Brief introduction to Patenting ATMPs

Dos and Don’ts & Questions to Consider

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Introduction and Table of Contents

This presentation provides a short introduction to patenting inventions as well as a brief summary of special considerations relating to patenting ATMPs. If you have any questions, you are most welcome to contact AWA for advice regarding protecting your specific invention.

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Managing IP Rights

Action Points

Step 1: Create

Step 2: Analyze and Protect

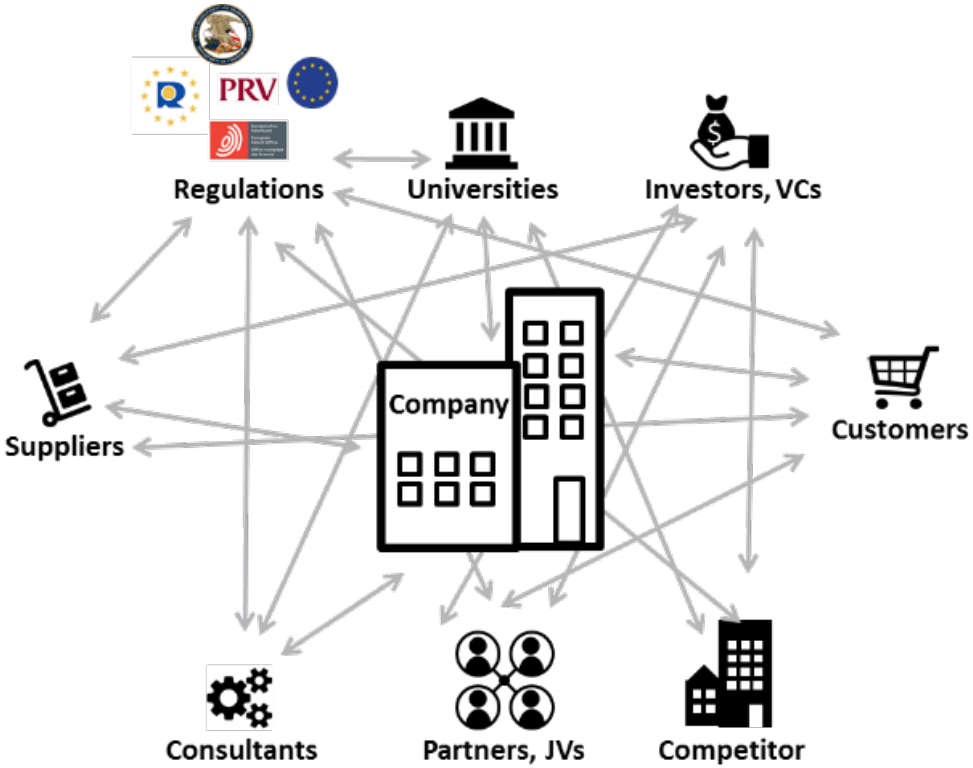
Step 3: Connect IP Strategy with Business Plan

Step 4: Profit

Why manage your Intellectual Property?

*To **strengthen your business position** by **controlling** your **relations** with competitors, suppliers, collaborators, customers etc.*

- To **block** competitors
- To ensure **FTO** (Freedom to Operate)
- To gain **bargaining power** over a supplier
- To **add** a **revenue** stream (licensing, sale of side ground)
- To participate in innovative **collaborations**
- To serve as a basis for **financing**



Introduction to Patents

What is a patent?

Patents are **time limited national rights of prohibition**.

The legal rights conferred by a patent are **negative rights**.

Thus, having a patent for your invention gives you the right to **stop others** from using your invention.

However, it does not automatically mean that you may use your invention in a commercial setting as there may be conflicting rights that belong to others, requirements for regulatory approval or the like.

A patent may be valid for **20 years** from filing the patent application, provided annuities/renewal fees are paid.

Patents are **national/regional rights** and the patent protection granted for an invention may vary between different jurisdictions.

Patents are granted to inventors for inventions

An invention is a **technical solution** to a problem.

An invention may be a **product** (for example a molecule, composition or a cell line), a **process** or **method** (for example method of production) or a **use**.

When an invention is ”**born**” the **inventor** thereby automatically gets a right to a patent on that invention. This means that everybody who gets the same idea will also get the right to patent. However, it is the inventor **FIRST-to-FILE** a patent application that will obtain the patent.

The right to a patent may be assigned by laws, terms of employment, transfer agreements, union agreements etc.
In Sweden, we have the **Professor’s privilege,** which means that teachers and researchers at universities own the right to their inventions and thus may apply for patents.

