Patenting and disclosure requirements of healthcare innovations

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WIPO
WORLD
INTELLECTUAL PROPERTY
ORGANIZATION

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- Introduction
- General patenting requirements
- Patent application filing and prosecution
- Patent/IP strategy
- Q&A

Introduction

IP Commercialisation professional (3 perspectives)

Objective – Clear, key considerations for inventions in the life sciences

Broad audience – different levels of IP understanding

General patenting requirements

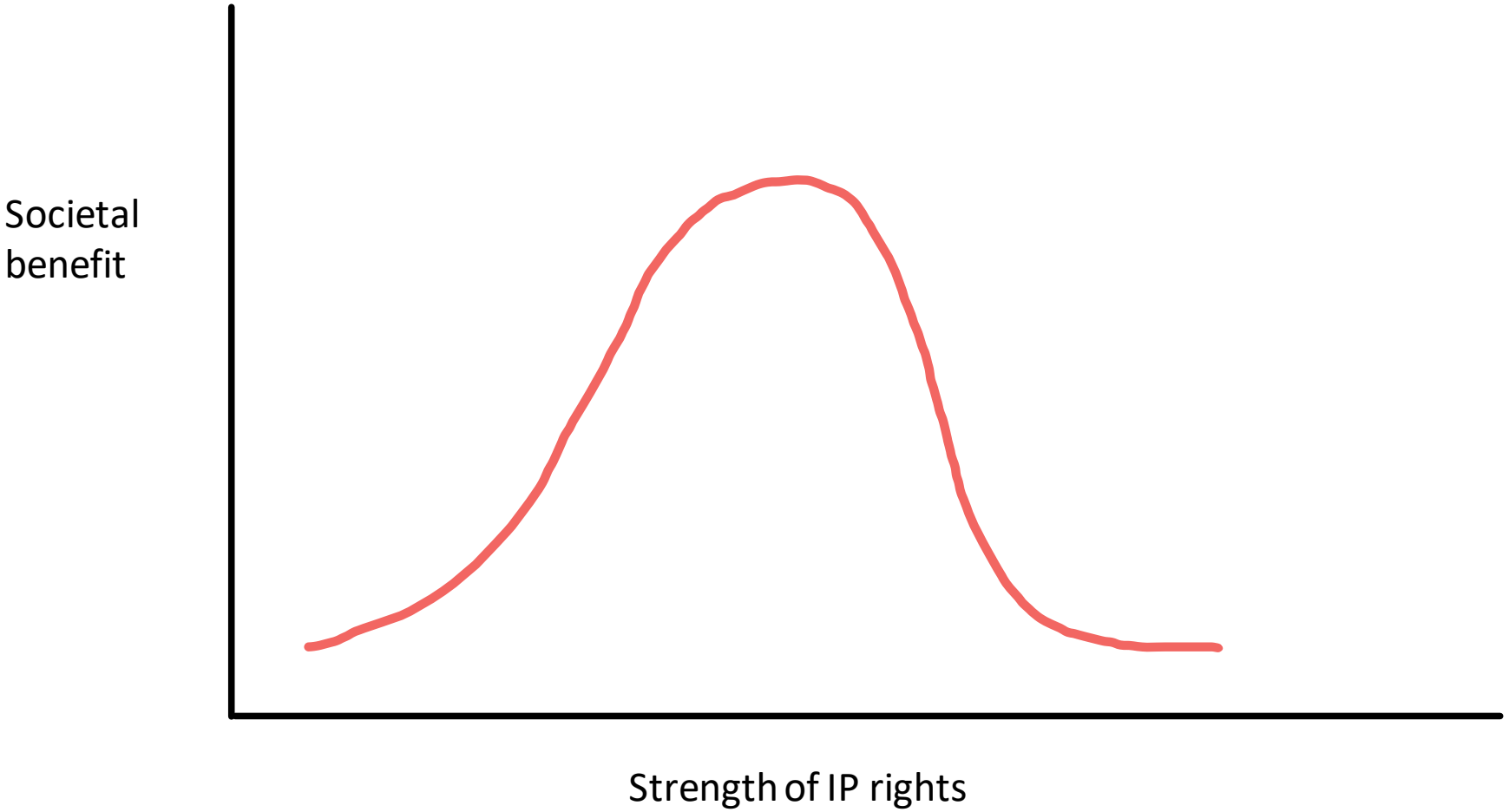
Patent/IP System

What is the purpose?

Is it actually useful?

