Commercialization- practical aspects & problems

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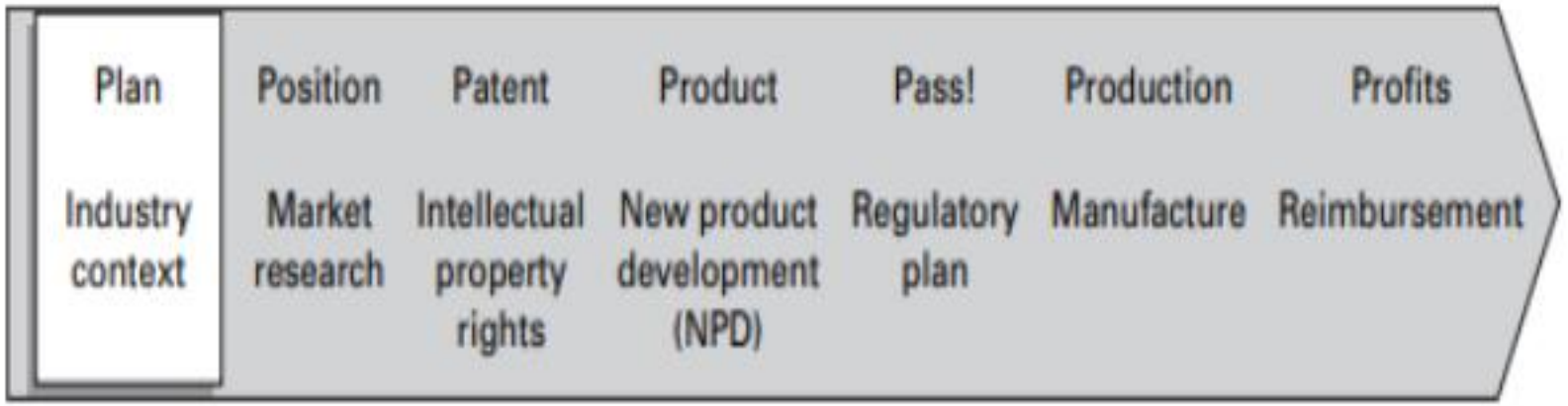
Commercialization

Commercialization can be defined as the process of turning an invention or creation into a commercially viable product, service or process.

- Commercialization may **require additional R&D, product developments, clinical trials** or development of techniques to **scale-up** production prior to taking the results of research to market.
- This is important because **not all inventors** or creators wish or **have the resources**, skills and appetite for risk to commercialize their own inventions or creations.



Roadmap of a product commercialization plan. Stage 1

Components of a product commercialization plan and roadmap

Plan	Position	Patent	Product	Pass!	Production	Profits
Industry context	**Market research**	**Intelluctual property rights**	**New product development (NPD)**	**Regulatory plan**	**Manufacture**	**Reimbursement**
Technology positioning and strategy, corporate portfolio strategy, industrial value chain context	Market need, Specific indication of interest, market size and segments, product characteristics	Intellectual property management and licensing strategy, Patent content for market protection, Business models	Stage gate new product testing and development plan, budget, Gannt chart	Regulatory strategy – working with FDA towards approval	Production planning	Coverage, Coding, Payment, Distribution, Marketing and sales planning

Commercialization practical aspects

Not all academic institutions or innovative businesses have the necessary **financial and technical capabilities** to take an invention or creation all the **way to market** by themselves.

Resources required

Converting an original or new idea, concept or design to a desired product available in the market place requires:

1. **Time**
2. **Funds (own or borrowed)**
3. **Creative effort**
4. **Innovative effort**
5. **Persistence**
6. **Focused management of the entire process from idea to market.**

- In the case of **biotechnology products** the main **markets** for such tend to be **international.** In many situations, an **organization** that owns **IP rights** to an invention will need **one or more commercial partners**.

Initial steps in the commercialization are to determine

1. Whether the invention is patentable;
2. Whether to take title to the invention and file a patent application;
3. The practical aspects of the patent application, such as whether funds are available for the application and
4. How quickly the patent application must be filed.