Consider your invention from a business perspective

IMPORTANT

Patents and other intellectual property rights are **business tools**. Therefore, it is important to **align** your patent strategy with your business model.

Consider how you are planning to **make money** of your invention?

- How are you going to attract investment?
- How far are you going to develop it yourself?
- Are you seeking partnerships?
- Are you going to take it to market/clinic yourself?
- Are you planning to license it to others or sell?
- Is big pharma your partner/buyer?

DO: ALIGN YOUR PATENT STRATEGY WITH YOUR BUSINESS PLAN e.g. consult a patent attorney or business coach/innovation office.

DO: ENSURE TO PROTECT YOUR INTEREST WHEN ENTERING A COLLABORATION AND SEEK ADVICE FROM EXPERTS e.g. consult a patent attorney.

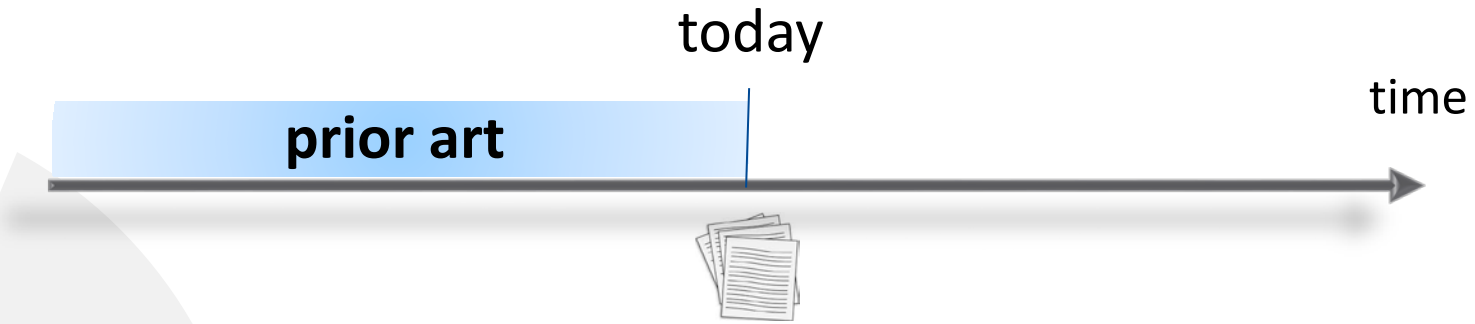
How is the **business environmen**t around your technology?

- Is it a competitive market segment? Who are your competitors and what are they doing?
- How does your technology differ?
- Are there any third party rights that hinder your plans? Do you have freedom-to-operate?

What criteria does my invention need to fulfill?

An invention has to be **NOVEL,** exhibit **INVENTIVE STEP** and be susceptible to **INDUSTRIAL APPLICATION** for it to be patentable.

These criteria have to be fulfilled in relation to **everything** that was **publicly available** on the day prior to filing day of the patent application.



IMPORTANT

DON'T: DISCLOSE YOUR INVENTION PUBLICLY PRIOR TO FILING A PATENT APPLICATION

DO: A NOVELTY SEARCH CAN BE A GOOD WAY TO FIND OUT WHETHER SOMEONE ELSE HAS MADE THE SAME INVENTION BEFORE STARTING AN EXPENSIVE PATENTING PROCESS e.g. consult a patent attorney for assistance. You may also search patent databases such as Espacenet (https://www.epo.org/searching-for-patents/technical/espacenet.html)

“everything that was publicly available”?

An invention is only novel if it has not been described **anywhere** in the prior art. It has to be non-obvious to a person skilled in the art considering the prior art to have inventive step.

Forms of prior art

- Published patents and patent applications
- Scientific publications, newspaper articles and books
- **Grant application**
- **Conference posters and abstracts**
- **Oral presentations**
- **Dissertations**
- Information on the internet, TV, radio
- Prior use
- Sales
- And more…

Availability

- Not necessary that the public has accessed it - If *could* have
- accessed, it is considered available
- Available if no secrecy agreement in place
- Sales

IMPORTANT

DO: BE CAREFUL NOT TO DISCLOSE YOUR INVENTION WHEN APPLYING FOR RESEARCH GRANTS and ENSURE TO CHECK SECRECY BOX IF AVAILABLE

DO: ENSURE TO HAVE NON-DISCLOSURE AGREEMENTS WITH COLLABORATORS, INVESTORS ETC

Patent claims

What a patent protects is defined by the **patent claims**.