– benefits vs costs to the society

Patent/IP System



Patenting requirements

- Patent eligible subject matter
- *Novelty*
- *Inventive step/Non-obviousness*
- *Industrial applicability*
- Sufficiency of disclosure
- Patents vs know-how/trade secrets

Patent eligible subject matter

Country/jurisdiction dependent

- No impediment for the medical act
- Discoveries, mental processes, natural phenomena

US – USC 35 – 101

EPO – Art. 53 EPC

JP – Art. 29 -30 Japan Patent Act

Novelty

Worldwide consensus – never disclosed previously in the public domain

Exceptions – Grace periods

Inventive step/Non-obviousness

Person having ordinary skill in the art – PHOSITA

Life science PHOSITA

- MSc/PhD level understanding
- No creativity

Inventive step/Non-obviousness

A – known concept in the art

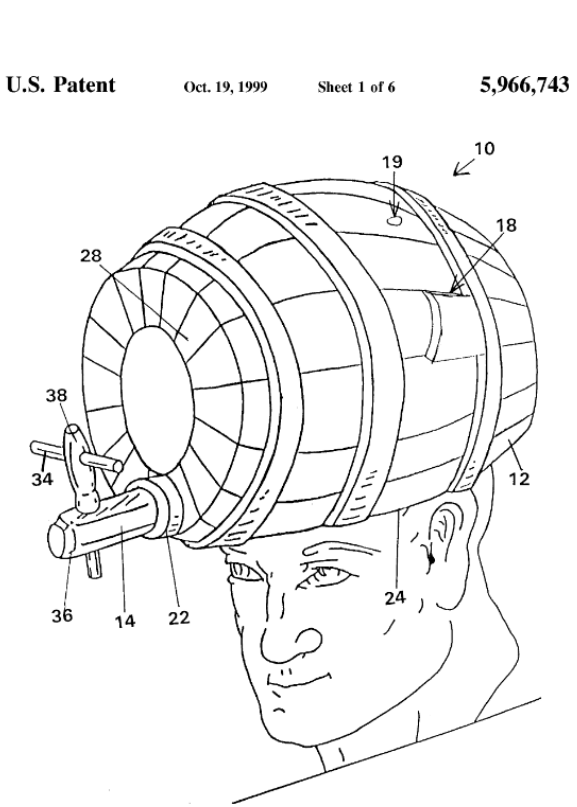
B – known concept in the art

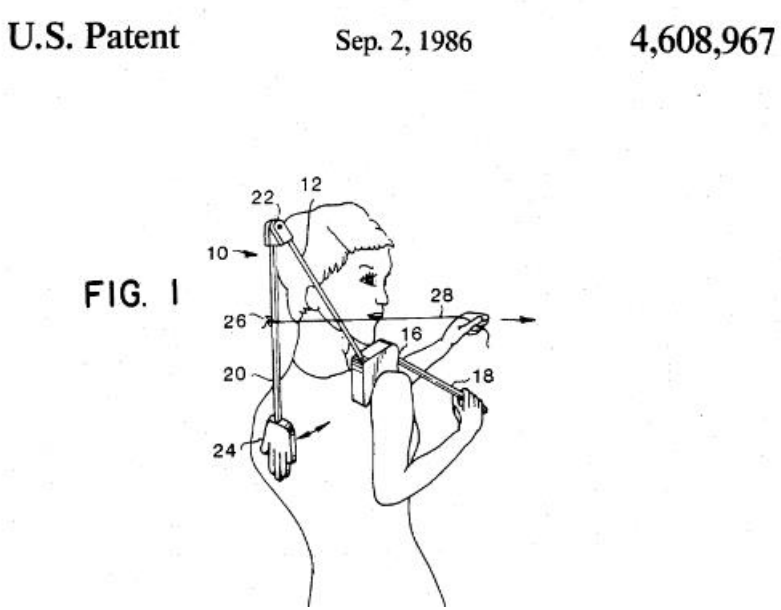
Invention is A+B

- Is it obvious to PHOSITA?

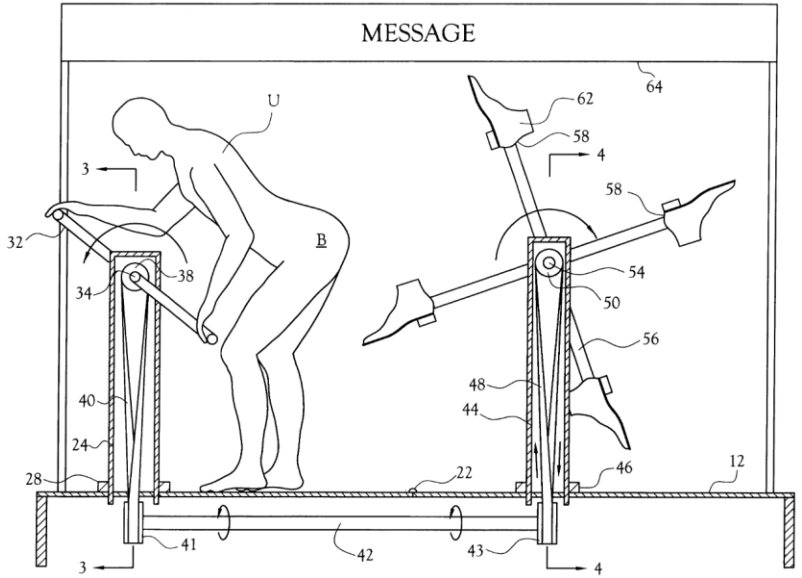
Industrial applicability

Invention should be useful or industrially applicable – Rarely (if ever) objections





User-operated amusement apparatus for kicking the user's buttocks – US6293874B1



Sufficiency of disclosure/Enablement

Sufficient and clear description – enable PHOSITA to reproduce invention

Certain biotech inventions – access to living biological material (Budapest treaty)

