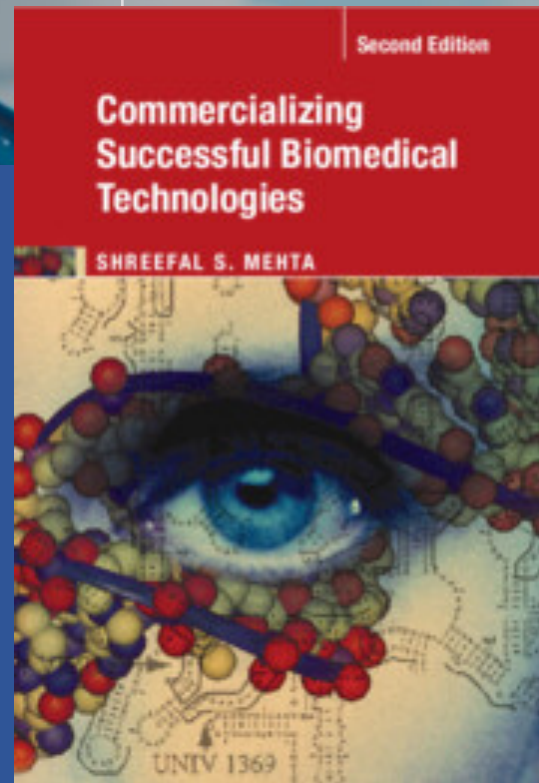


Commercializing Successful Biomedical Technologies 2nd Ed.

Shreefal Mehta



Plan

1
Industry
context

Position

2
Market
research

Pitch

3
Start a
business
venture

Patent

4
Intellectual
property
rights

Product

5
New product
development
(NPD)

Pass

6
Regulatory
plan

Production Profits

7
Manufacture

8
Reimbursement

Intellectual property and licensing

Shreefal Mehta

Chapter 4

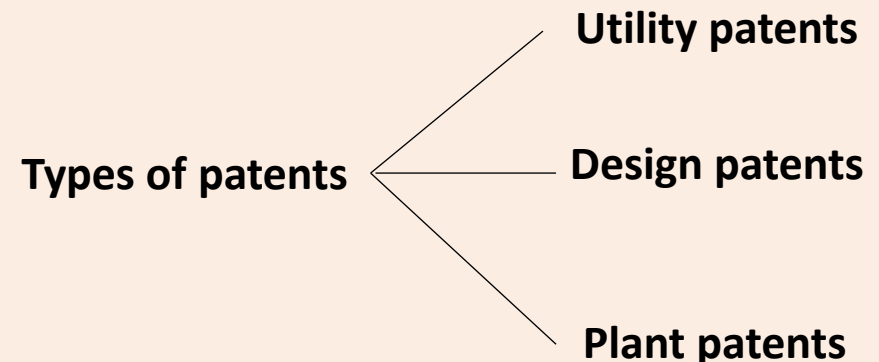


Intellectual property

- **“Intellectual property”**: commercially valuable rights
- Result from formally codified inventions, literary or artistic works, or other representations of creative thought or particular symbols of commerce.
- **Includes:**
 - **Patents**
 - **Trademarks**
 - **Copyrights**
 - **Trade secrets**
- Intellectual property or “IP” has value only when the underlying work is being developed and commercialized
- Origin of the word “patent” is the latin patere, which means “to lay open” (for public viewing)

Types of patents

- In exchange for disclosing an invention to the public, the inventor or patent holder receives protection for the invention, for a limited period of time(usually 20 years)
- The patent holder can exclusively block others from making, using or selling the invention
- **The advantage:** dissemination to the public of the detailed methods, further development of new technology based on this invention
- patent is NOT an exclusive right to make, use, and sell the invention, but only a right to block others.