Considerations to file a patent application include:

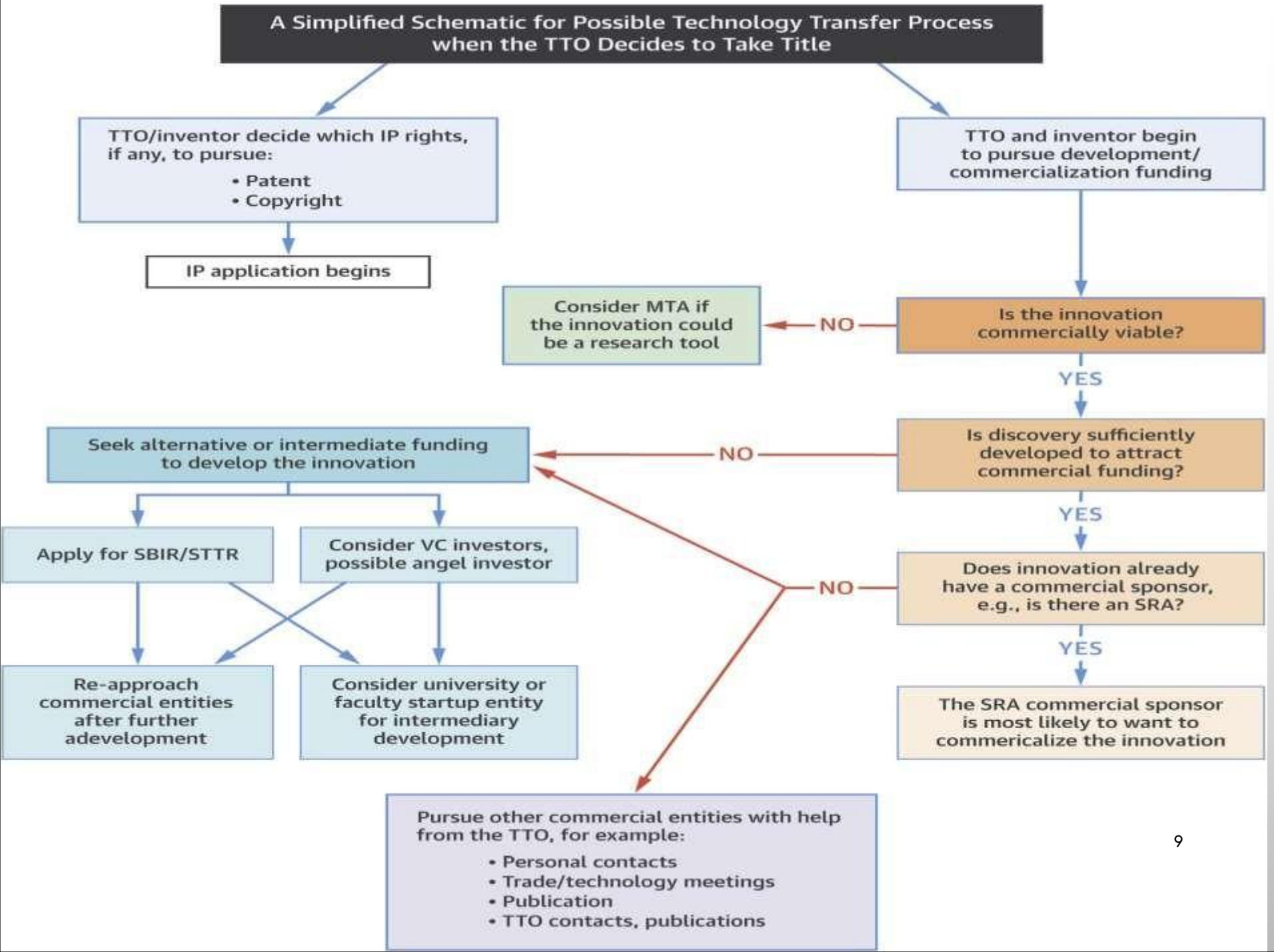
1. Whether the discovery is patentable;
2. What the likely uses of a discovery are;
3. Whether a discovery has "sufficient" commercial potential;
4. Whether significant additional investment (research, development, regulatory approval steps, marketing, and so on) is needed;
5. Whether the discovery is something without significant commercial value, but nevertheless has potential for social impact through noncommercial channels.