Patent claims are the ”**laws**” of the patent, defining what the patent prohibits others from doing. Therefore, the wording of the claims is of great importance.

The patent **law varies between different jurisdictions,** affecting if and how an invention may be protected. It is important that a patent application is drafted taking into account the patent law in all countries of interest.

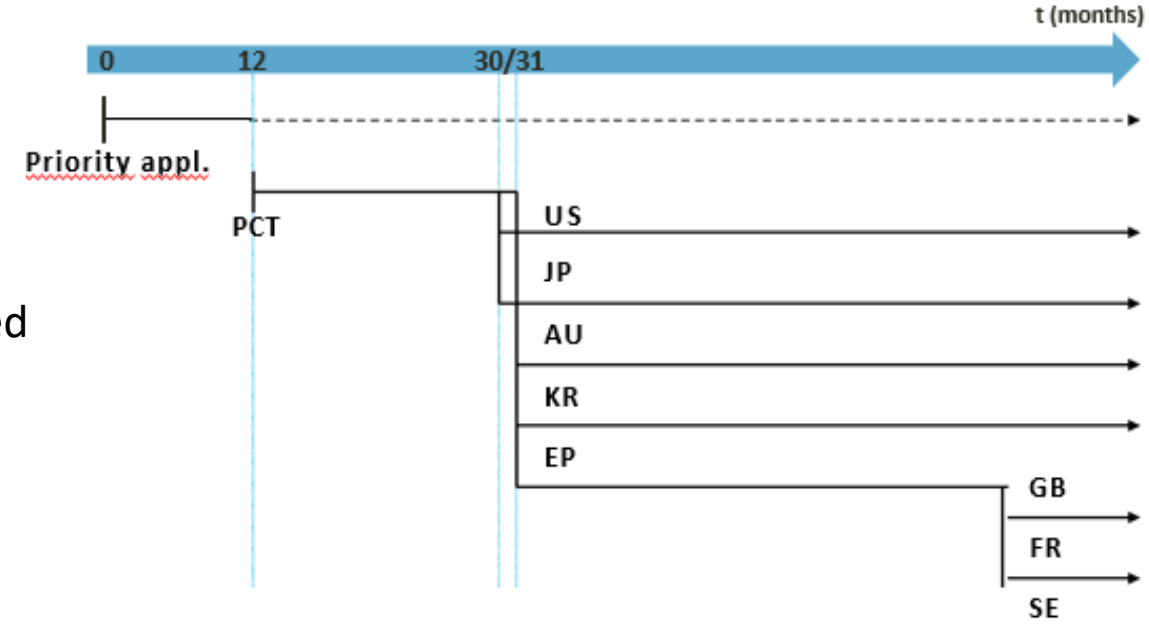
Different patent claims may be granted in different countries due to differences in law and due to a subjective national examination process.

Common filing strategy

Commonly a first patent application, so called **priority application,** is filed in a country/region where the applicant is based.

Within **12 months** of the first filing, a second application claiming priority for the same invention is filed. The second application is often an **international (PCT) application**, which allows for “buying time” while obtaining a patentability opinion from the Authority. This also delays the business decision of where to prosecute the application.

Within 30/31 months from the first filing, the international application is **nationalized** into applications in different countries where protection is desired. The nationalized applications are prosecuted into **national granted patents**.



Filing a patent application

It is important to file a first **quality** patent application as this improves chances of obtaining a granted patent right.

- It is a common (mistaken) belief that a poor first application may be improved later.
- Saving at this early step will often lead to higher costs later and may lead to not obtaining desired protection.

The filing of the first patent application in one country **starts the clock** for the next procedural steps.

- You need to apply for a patent for the same invention in other countries within 12 months (with priority). Priority means that the filing date of the first application is used for evaluation of patentability in light of the prior art.
- If you wish to start over and reset the clock, one must withdraw the first application.

IMPORTANT

DO: ENSURE THAT THE FIRST PATENT APPLICATION IS OF GOOD QUALITY
DO: SINCE THE FIRST FILING STARTS THE CLOCK, SECURE FINANCING FOR PATENT COSTS EARLY ON
DON´T: FILE TOO EARLY - SINCE THE FIRST FILING STARTS THE CLOCK, MAKE SURE YOUR INVENTION IS DEFINED AND EXPERIMENTALLY VERIFIED

Patenting of ATMPs

A few words on Life Science inventions

In addition to the regular patentability criteria, some special considerations apply to life science inventions. For example in Europe legal exemptions to patentability are based on ethical and moral considerations.