USA – Section 112 of 35 USC

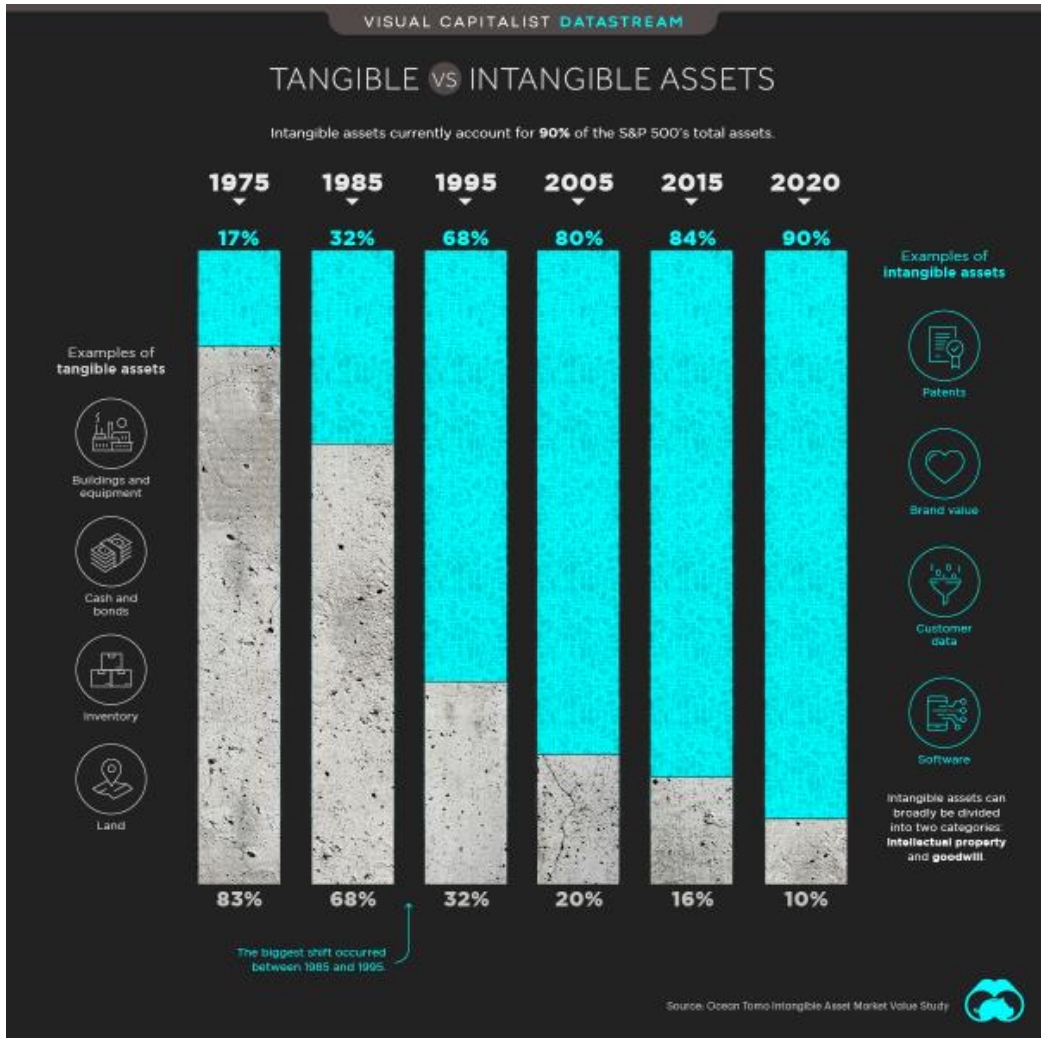
Europe – Art. 83 EPC, Part F Guidelines for examination

Japan – Art 36(4)(i) Japan Patent Act

Patents vs know-how/trade secrets

Patents – usual pathway of protection

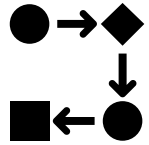
Trade secrets/know-how alternative (Duration, Disclosure, Cost, Scope, Territoriality)



Trade secrets

"Confidential business information which provides an enterprise a competitive edge"

