEQ ID No. 1 or a sequence with 90% sequence identity to said sequence.
2. A nucleic acid molecule encoding the polypeptide as defined in claim 1.
3. A vector comprising the nucleic acid molecule as defined in claim 2.
4. A host cell containing the vector as defined in claim 3.

Example

5. A method of producing a polypeptide as defined in claim 1 comprising culturing the host cell of claim 4 under conditions to express said polypeptide and isolating said polypeptide.
6. A polypeptide as defined in claim 1 for use in therapy.
7. A method of treating disease X comprising administering a polypeptide as defined in claim 1 to a patient.
8. A polypeptide as defined in claim 1 for use in treating disease X.
9. An antibody which specifically binds to a polypeptide as defined in claim 1.

Techniques to reduce money spent and time to grant

- Mechanisms for **accelerating prosecution**:
 - select filing route (national vs international/regional)
 - accelerated prosecution possible in many countries
 - Patent Prosecution Highway
 - avoid taking extensions
 - pay exam fees early
 - be pragmatic about what is patentable
 - seek early grant of core subject matter and use divisional/continuation applications for the rest

Techniques to reduce money spent and time to grant

Mechanisms for **reducing costs (1)**:

- * Pre-application review:
 - consider patentability, value of patent protection and countries of interest
 - identify scope of protection that will be necessary
 - conduct pre-filing searching to assess prior art
 - conduct experiments to support full scope of claims

Techniques to reduce money spent and time to grant

Mechanisms for **reducing costs (2)**:

* Filing the application:

- file the best possible first application, with fall-backs
- be selective in country choice
- consider languages – translations of long specs are expensive
- consider filing nationally

Techniques to reduce money spent and time to grant

Mechanisms for **reducing costs (3)**:

* Prosecuting the application:

- avoid extensions
- be pragmatic
- Patent Prosecution Highway may be helpful
- pre-filing actions are key to reducing time and expense

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Sources of Information

General information

UK Patent Office: www.ipo.gov.uk/patent.htm
European Patent Office: www.epo.org
Chartered Inst. of Pat. Attorneys: www.cipa.org.uk
Dehns: www.dehns.com/site/information/information_sheets/

Patent Searching

Espacenet patent database: <http://worldwide.espacenet.com/>
US Patent Office database: www.uspto.gov/patft/index.html


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