Grand Challenges
African Drug Discovery Accelerator

Drug Discovery and Development Course

Patent Strategy, when to protect your innovation?

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Learning objectives

- Understand what a patent application is and why it is important
- Understand what can be patented and why
- Understand enough, as drug discovery scientists, the important legal features of a patent application
- Be aware of the difference between inventorship and authorship, and the risks of early compound structure disclosure

Patenting – things to think about

- Who can help?
- What is a patent?
- Why and where do you file a patent?
- What can I file?
- When to file?
- What is the process of getting a patent?
- How to assign inventorship?
- What is the scope and how to select examples?
- Can additional examples be added?
- What are the claims?
- What can be published and when?
- What about additional fillings?

Who can help?

- Patent attorneys take responsibility for drafting and filing patent applications
- Scientific legal discipline requiring incredible attention to detail, organisation and punctuality
- Your institution will have assigned patent attorneys who can advise on when and how to patent, and then support you with the draft and filing
- Your legal or tech transfer team likely to be the conduit
- Collaboration with the project team – principally medicinal chemistry
- If you file a patent do it well!

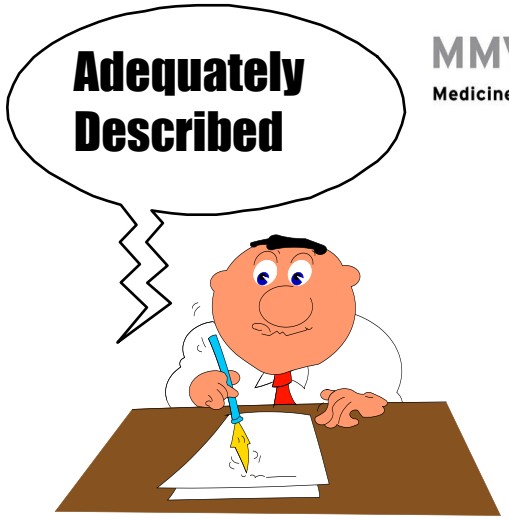
What is a patent?

- A legal right granted to inventors for their invention
- Inventors may own or assign their ownership to an employer
- The right to prevent others from making, using, selling their invention
  - A patent does not give you a right to sell your invention, rather the right to prevent others from selling it
- For a limited period of time (usually 20 years from the filing date)
- In particular countries (geographical scope)

Why and where to file a patent?

- If working on commercial diseases then patenting is driven more by exclusivity
  - Establishes a monopoly that prevents other companies selling your drug
  - Enables costs of R&D to be recouped and deliver a profit
- Gives you freedom to operate – no-one can prevent you acting
- Even if working on a neglected tropical disease it is a valuable asset to attract Pharma partners and reinforce quality
- A patent needs to be filed and approved in every country in which the right might be exercised (e.g. manufacturing or sales)
- Generally, the MMV default list is USA, China, Japan, Brazil, India, South Africa and EU (Germany, France, Spain, Netherlands, Italy, Turkey, Switzerland and UK)
- Choice made by the filing institution

What can you file?



- Must be Useful, Novel and adequately described
  - Use = treat or prevent a disease (i.e. not inhibit a target)
  - Novel = either an undisclosed compound that is not obvious, or an undisclosed use of a compound – reduced to practise
    - A compound without biological activity or a virtual compound would not be patentable
  - Enabled so that someone “skilled in the art” can reproduce invention
  - All terms e.g. “alkyl”, “aryl”, “optionally substituted with X” must be defined
- Medicinal chemistry
  - Chemical compounds, chemical intermediates, isomers, salts, new physical forms (crystal forms, polymorphs, solvates, hydrates), chemical processes
- Other: Biotechnology e.g. DNA, RNA, proteins; formulations, combinations