Patents are not to hinder healthcare professionals in their professional activities and not to hinder providing good patients care.

=> In Europe methods of treatment, surgery or diagnosis on the patient's body are not patentable, however products used in such methods may be protected.

=> In the US, methods of treatment are patentable as health care professional are exempted from infringement, but diagnostic methods are becoming increasing hard to protect as are seen to relate to nothing more than natural processes that occur in the body.

Exemptions are there to ensure the human body and its parts, including gene sequences, are not patentable.

=> In Europe gene sequences **isolated** from their natural environment may be patented.

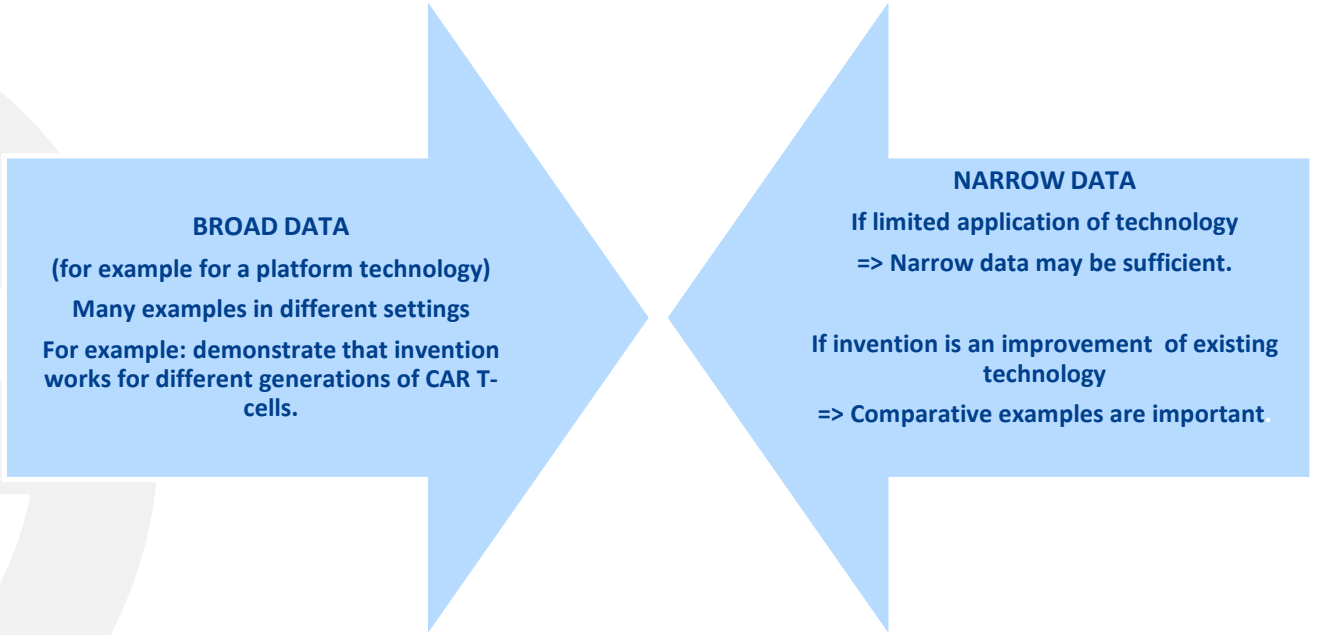
=> In the US, patents for a product in any field of the technology are not allowed if the same **product can be found in nature**, even if the product has been isolated from its natural environment, for example gene sequences and cells.

The importance of data in the patent application

Experimental data is included in the application to **support** that the claimed invention works as described.

- Limited data may lead to a more narrow scope of protection while broad data may lead to a wider protection scope.
- For a wider protection scope, it is recommended to include many different example embodiments instead of in depth details on few embodiments of the invention.

Data is also considered by the for determining **plausibility** that the invention will work as stipulated based on extrapolation of data (for example as treatment for a disorder).



IMPORTANT

DO: CONSIDER THE BALANCE BETWEEN EARLY FILING AND COLLECTING DATA AND ADAPT FILING STRATEGY.

Special considerations for Advanced Therapeutic Medical Products

The ATMP-field is quickly evolving and along with it, patent practise is currently developing and adapting. Despite exceptions to patentability, multiple aspects of cell and gene therapies are eligible for patent protection.