The **decision** that an invention has **sufficient potential commercial value for a patent** application depends on many factors.

1. **Future royalty revenue of the license.**

   Ex: Stanford's Office of Technology Licensing, refuses to patent inventions that not generate at least $100,000/year in royalties.

2. Whether a **commercial entity** is already **interested** in the discovery and is capable of developing it. (Sponsored research agreements)
3. How broad or enforceable the resulting **patent** is likely to be, and whether **copyright** is a more suitable IP tool.


A Simplified Schematic for Possible Technology Transfer Process when the TTO Decides to Take Title
TTO/inventor decide which IP rights, if any, to pursue:
• Patent
• Copyright
IP application begins
TTO and inventor begin to pursue development/ commercialization funding
Is the innovation commercially viable?
NO
Consider MTA if the innovation could be a research tool
YES
Is discovery sufficiently developed to attract commercial funding?
NO
Seek alternative or intermediate funding to develop the innovation
YES
Does innovation already have a commercial sponsor, e.g., is there an SRA?
NO
YES
The SRA commercial sponsor is most likely to want to commericalize the innovation
Apply for SBIR/STTR
Consider VC investors, possible angel investor
Re-approach commercial entities after further adevelopment
Consider university or faculty startup entity for intermediary development
Pursue other commercial entities with help from the TTO, for example:
• Personal contacts
• Trade/technology meetings
• Publication
• TTO contacts, publications

TTO = technology transfer office
MTA = materials transfer agreement
SRA = sponsored research agreement
SBIR = small business innovation research (grant)
STTR = small business technology transfer research (grant)
VC = venture capital

Patent application can take **2 to 5 years**.

As soon as a patent application is submitted, TTO will then partner with the inventor to market the patent to **find a licensee** to provide resources for technology derisking to increase its marketability.

The quality of IP management:

- **Technological and commercial merit of IP** should be assessed at a very early stage in order that **successful commercialization** can occur.
- Each **situation** should be **analyzed** taking into account the nature of the IP, the market conditions, the financial position of the IP owner and the available resources.
- The likelihood of **commercial success** increases when management ensures that there is clear **customer demand** for the new products or services and a profitable way to bring them to market.
- **Specific factors** such as speed of market entry, the degree of control required and the potential for growth are considered important in selecting the appropriate **commercialization vehicle**.

Legal vehicles for the commercialization of IP

There are two chief legal vehicles by which owners may commercialize their intellectual property.

1. To sell or assign the IP
2. To license the IP rights.

1 .Assignment / Sale:

When rights are assigned (other than partially), the recipient or assignee acquires ownership of all rights which previously belonged to the assignor, although the assignor may take a license back from the assignee.

- This can be done **between two independent parties**, but it can also be done on an internal level and form part of employment agreements and **agreements** with consultants or contractors.
- Assignments of intellectual property rights can be done either via sales or via transfers, i.e. **with or without** direct **financial compensation**.

Patent laws require the assignment to be in writing to effectively assign the intellectual property.

1. The parties wish to add other conditions to the transfer of the IP such as a license back to the seller, warranties concerning the IP or a restraint of trade clause;
2. The parties wish to clearly document their intention to transfer full title to the IP.

Checklist for assignment

1. Do you want to avoid having to enforce the IP?
2. Have you determined that the IP is not a core asset for the conduct of your business, present or future?
3. Do you want to avoid any future involvement with the IP, including in particular the ongoing costs and administration requirements in maintaining registration of the IP?
4. Is any ongoing use of the IP likely to be for a limited time or purpose?
5. Is the IP unlikely to establish or maintain a strategic market or alliance position for the enterprise?
6. On balance, is there no alternative approach to commercialization better suited to your objectives?