What cannot be patented

- Laws of nature
- Physical phenomena
- Abstract ideas that are not conceptualized
- Literary, dramatic, musical, and artistic works (these can be copyright protected)
- Inventions which are:
 - Not useful
 - Offensive to public morality
- MOST LIVING THINGS CANNOT BE PATENTED UNLESS THEY ARE NOVEL, USEFUL AND NON-OBVIOUS (i.e. made by man)
- Naturally occurring biological subject matter, including bacteria, viruses, and human or animal stem cells and cell lines, are considered to be patent ineligible.
- NOTE: If a product of nature is new, useful and nonobvious, it can be patented if it has been fashioned by humans
 - ✓ Genetically engineered microbes, animals
 - ✓ New Plants sexually or asexually reproduced by man
 - ✓ Natural compounds, proteins, and nucleic acids purified away from the human body may be patented in purified state in some countries and not in others.

Subject Matter Eligibility Test (USPTO)

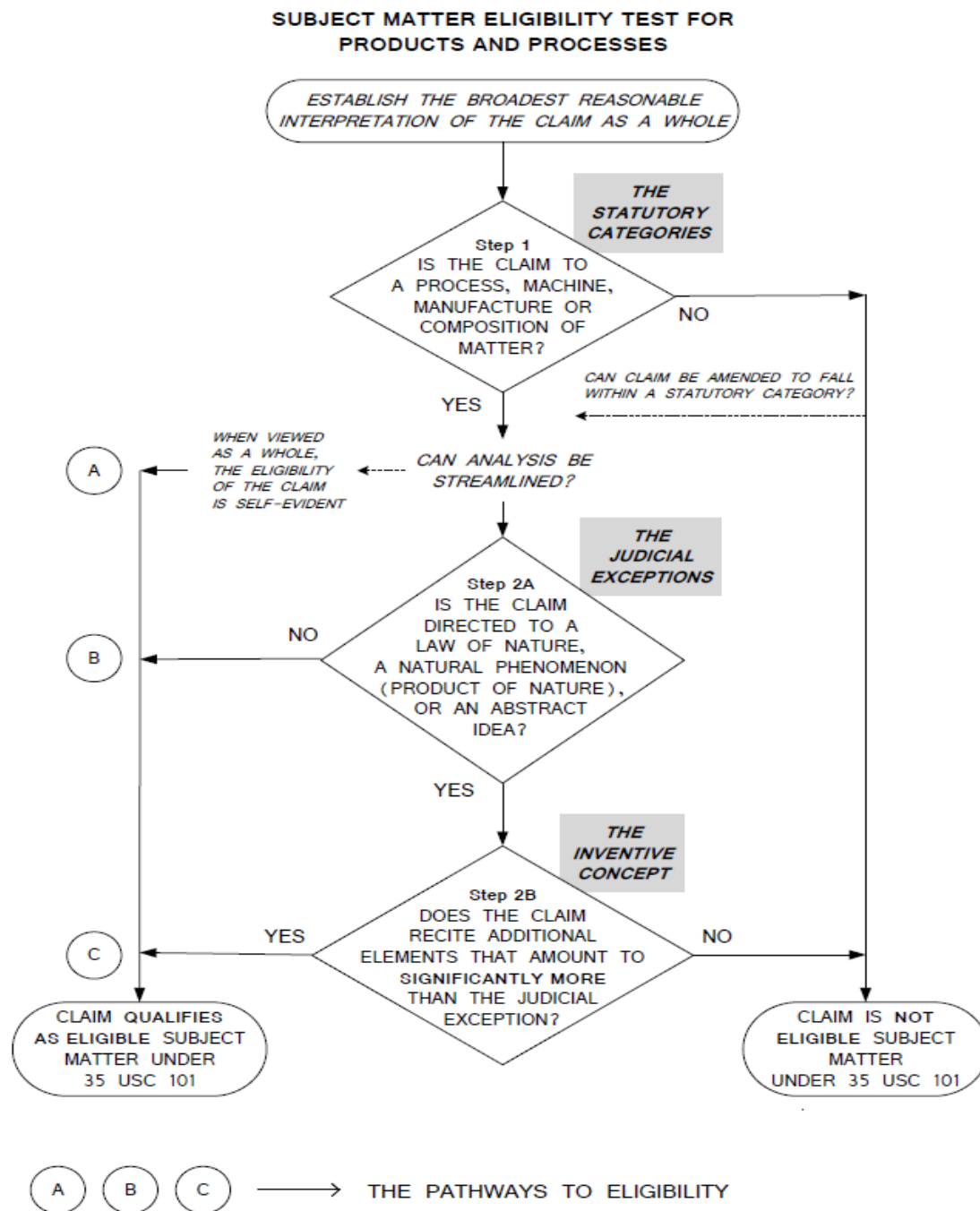


Figure 4.01 In BOX 4.1

Characteristics of a patented invention

- Novel (not previously known, used, sold, on sale, marketed)
- Utility (useful task, some use for invention)
- Non-obvious to a person with knowledge in the field
- Adequately described to the public at time of filing
- Enable a person with knowledge in the field to make and use it
- Best mode or effective mode must be disclosed
- Described in clear, unambiguous, and definite terms



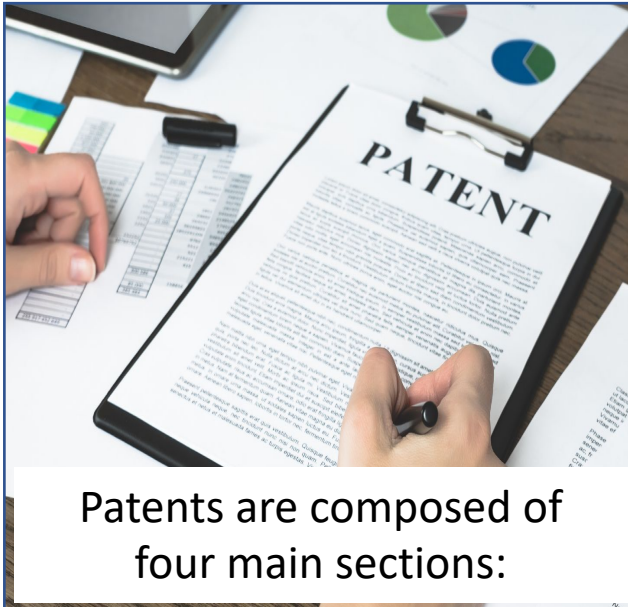
What is in a patent?

Face page:

Normally contains the patent number, date of issue Application, inventors, assignees abstract and title of patent

Description :

adds detail to the claims by virtue of examples and background. Description cannot be modified once it is filed.



Patents are composed of four main sections:

Claims:

The language in the patent claims is critical to legal definition and defense of the patent holders' rights and the use of single word can change the legal rights of the patent holder