- *Secret*
- *Commercial value as a secret*
- *Steps to keep it a secret*



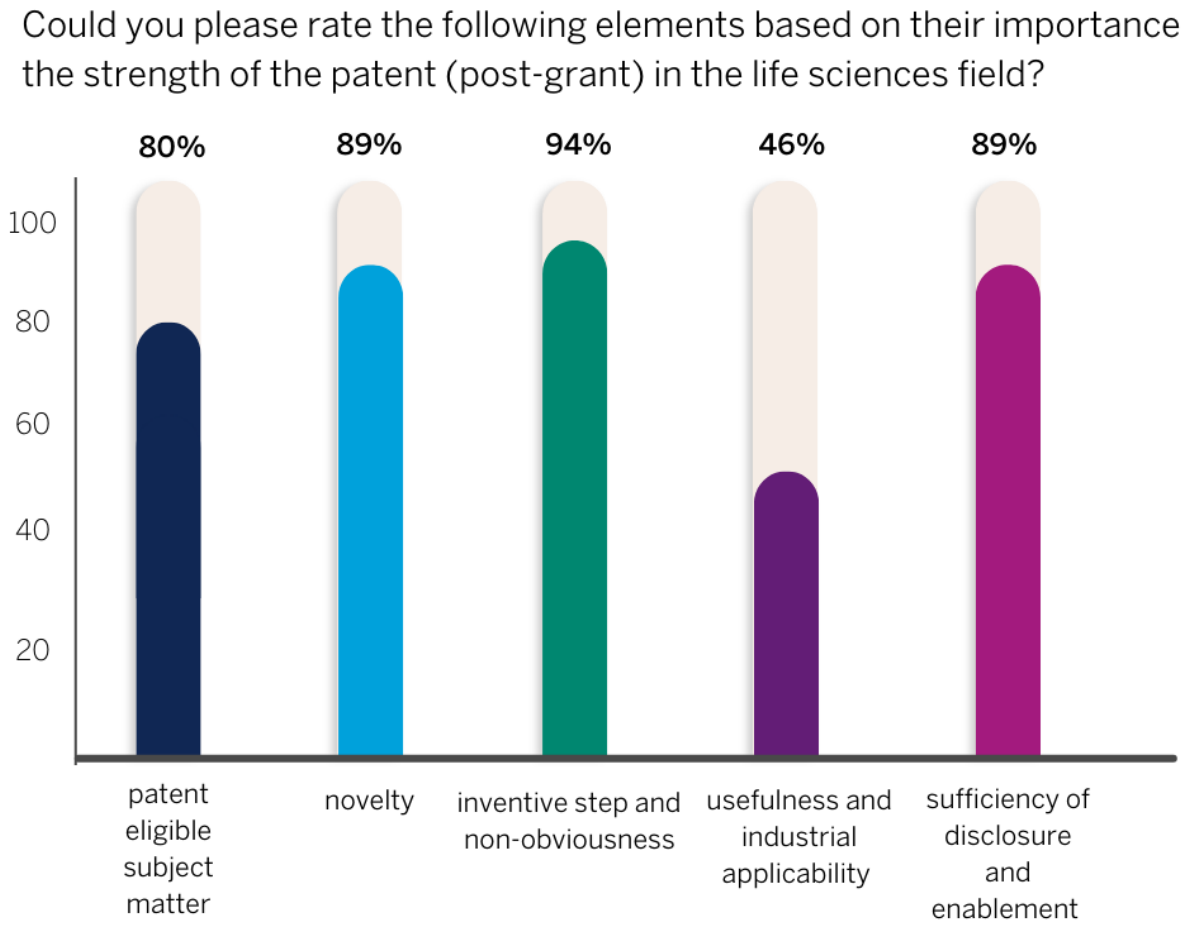
Know how

“factual knowledge not capable of precise, separate description. However, when used in an accumulated form, after being acquired as the result of trial and error, gives to the one acquiring it an ability to produce something which otherwise would not have known how to produce with the same accuracy or precision found necessary for commercial success.” - Mycalex Corporation v. Pemco Corporation, 64 F. Supp. 420 (D. Md. 1946)

Know how

- *Negative information (failed experiments, conditions, etc.)*
- *List of raw materials provider*
- *Right experimental conditions*

Impact of key patenting requirements on patent strength



Data sources and support of claims

- Data presentation
- Data types
- Patent application structure
- Claim support

Data presentation

Ideally – Same guidelines for publication of peer reviewed life sciences research

First to file system – compromise

Use of post filing data during prosecution

Data presentation - Sequences

ST 26 (from ST. 25 July 2022)

Sequences of:

- 10 or more nucleotides
- 4 or amino acids

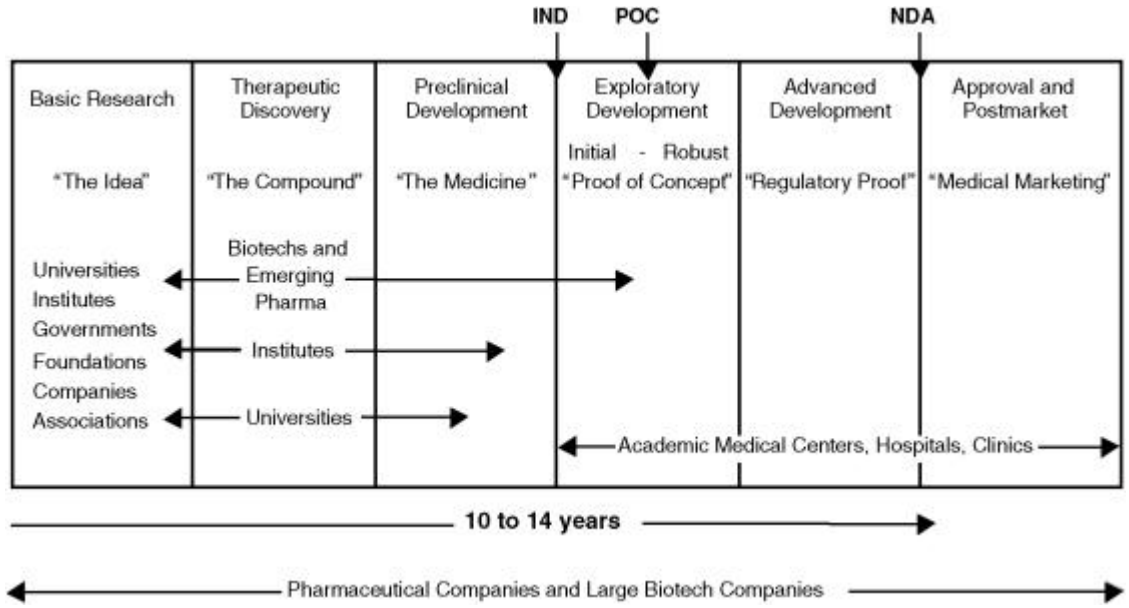
International Nucleotide Sequence Database Collaboration (INSDC) requirements