Types of filing

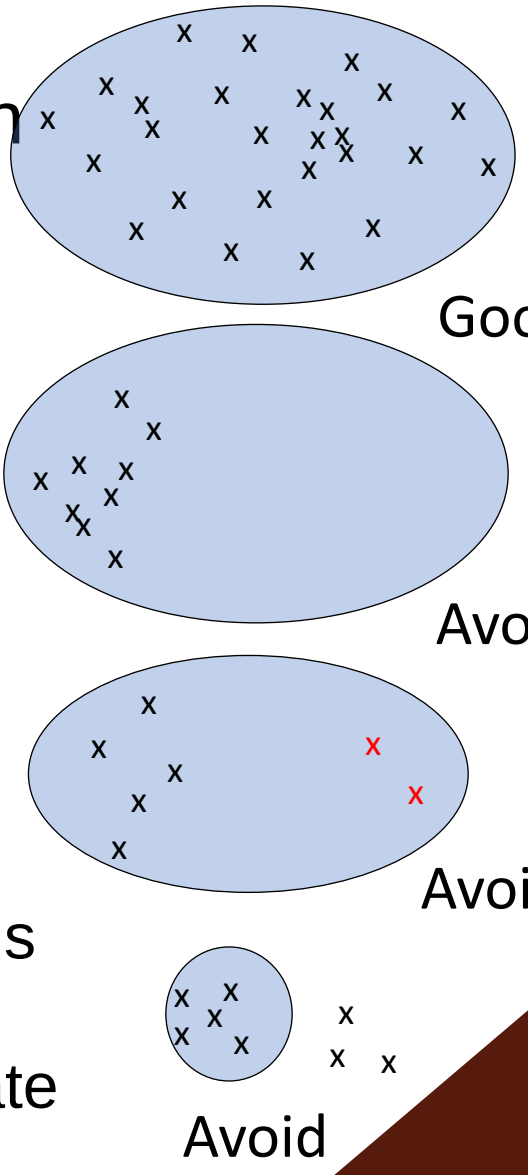
- Composition of matter
  - “Compound *per se*” means that novel chemistry is claimed
  - “Use” means that a use for the chemistry is claimed and justified
  - This type of patent is the strongest – novel chemistry and use

- Use patent
  - Even if chemistry is published, a new “use” can be discovered
  - Such known chemistry can then be patented for the new “use”
  - Weaker type of filing – as no protection on the compounds *per se*
  - May even require a license from a third party

- Others

When to file a patent?

- First to file gets the patent (US slightly different and can go back to the date of the invention)
- Timing depends on circumstances
  - Urgent competitive areas tend to file earlier
  - Non urgent/ first in class tend to be later
- MMV strategy is to file late, around candidate selection and file narrow
  - Does have advantages in you can better define the scope
  - Less filings potentially needed
- What constitutes ‘narrow’?
  - Two examples: one 15 compounds and one ~250 compounds
  - 250 examples too many? expensive and unnecessary
  - 15 too narrow? possibly ok if you are confident your Candidate Drug is covered, and you will not work outside that scope



Filing procedures

- PCT (WIPO)
  - Patent Cooperation Treaty (PCT) - applicant files 1 patent application and potentially accesses 150 countries
  - Harmonisation saves a huge amount of time and money
- National phase
  - 30 months post filing
  - Translations and filings in each individual country
  - Patent costs high – but are 3 years post filing at which point the importance of the filing and likelihood of granting may be clear
  - Patent prosecution in each country