In general, **genetic constructs, vectors and genetically manipulated cells are patentable**. Thus, if the product that is administered is **structurally or functionally distinct** to previously described populations of cells, it may in principle be protected. However, if the population is patient specific it may be difficult to obtain a product claim which captures the product sufficiently. For many therapies, claims to a modified population of cells expressing the specific construct may be suitable as well as claims to the constructs, genes, peptides and/or vectors themselves used in manipulation.

Even where cell populations are not structurally or functionally distinct method claims may also be very valuable, for example directed to the **methods used for culturing, differentiation, manipulation and or preservation** of cells. Patents relating to treatments and treatment regimens may also play an important role in patent portfolios.

If cells are patient specific and one cannot define them with common features, method protection will likely be even more important. However, if a product is an ”off-the-shelf” cell therapy product, product protection is particularly desirable (in addition to method protection).

In vitro differentiated cells and stem cell populations may be patented if one can distinguish them from other previously described cells (and in the US, also from cells occurring naturally in the body). As this may be challenging, method protection may be important in this case as well.

Examples of structural and functional features

- **Structural features** describe the ”appearance” and physical properties of the invention.
- For example, a cell line may be characterized by structural features, such as…
  - *Presence of a recombinant vector, which vector comprises a given sequence.*
  - *Expression or presence of a recombinant protein/receptor/biomarker or the like.*

- **Functional features** describe the functional properties and what the invention is capable of doing. The application should include a description of how the functional features should be measured.
- For example, a cell line may be characterized by functional features, such as…
  - *Ability to induce a immune responce*
  - *Ability to bind a target, for example with a certain affinity.*

Example: *A cell comprising a chimeric antigen receptor (CAR) comprising from N-terminus to C-terminus: (i) an I domain of the a_L subunit of human lymphocyte function-associated antigen- 1, (ii) a transmembrane domain, (iii) at least one co-stimulatory domains, and (iv) an activating domain, wherein said I domain is capable of binding ICAM-1 at an affinity between about 1 mM to about 1 nM.*

If your invention relates to cells populations/cell therapy

Consider what **novel features** define your cell population?

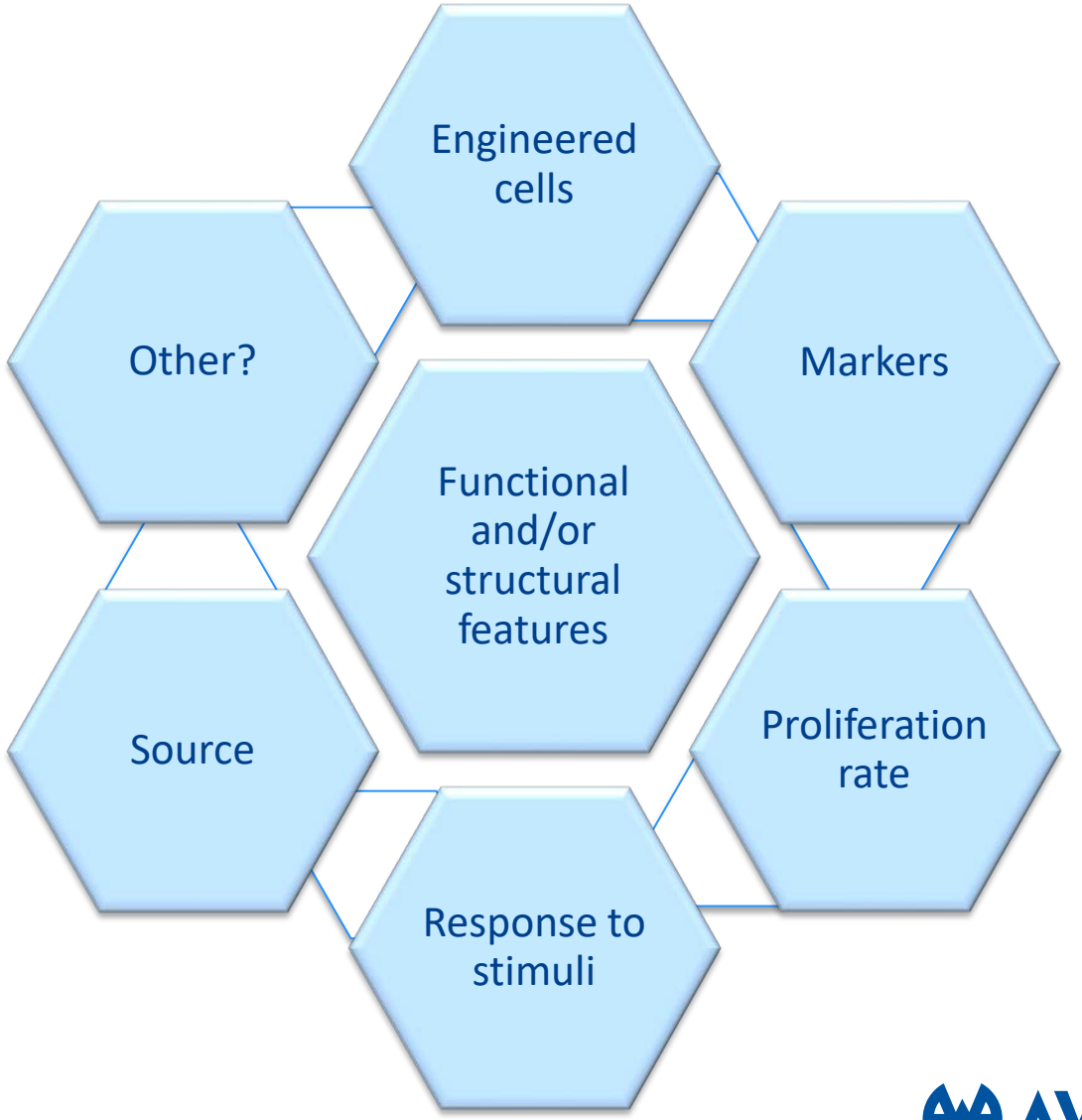
- Functional features?
- Structural features?
- Combination thereof?