Drawings:

Help to convey more specifics on the invention. Help to substantiate the application and reduction to practice of the invention

Priority date, grace period, and public disclosure

- Priority date : the date of filing of the first patent application.
- Any public disclosure before the date of filing is viewed as prior art in many countries and can invalidate the patent application as not being original, even if the public disclosure was by the inventor



How much does it cost to get a patent?

- Lawyers' fees to draft the first patent application -\$3,000 to \$15,000
- Foreign filing fees, adding up various nations' patent offices where you choose to file - \$30,000 to \$50,000
- local lawyer's translation and representation fees \$40,000 to \$80,000 depending on how many countries are selected
- Above costs vary based on type of patent, length, complexity, etc.
- Maintenance fees to US PTO due after being granted the patent

Considerations before filing a patent application

- Cost estimates and budget allocations
- Clarify business purpose/applications of the patent
- Confidence in ability to obtain and enforce the patent
- Return on investment estimates
- Freedom to operate (FTO) assessment



Checklist for filing a patent application

- ✓ Write up a detailed disclosure (description) and confirm eligibility of the subject matter
- ✓ Is the idea or invention conceptualized at the minimum required to file patent application

STEP 1:

Conception exists when there is a formation in the mind of the inventor of a definite and permanent idea of the complete and operative invention as it is to be used

STEP 2:

Conception is completed when someone ordinarily skilled in the field could perform the process or make the composition, when the concept is conveyed to them, without unduly extensive research or experimentation.