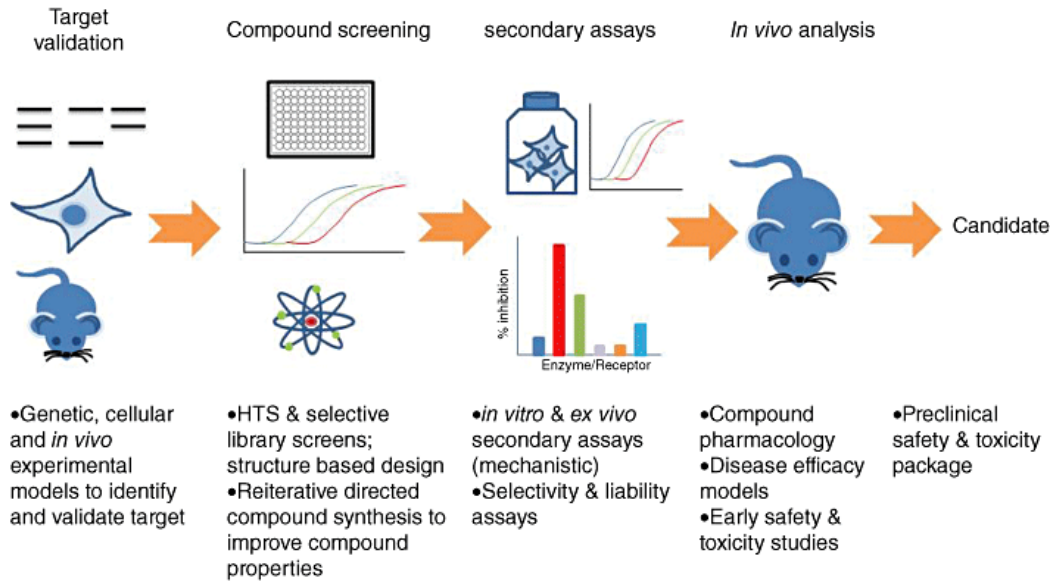
Nucleotide analogues or D amino acids or branched sequences.

XML vs TXT format

Data types

Therapeutics – Drug development pathway





https://doi.org/10.1111/j.1476-5381.2010.01127.x

Data types

Diagnostics

Medical Devices

Relevant data for PHOSITA

https://doi.org/10.1111/j.1476-5381.2010.01127.x

Patent application structure

Description (title, technical field, background art, summary of the invention, brief description of drawings, detailed description)