(This will differ from case to case…)

Is your cell population **novel** or is it **merely a characterization** of a previously known population?

IMPORTANT

DO: PLAN EXPERIMENTS WITH THIS QUESTION IN MIND TO FACILITATE PATENT PROSECUTION AND GRANT.

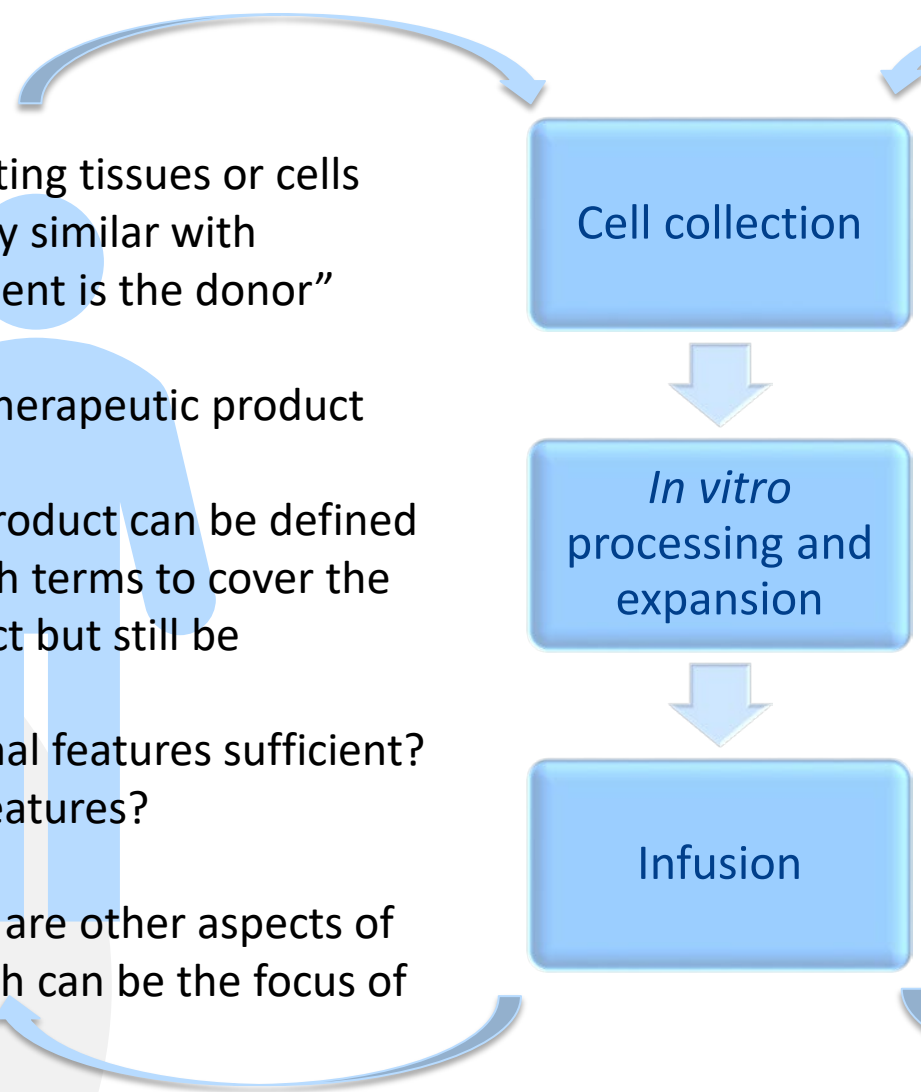


Autologous vs allogeneic products in cell therapy

IMPORTANT

Autologous
"relating to or denoting tissues or cells which are genetically similar with recipient - the recipient is the donor"

- Patient specific therapeutic product
- Consider if the product can be defined in general enough terms to cover the autologous aspect but still be patentable?
  - Are functional features sufficient?
  - Structural features?
- Consider if there are other aspects of the product which can be the focus of the protection?