- ✓ Identify the specific class and code for your technology
- ✓ Find out if any prior art exists – do at least a preliminary search on conference abstracts and publications
- ✓ Determine the inventor(s) : Each inventor, to be considered an inventor, must have made a contribution, individually or jointly, to the subject matter of at least one claim of the application
- ✓ Choose an attorney to draft the claims.

Patent prosecution process

Step 1

- Document - the invention date

Step 2

- File provisional patent with USPTO (US Patent and Trademark Office)
- you have 1 year to submit a full application in other countries through the PCT process (Patent Cooperation Treaty)

Step 3

- One year after the provisional filing, submit a full, non provisional patent application to the USPTO.
- Simultaneously submit a PCT application

Step 4

- Applications get published and are available for public review typically 18 months after application date.
- For PCT filing, an International Searching Authority, typically an examiner in the receiving country patent office, conducts a search and issues an International Preliminary Report on Patentability (IPRP)

Step 5

- At 8 months after PCT submission (20 months from priority date), the applicant has to select the final countries desired for final filing

Step 6

- At 30 months from submission into the PCT process, the patent enters national phase filing in the countries that were finally selected.
- Fees for individual countries will come due when national phase applications are filed

Step 7

- U.S. patents will issue anywhere from 2 to 5 years from initial application
- depending on the backlog at the Patent Office and the specific issues in the application.