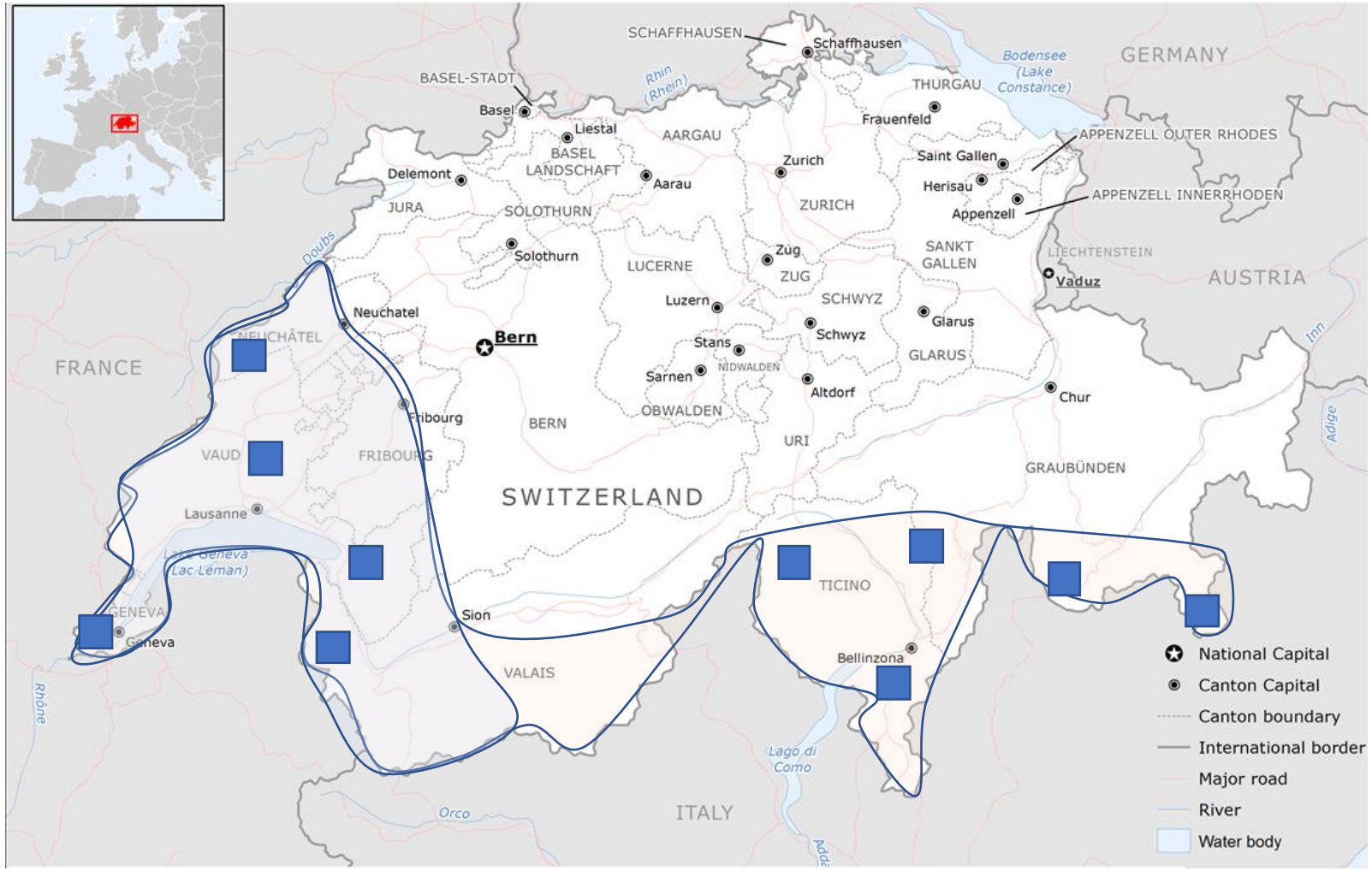
Claims

Drawings

Abstract

https://www.wipo.int/publications/en/details.jsp?id=4584 (WIPO Patent Drafting Manual)

Data for claims support



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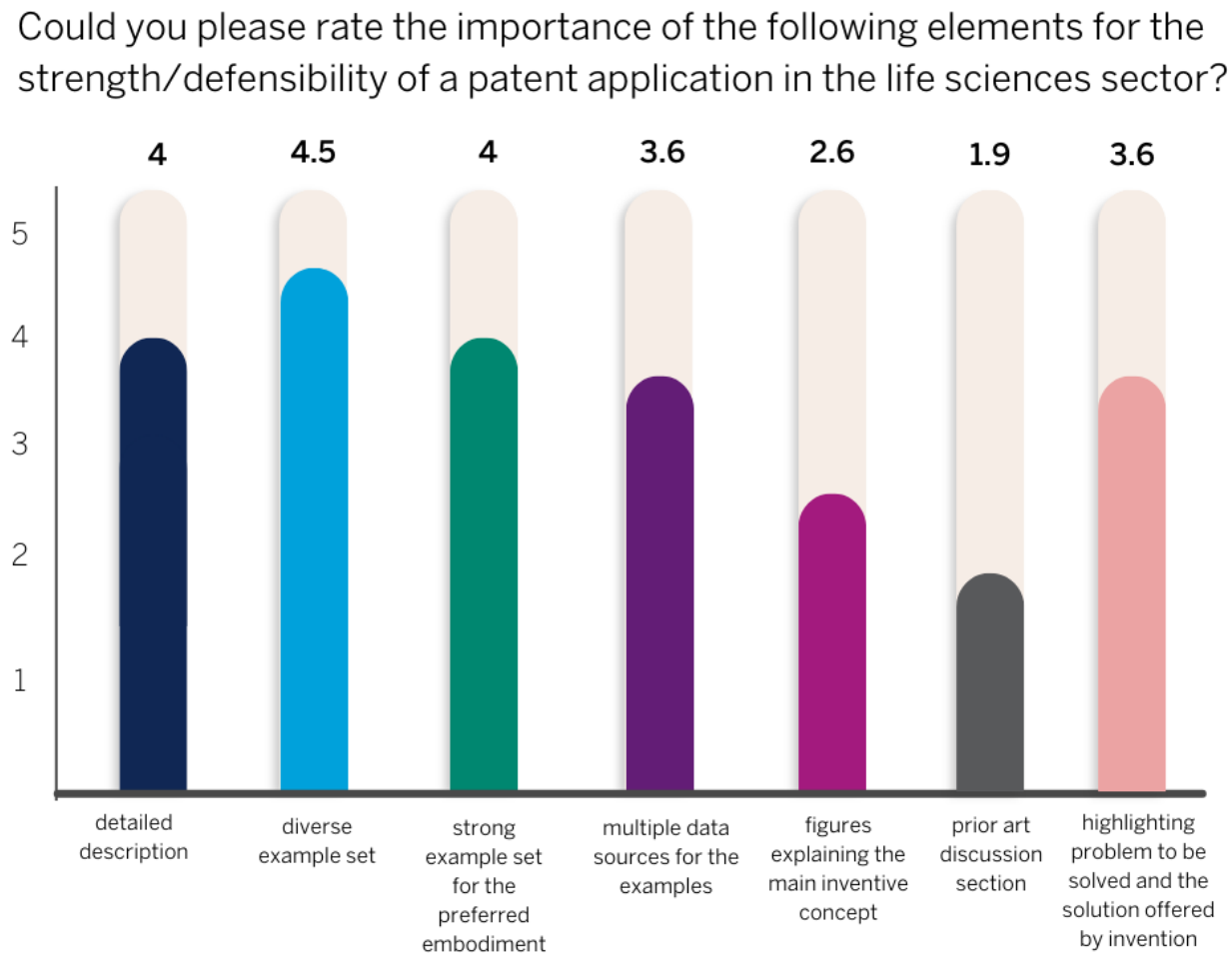