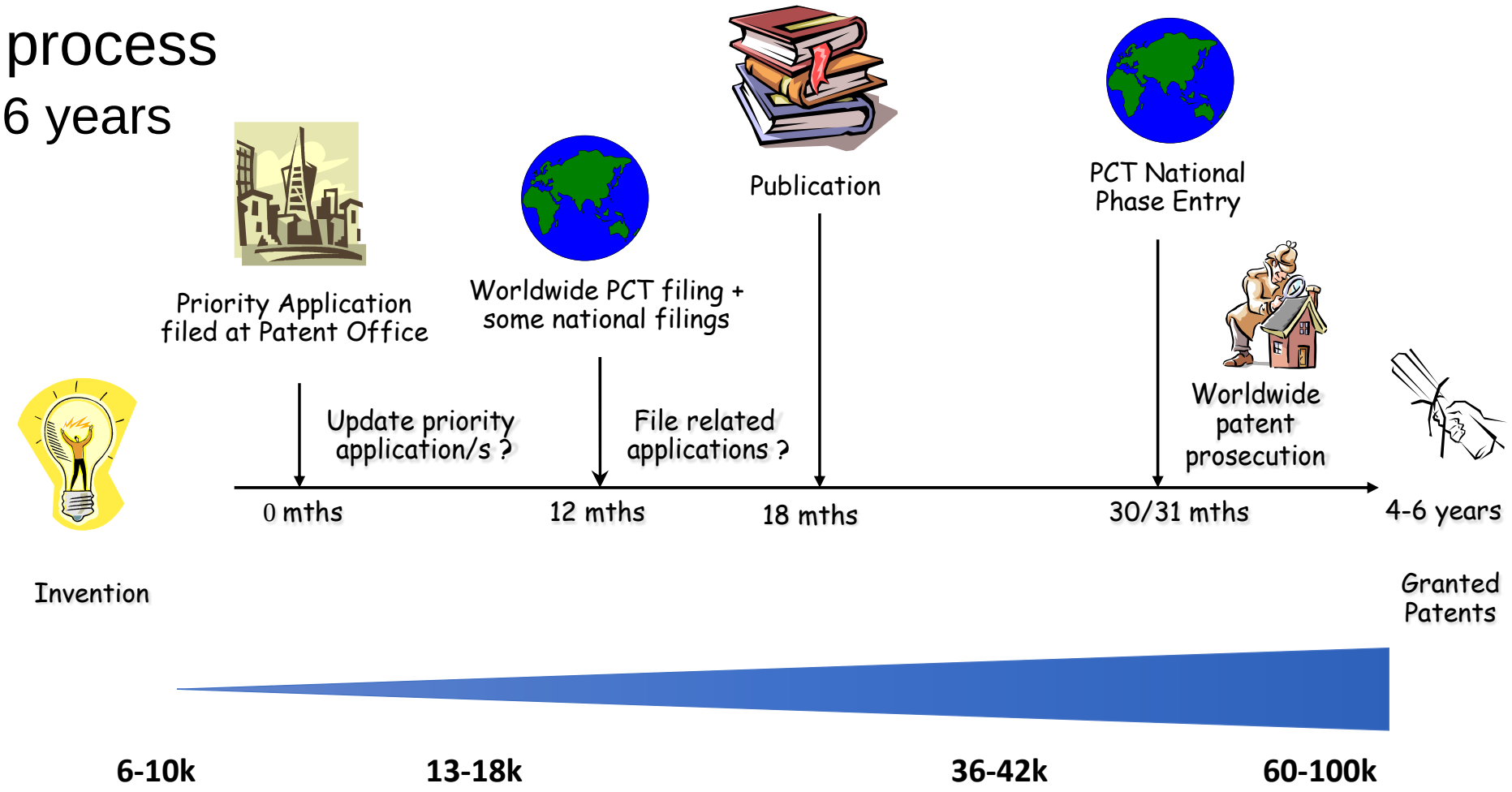
Filing procedures - Africa

- South Africa
  - Strong IP infrastructure
  - Signatory to PCT

- Africa harmonisation
  - ARIPO (African Regional Intellectual Property Organization) – 22 countries
  - OAPI (Organisation Africaine de la Propriété Intellectuelle) – 17 countries

What is the process of getting a patent?

- A lengthy process
  - Up to 4-6 years



- Maintaining a patent portfolio is expensive but can be valuable

Inventorship

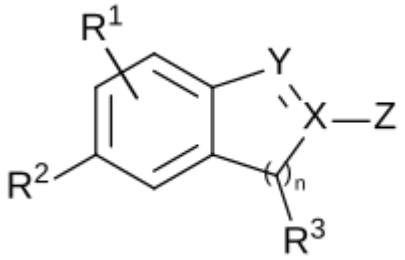
- Patent inventorship is a legal determination of who contributed to the claimed invention
- Only individuals who made a contribution to the idea embodied by the claimed invention are inventors
- This means individuals who have put in a lot of effort on a project, e.g. making examples or testing cpds, will not necessarily be an inventor
- Being named as an inventor on a patent is not the same as being named as an author of a scientific paper
- Naming the wrong inventors may have adverse legal consequences
- Inventorship is always decided by a Patent Attorney
- One option to keep a record of suggested ideas as you go along
- Can use standard templates

Mentimeter

- Question Yes/ No/ Maybe
- “Do you think intellectual property and patents are i) a good thing or ii) a bad thing?”