Grace Period for Prior Art Consideration

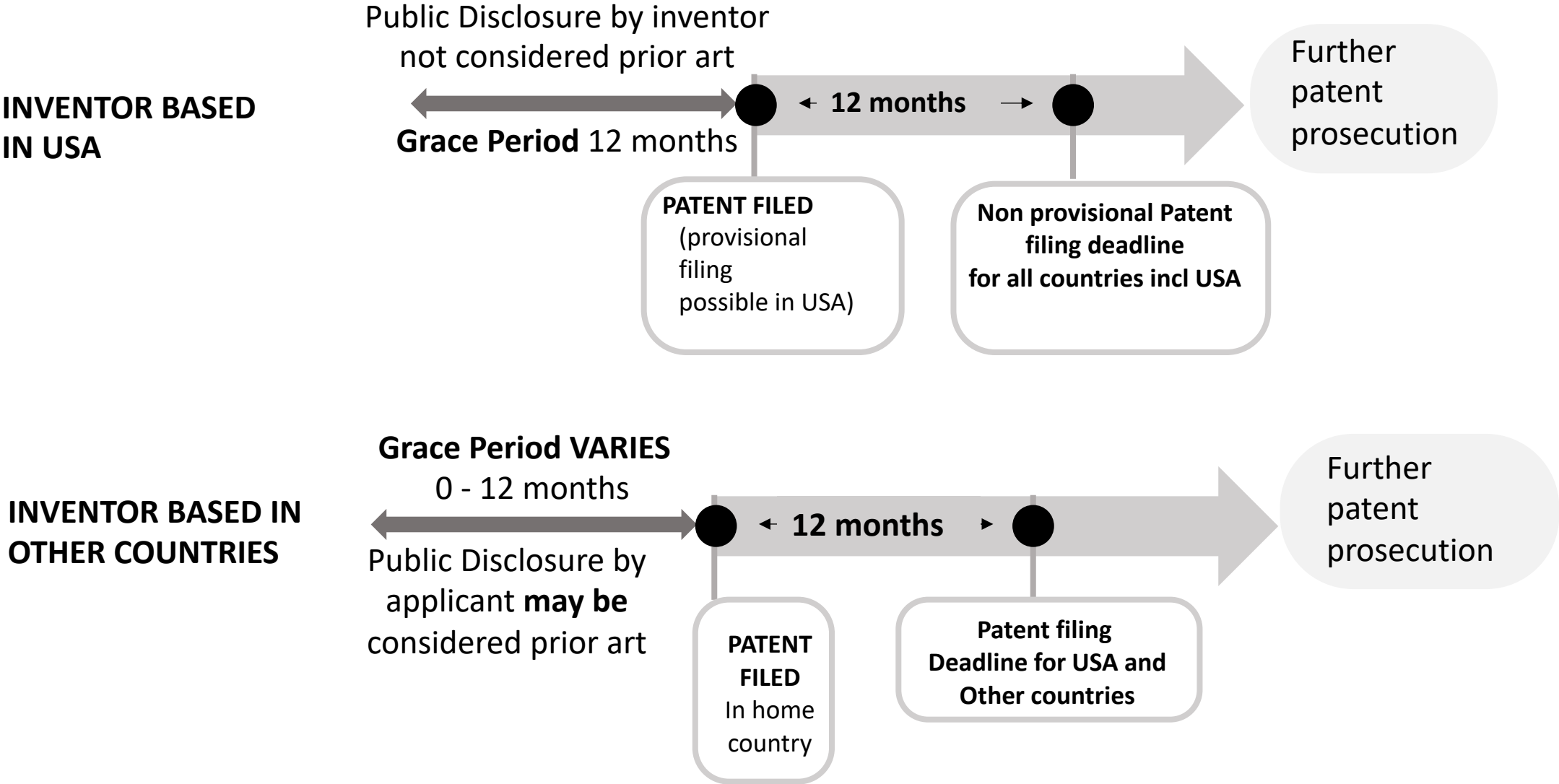


Figure 4.2

Patent Prosecution Timeline

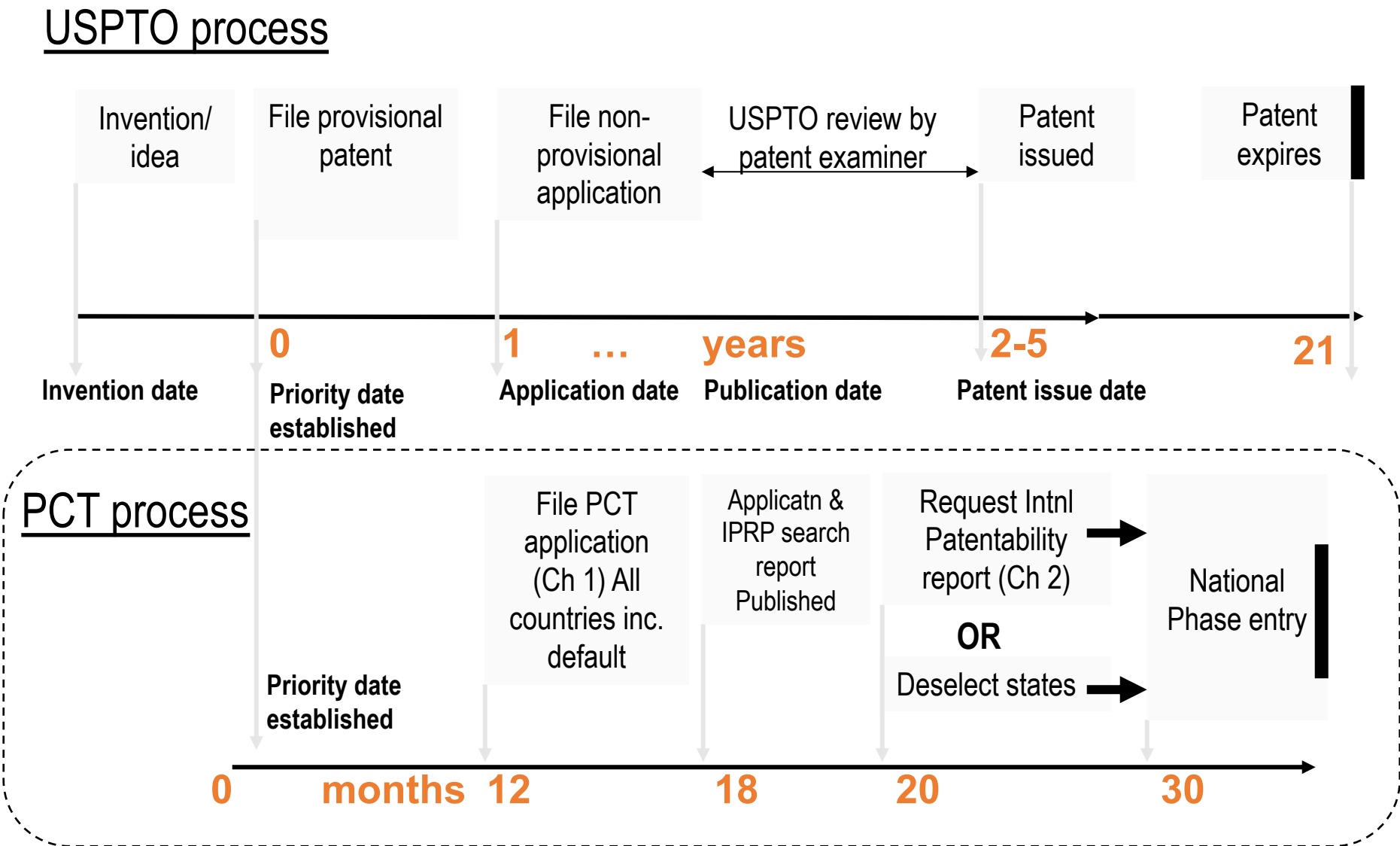


Figure 4.3

Patent Infringement

- Patents give you the right to block anyone else from selling your invention
- Your rights in this regard are limited to the legal boundaries of the country that has granted the patent
- There are two main ways to examine whether someone is infringing your patent or you are infringing someone's patent:

1. Literal infringement

someone's activities can be seen to specifically infringe on the claims of the patent, literally

2. Doctrine of equivalents

a patent claim that is not literally infringed may be infringed if the accused product or method is legally "equivalent" to what is literally claimed

- It is a good idea to check the validity of the patents before embarking further into the process
- The main issues remaining then relate to the extent of damages claimed by the plaintiff and the possibility of establishing willful infringement

"Freedom to practice" or "freedom to operate"

when licensing in or buying or selling patents, a "freedom to operate" statement should be sought from a lawyer, establishing the ability to commercialize and capture the value of the patent.