Allogeneic
"relating to or denoting tissues or cells which are genetically dissimilar with recipient "

- Potential for "off the shelf" product
  => may be important to protect the product *per se*
- How to define the cell product? Does it differ from known cell populations?
- Donor matching or not?
  - Differences between products?

If your invention is a method

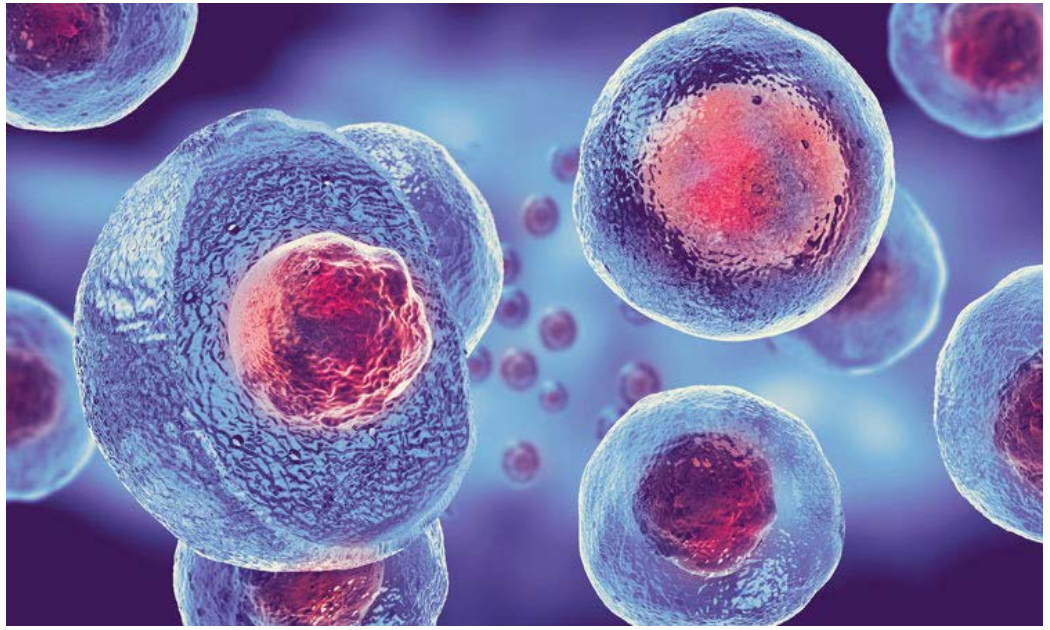
IMPORTANT

If your invention is a method it is important to consider what steps of the method are key for obtaining the advantages of your method.

- does one need to perform all the steps A to Z to obtain the advantageous effect or is step G the key step?

It may be important to provide data that compares the results obtained by your method to results of known methods.