Structure of a patent

- Title and background of the invention – setting the context
- Summary of the invention – e.g. chemical series treating malaria
- Detailed description of the invention
  - Define the scope of the patent application
  - Markush structures with definitions
- Experimental
  - Synthesis of every example and biological data
- Claims
  - Legal heart of the filing
  - These will be reviewed by a patent examiner and potentially contested
  - If a claim is rejected at prosecution, then that IP cover is lost

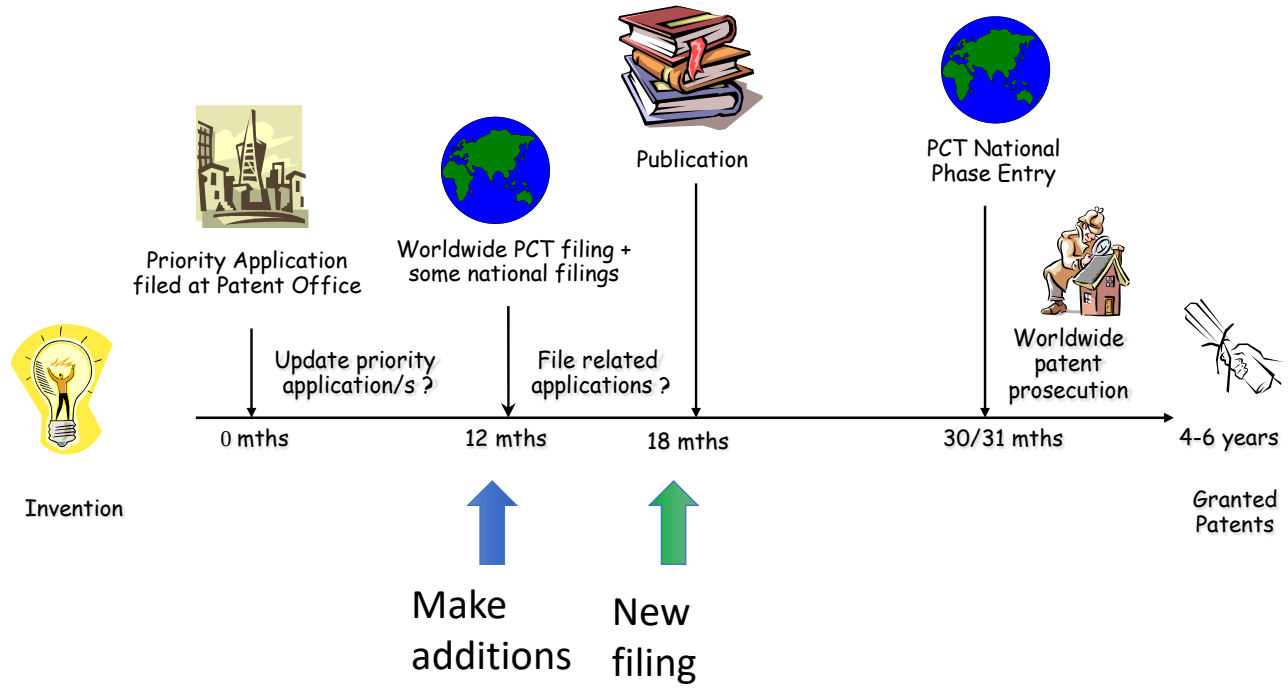


Scope and Examples

- Prior art means – any information that is published or disclosed that could affect the “novelty” claim of your patent application
- Be aware of the prior art
  - Get advice from a patent attorney as to what is novel
- Scope is the chemical breadth claimed by the patent application
  - It is justified on the basis of synthesised and tested chemical examples
- Do not try to cover too much – focus on your most interesting compounds
- It is worth covering enough that it does not allow others to easily bypass or bust your patent
- Include the assays used and the activity of the molecules
- Do not hide anything