Licensing from university

Conflicting Values &
Common Interests

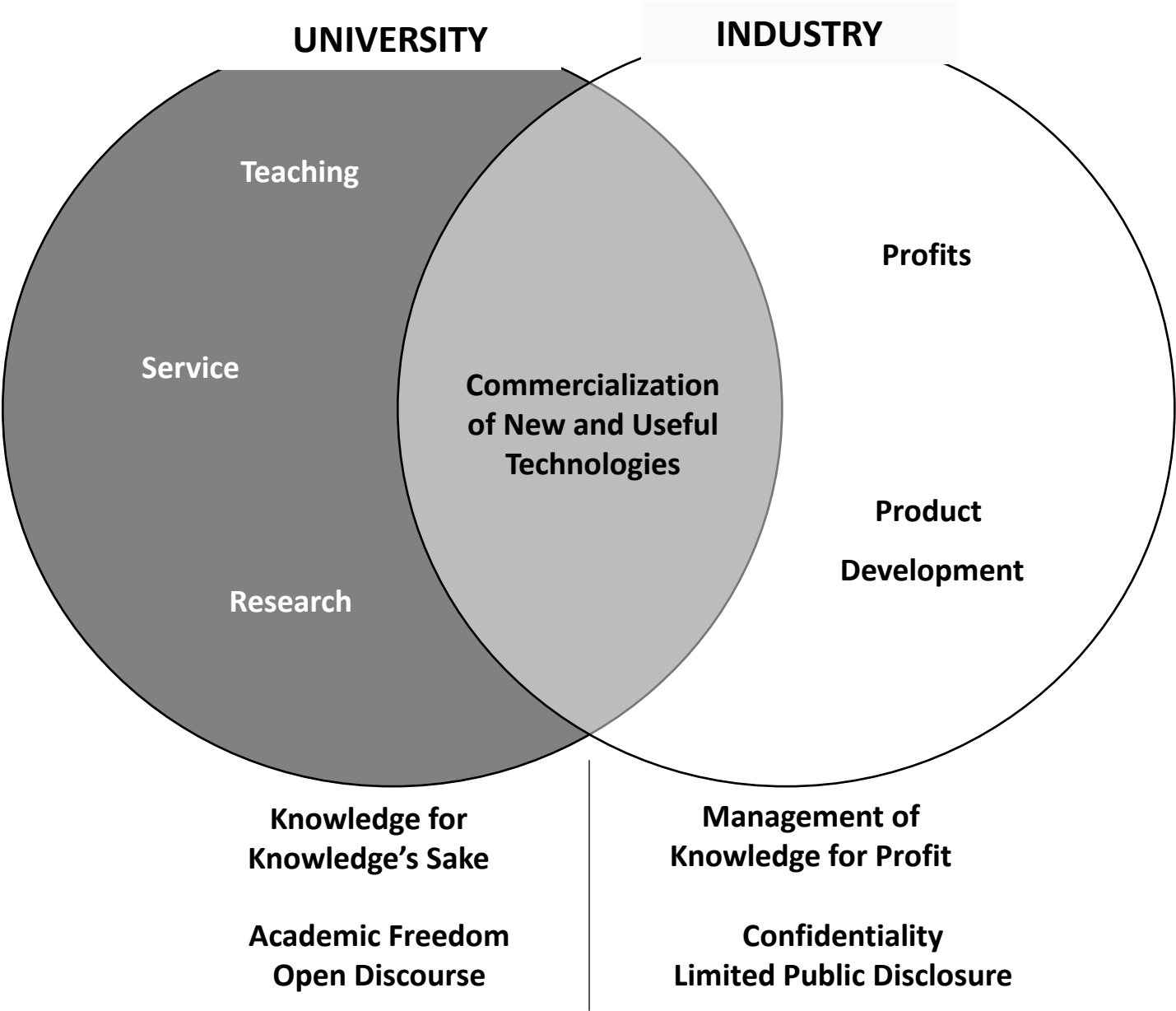


Figure 4.4

Trademarks



- Trademarks are usually some combination of words, phrases, symbols or designs that identifies and distinguishes the source of the goods of one party from those of others
- A service mark is a similar combination of words, phrases, symbols, or designs that identifies and distinguishes the services of one party from those of others
- Claim rights in a mark, use the “TM” (trademark) or “SM” (service mark)
- You do not have to register a trademark to use one or have legal claims
- While not required, a trademark registration provides important legal benefits.
- The federal registration symbol “®” can be used only after the USPTO actually registers a mark
- A trademark is renewed every 10 years indefinitely, as long as it is still in use.
- Cost about \$275 (for electronic filing) to file an application
- The Madrid Agreement and Protocol (effective in the United States from 2003 onward) allows the U.S. trademark registration to serve as the basis for international coverage in countries party to the Madrid Agreement

Copyrights

- “A copyright is a form of protection provided to the authors of ‘original works of authorship’ including literary, dramatic, musical, artistic, and certain other intellectual works, both published and unpublished
- The copyright protects the form of expression rather than the subject matter of the writing
- Copyright protection exists from the time the work is created in fixed form. The Copyright in the work of authorship immediately becomes the property of the author who created the work and lasts for 70 years after the death of the author.