2. Licensing:

- **Licenses allow patent owners to share inventions or other intellectual property in a controlled manner and to receive revenue (e.g. royalties) or other benefits (e.g. access to another firm's knowledge).**
- A **public research organization or SME** may not be in a position to undertake the direct exploitation of IP rights.
- Accordingly, assuming that the **entity owns** the intellectual property, in order to exploit the **financial potential** of an invention fully, it can consider finding an appropriate licensee for the IP.

- A patent for example is licensed when the owner of the patent (the **licensor) grants permission** to one or more entities (the **licensee**(s)) to use the patented invention for **mutually agreed** purposes in a mutually agreed manner.
- In such cases, a licensing contract is generally signed between the two parties, **specifying the terms and scope** of the agreement.
- If a **suitable licensee** is found and the terms of the license agreement are **properly drafted**, such an arrangement can represent a **secure source of income** for the licensor while **minimizing costs and risk**.

- An independent entrepreneur or **inventor**, it is often advisable to start the **search for licensees** as early as possible in order to guarantee a revenue stream that will be useful to **cover the costs of patenting**.
- It is critical to find the **right partner**(s) to generate profits from the commercialization of the patented invention.
- The **best licensee** will probably have a direct strategic fit with the **technology**.
- A licensee who seems to have complementary rather than competing technology and is looking to **expand its product range** is likely to be a more suitable partner.

What can be licenced?

1. **Technical information** such as formulae, techniques and operating procedures,
2. **Commercial information** such as customer lists and sales data, marketing, professional and management procedures,
3. **Trade information**, process or device occurring or utilized in a business activity.

Types of licenses

There are three main types of licensing agreements **depending on the number of licensees** who will be allowed to use the licensed intellectual property.

1) Exclusive **2) Sole** **3) Non-exclusive**

1. Exclusive license:

A **single licensee** has the right to use the intellectual property, which cannot even be used by the owner.

An exclusive license **permits only the licensee** and persons authorized by the licensee to exploit the invention.

2. Sole license:

This permits the licensee to work the intellectual property, **prevents** the grant of **additional licensees**, but allows the **owner** to also **work** the intellectual property.

3. Non-exclusive license:

This allows the **owner to retain the right** to exploit the licensed property as well as the right **to grant additional licenses** to third parties.

Owner and all licensees the have the right to use the intellectual property.

Table 1. Summary of mutual benefits of licensing

Benefits to licensee	Benefits to licensor
Savings on R&D investment	Creates new revenue streams by realizing the full potential of the technology
Eliminates risks associated with in-house R&D	Expands customer awareness
Reduces time to market	Helps overcome the challenge of establishing the technology in foreign countries and lowers costs and risks
Ensures that products are leading edge	Provides savings on distribution and marketing expenses
Adds new product lines to a portfolio	Provides a means of avoiding litigation
Strategic partnerships can be formed	Strategic partnerships can be formed

Conditions necessary to obtaining a commercial return

To obtain commercial returns from IP, certain conditions must exist.

1. The **existence of a customer** or the ability to create customers; and
2. An entity **controlling the manufacture and sale** of the resulting products.

Commercialization- PROBLEMS

- The development of **new chemistry-based products** for life science markets requires the **expertise of talented researchers**.
- However, these same **researchers** are typically **not** prepared to **solve** the many other **critical problems** necessary for successful **commercialization**.
- **Without** the requisite **expertise** in scale up and commercialization, many **early-stage companies** find that competitors beat them to the market or resources **run out** before success can be achieved.

Four principal problems includes:

1. Scaling manufacturing to meet commercial requirements
2. Ensuring regulatory compliance of products
3. Securing adequate funding for product development and manufacturing
2. Protecting intellectual property

1. Scaling manufacturing to meet commercial requirements

- **Early** development stages usually rely on **small scale batch** synthesis.
- Drug development, for example, is often done virtually to **minimize costs**.
- The **conceptual ideas** developed are used to **attract** additional **investments** that enable real, but more costly, development activity.
- At **larger scales**, obtaining raw materials and identifying appropriate and cost effective manufacturing partners represents a significant **challenge**.