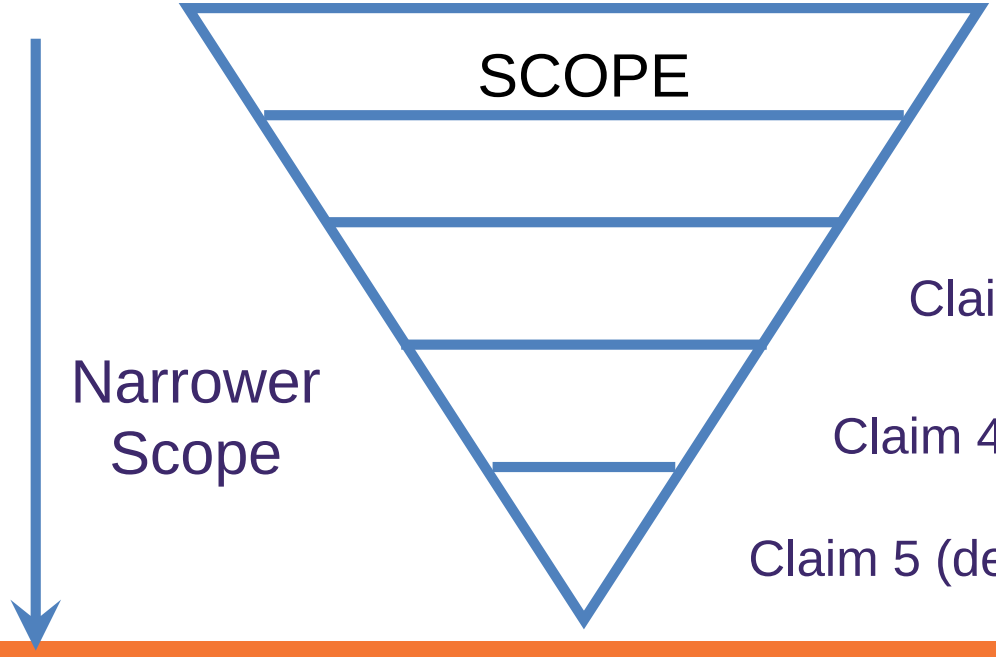
Adding Examples

- You can add examples or modify the scope up until the priority application
  - Make sure you allow time to incorporate
  - Realistically you have 10-11 month after the original filling
  - Changes to scope will have that new priority date
- New filings can be made up to publication without your patent counting as prior art



Claims

- These are actually the most important part as they define what will be granted
- Do not be surprised if these change during prosecution – they usually do
- Remember a patent application or published patent is not a granted patent
- This is where you might have used “preferably” and “more preferably” to help define the dependant claims
- So, if you lose claim 1 you still keep the most important ‘compounds’



Claim 1 (independent)

Claim 2 (dependent on claim 1)

Claim 3 (dependent on claim 2)

Claim 4 (dependent on claim 3)

Claim 5 (dependent on claim 4)

Publications

- MMV has a strong drive to publish as do you and many of your collaborators
- However, a publication might invalidate your claim(s)
  - Remember a publication can be anything prior to the patent filing date
  - Written (paper, internet article or abstract), oral (lecture, chat room, conversation), prior use
- If you make changes to the patent during the 12 months after the initial filing, your changes get that new date
  - Make sure you do not “prior art” yourself with your own publication!

Additional filings

- These can be made up until your patent publishes without your patent counting as prior art
- In terms of cost this is best avoided, and the file late approach reduces the need for this

- Process chemistry or formulations (discussed 18/3/24)
- Generally, not worth the expense for MMV
- Could publish and remove novelty
- Obviously, there could be exceptions eg if its your formulation that's the project

Summary

- Make sure your project has given thought to a patent strategy
- Make sure you align any publications with your patent strategy
- Keep a note of who has contributed to the invention and use an inventorship form
- Remember an inventor is not the same as an author on a paper
- When sharing information with the patent attorney:
  - Provide data table
  - Structure, IUPAC name, project number, potency
  - Be careful what you write
  - “We haven’t made an invention yet”, “It was obvious to .....”,“It was a mere replacement of X for Y” – disastrous statements!
- Many inventions may appear obvious with hindsight, but were anything but that beforehand
- Seek advice when needed

References

- https://www.youtube.com/watch?v=6ZNC5jA3VSw
- https://www.wipo.int/pct/en/users/summary.html
- https://www.wipo.int/directory/en/details.jsp?country_code=ZA
- https://www.debeerattorneys.com/post/what-is-wipo
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Define your patent strategy

If you plan to patent, be clear on your publication strategy

Inventorship is not authorship

Patents are defensive and can raise value of a candidate drug

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