Trade secrets

- Trade secrets are also commonly termed as know-how
- One of the most famous examples of a trade secret is the Coca-Cola formula
- While trade secrets are not commonly used as the sole means to protect commercialization rights for discoveries or inventions, their use as know-how is increasingly useful in the detailed processes of biopharmaceutical manufacture
- ***Note, however, that the “best mode” of practicing an invention must be included in any patent filed for that invention; it cannot be held back as a trade secret.***

IP commercialization and technology transfer

- The limited monopoly granted by a patent gives some degree of assurance of possible revenue streams for a new product, especially products that cost a lot of money and time to bring to market
- A patent is used to generate revenues (and profits) by blocking others from selling products based on that invention, or in the shorter term, patents can be tools to raise financing, by:
 - ✓ Licensing the patent to others who wish to sell the patented product and collecting royalties and payments from them, retaining ownership of the patent
 - ✓ Selling the patent
 - ✓ Using the patent position to drive strategic partnerships
 - ✓ Attracting investment
 - ✓ Getting debt financing

Licensing agreement

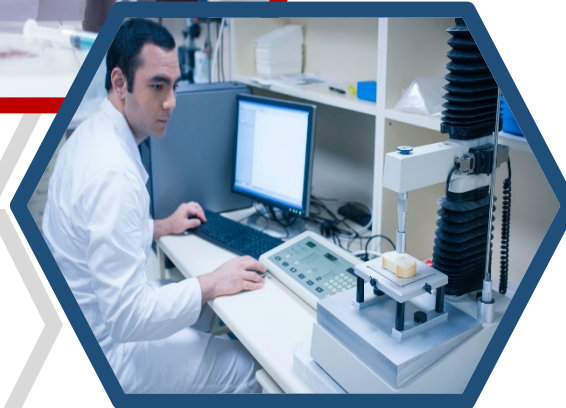
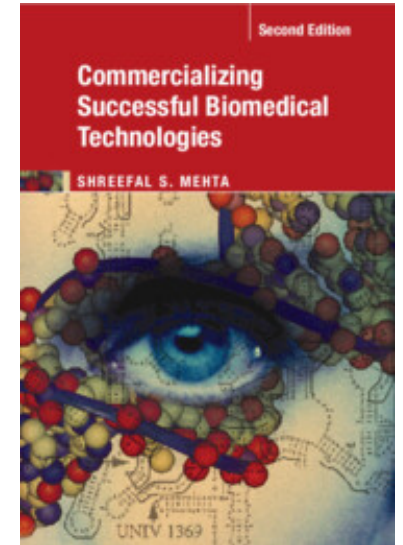
- A license is a commercial and legal transaction to transfer patent rights from licensor to licensee.
- A license agreement gives the licensee one or more of the following: the rights to make, to use, to have made or to sell the products based on the patented invention
- Know what rights are being licensed - the field of use for which the rights are being granted, the territory in which the rights are being granted and whether or not the license is to be exclusive, nonexclusive, or sole
- The grant of rights clause describes the scope and subject matter

Licensing terms (contd.)

A general list of financial terms typically included in a license agreement includes the following:

- Up-front payments
- Patent prosecution and maintenance fees
- Milestone payments
- Royalties
 - ✓ A rule of thumb sometimes used by many licensors is the 25% rule - royalty that is equal to 25% of the expected pre-tax net profits
- Sub-licensee and sublicense fees
- Minimum annual royalties
- Equity considerations (if any)
- Royalty anti-stacking provisions





Thank you...