Focus on inventive step and novelty

Balancing act
- data & date of filing
- exemplification & breadth of claims

Patent application filing and prosecution

Obtaining patent protection

- Claims
- Life science & the international patent system
- Filing and prosecution

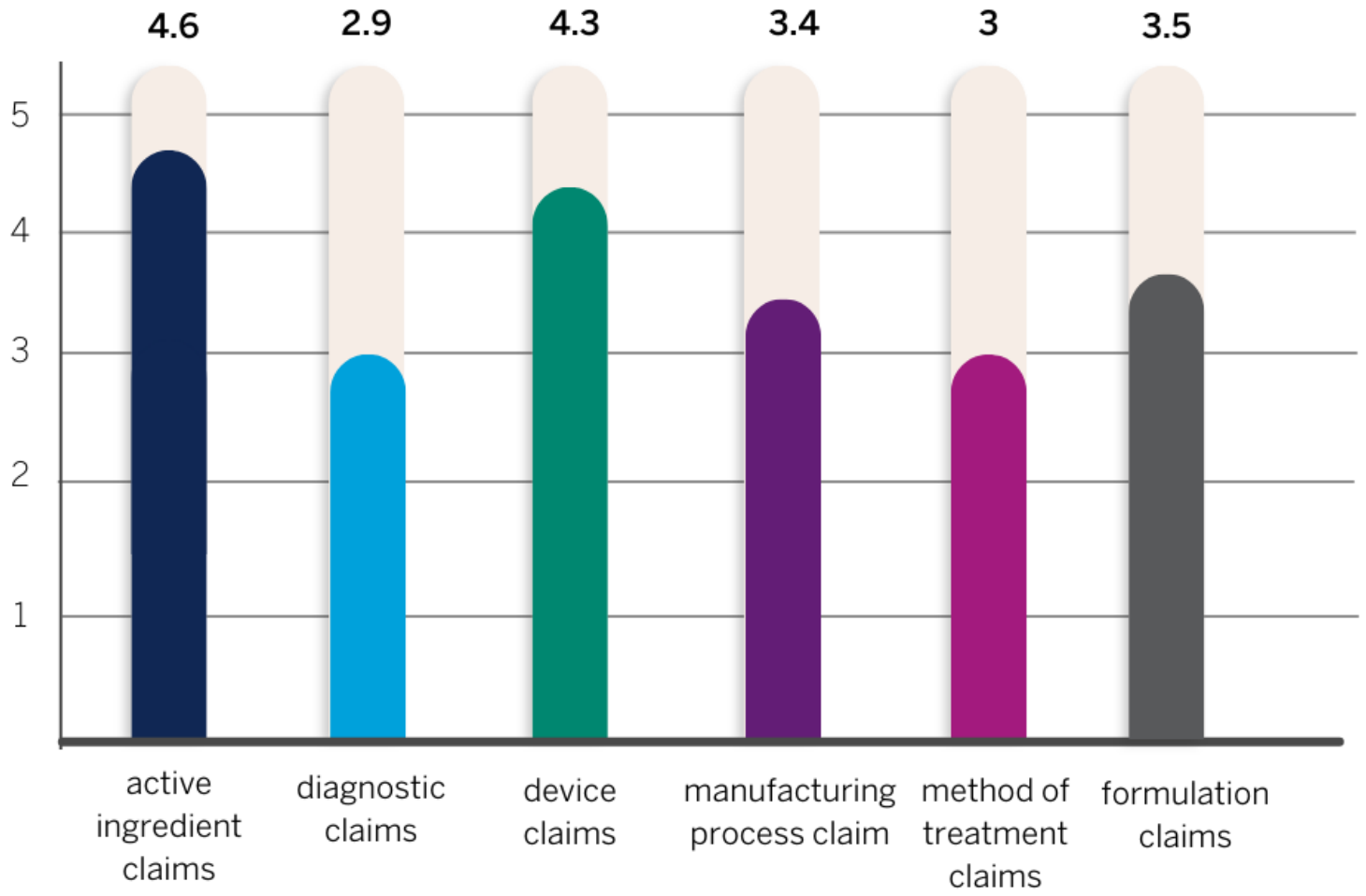
Claims

Define legal protection (description & examples)

Claim types – product/composition of matter (API/device); process/method; product by process, use claims.