- The **successful transition** of technology from the laboratory bench to the macro-level within a commercial production environment is certainly **not** a **trivial** undertaking.
- **Start-ups must utilize** production facilities that satisfy the necessary requirements of timeliness, cost-effectiveness, regulatory compliance, and sometimes geographical proximity.
- If the **proper** manufacturing facilities and/or raw material providers cannot be located in an efficient manner, irreplaceable **time and money are lost**.

2. Ensuring regulatory compliance

- Drugs and other products manufactured for human consumption must **comply with governmental or industry-specific regulations.**
- For pharmaceuticals, it is the current Good Manufacturing Practices **(cGMP) of the FDA**.
- Food grade and **kosher regulations** may apply to food and nutritional products.
- During the **R&D phase**, companies can minimize expenditures by producing test quantities using **non-compliant batch production** methods.

- However, converting these processes to meet regulatory requirements for **scaled-up commercial production** can be extremely **time-consuming and costly.**
- Frequently a **change in facilities** is also needed, further complicating matters.
- In the production of **pharmaceutical products**, cGMP regulations, for example, require that all commercially produced drugs and pharmaceutical products **meet** stringent **assay, quality, and purity** requirements.
- Facilities must have appropriate **quality management systems** in place that can **detect, investigate, and correct product quality deviations**.

- Investigational new drug **(IND) submissions** to the FDA can easily be **delayed and rejected** by insufficient data, inadequate reporting or insufficient cGMP reference standards.
- This may **necessitate** rapid preparation of clinical trial batches and validation and/or production of **GMP-grade** material to serve as a **reference standard** itself.
- The supply of **specialized intermediates and precursors** for life science applications may necessitate specific **ISO certification** on the commercial scale.
- This is becoming increasingly relevant as medical device companies request custom synthesis services for **new excipients** and **components for novel drug-device** combinations.

3. Securing adequate funding for product development and manufacturing

- While there are many potential sources of funding for product development, **obtaining funding** is nonetheless highly **competitive**, and each investor or funding organization will have **different requirements**.
- Funding sources include **venture capital** (VC) groups, **angel investor consortiums**, and grant opportunities such as **Small Business Innovation Research** (SBIR) available through governmental agencies such as the National Institutes of Health.
- Identifying the **proper grant options** for the technology in question, as well as employing experts with **grant-writing expertise**, is of paramount importance.

- It is vital for **start-up organizations to "get in front" of VC** and angel boards to make a pitch for their **novel technologies.**
- **External vendors and partners** with existing **relationships** with such **funding organizations** are attractive options for young companies in need of capital.
- In addition, companies can also **license their technology** to commercial partners with synergistic or complementary technologies.
- **Big Pharma** typically leverage their resources in this way to bolster **R&D pipelines**.
- In order to do this, however, **proof-of-concept work, data collection, and analysis** must be conducted to **convince potential investors** to fund its product development activities.

- This is often one of the **most expensive and difficult steps** in the life of a start-up.
- While these fledgling companies typically **confirm the bioactivity of a drug candidate** on their own, the ability to prepare a comprehensive technical package suitable for **licensing or transfer** often remains beyond their internal capabilities.
- Thus, it is important for these outfits to identify **external resources** capable of handling **synthesis, testing, and formulation** work at all scales.

4. PROTECTING INTELLECTUAL PROPERTY

- ✓ Companies must **balance** the need to avoid any **patent infringements** or protect their own **intellectual property** (IP), and **safely share** their confidential process information with development partners.
- ✓ IP should be **cross-referenced** against existing patents and then protected during **development and technology transfer**.
- ✓ While this is typically conducted internally by **legal staff** or through a contracted **external law firm**, any **perceived gaps** may need to be addressed through additional laboratory work.

For instance, a **start-up may need to**

1. Prepare additional patent example compounds,
2. Quickly synthesize competitive samples,
3. Perform analytical measurements for confirmation of substantive differences/similarities of target compounds,
4. Identify trace contaminants and
5. Elucidate impurity profiles.

A start-up needs this work performed expeditiously to **maximize future income** within their limited patent life.