Consider whether your method results in a product that is different from known products? If so, how is that product distinguished from known products? Does the method impose any specific characteristics to the product? It may be possible to protect that specific product.



https://www.drugtargetreview.com/news/36738/biomaterial-stem-cell-strokes/

A summary of Dos and Don’ts

Don’t disclose your invention publicly prior to filing a patent application (slides 7-8)

Do a novelty search to find out whether someone else has made the same invention before starting an expensive patenting process (slides 7-8)

Do ensure that the first patent application is of good quality (slides 9-12)

Do consider the balance between early filing and collecting data and adapt filing strategy (slides 9-12)

Do strategically plan experiments with your patent application in mind (slides 9-12 and 15-19)

Do consider your invention from a business perspective (slide 6)

Do ensure to have non-disclosure agreement with collaborators, investors etc (slide 8)

Do be careful not to disclose your invention when applying for research grants (slides 7-8)

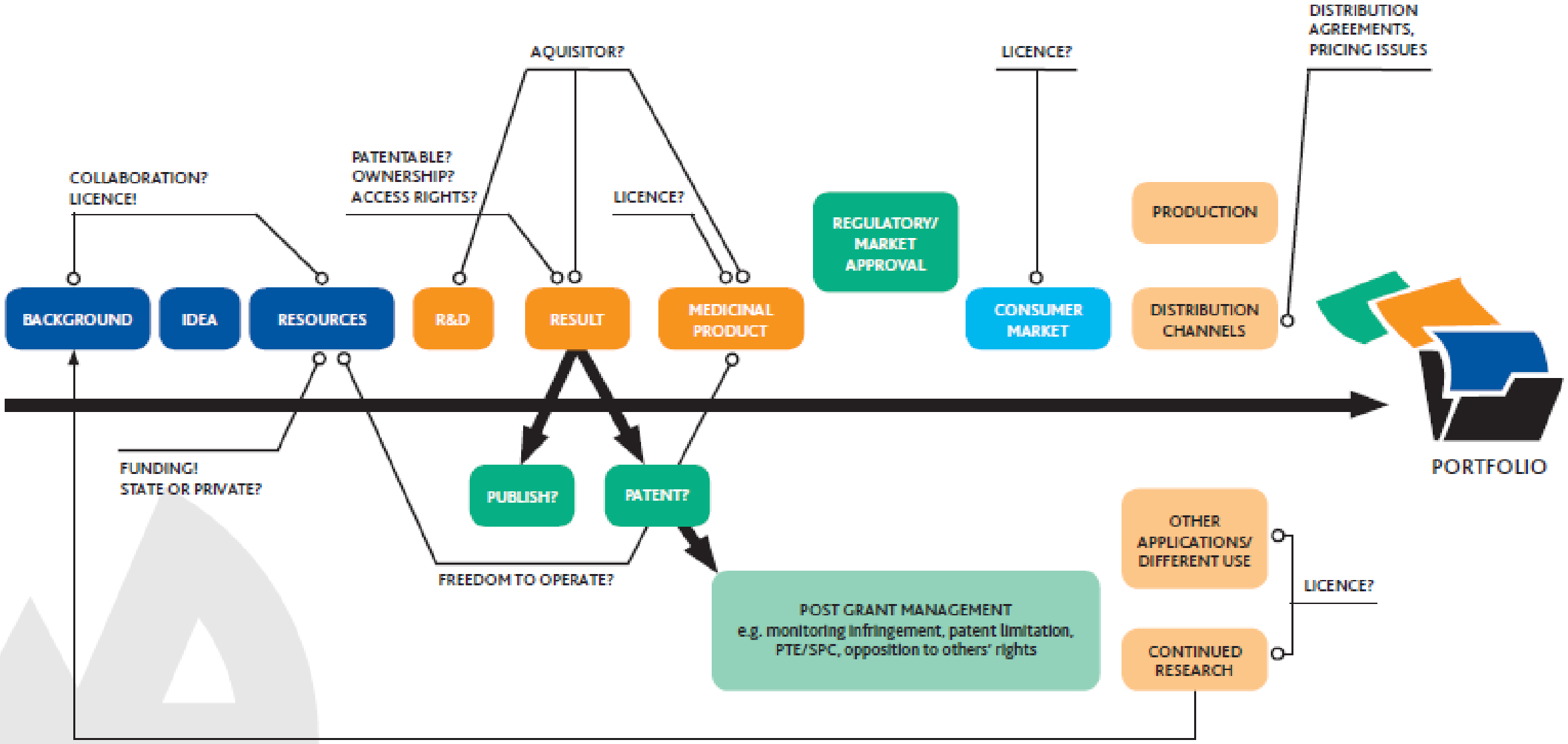
Do ensure to protect your interest when entering a collaboration and seek advice from experts (slide 7)

You are most welcome to contact AWA for advice regarding protecting your invention

Understanding what lies ahead

- using IP to move from idea to profit

Connecting Step 1, 2, 3 and 4



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