Claims

Could you please rank the defensibility strength of the claim types below, considering that there is a proper support within the specification



Life science and the international patent system

- PCT
- TRIPS
- Budapest Treaty
- Biotechnology Directive

Patent Cooperation Treaty

WIPO – 1970 - 157 countries part of the Treaty

Filed (national or resident)

International Searching Authorities (ISA) and International Preliminary Examining Authorities (IPEA)

https://www.wipo.int/pct/en/guide/index.html

Trade-Related Aspects of Intellectual Property Rights (TRIPS)

Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS)

All member nations of the World Trade Organization (WTO). (Signed 1994, effective 1995)

Procedures & remedies IP rights holders

Incentivize innovation and disclosure - key part of the "social contract".

Budapest Treaty

Sufficiency of disclosure cannot be fulfilled without a biological material

International Recognition of the Deposit of Microorganisms for the Purposes of Patent Procedure – adopted in 1977 (in force since 1980)

49 International Depositary Authorities

Biotechnology Directive

The European Biotechnology Directive (Directive 98/44 EC) - patenting of biotechnological inventions in European Union member states. (incorporated into the EPC in 1999)

EPO – prosecution & grant.

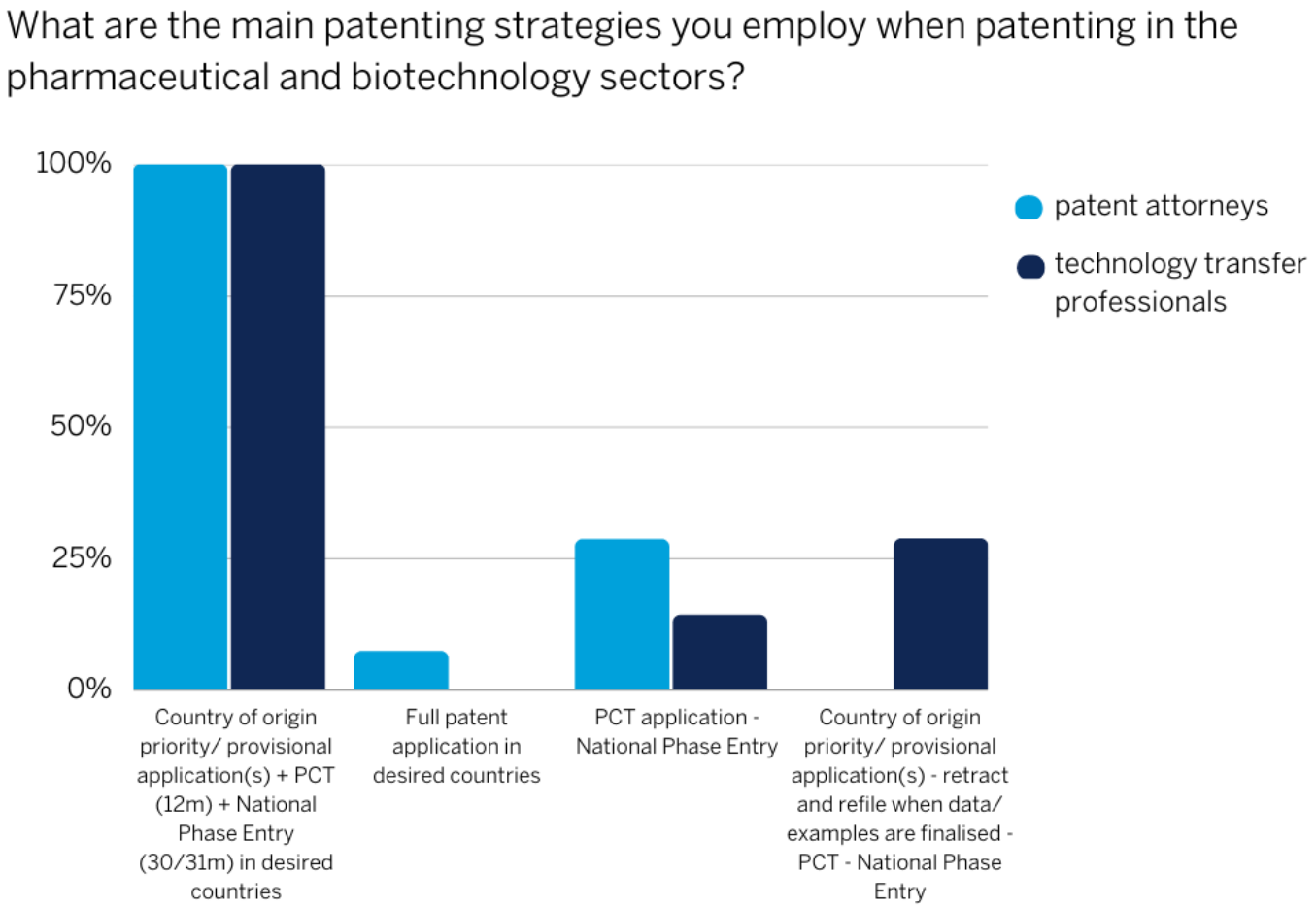
- Essentially biological processes for the production of plants or animals (breeding) are excluded from patentability – Directive Art 2(2) (EPC Rule 26(5)).
- Exclusion from patentability of uses of human embryos for industrial or commercial purposes – Directive Art 6(2)(c) – EPC rule 28(c).
- Requirement of disclosure of the industrial application of gene sequences Directive Art 5(3) – EPC rule 29(3).

Application filing

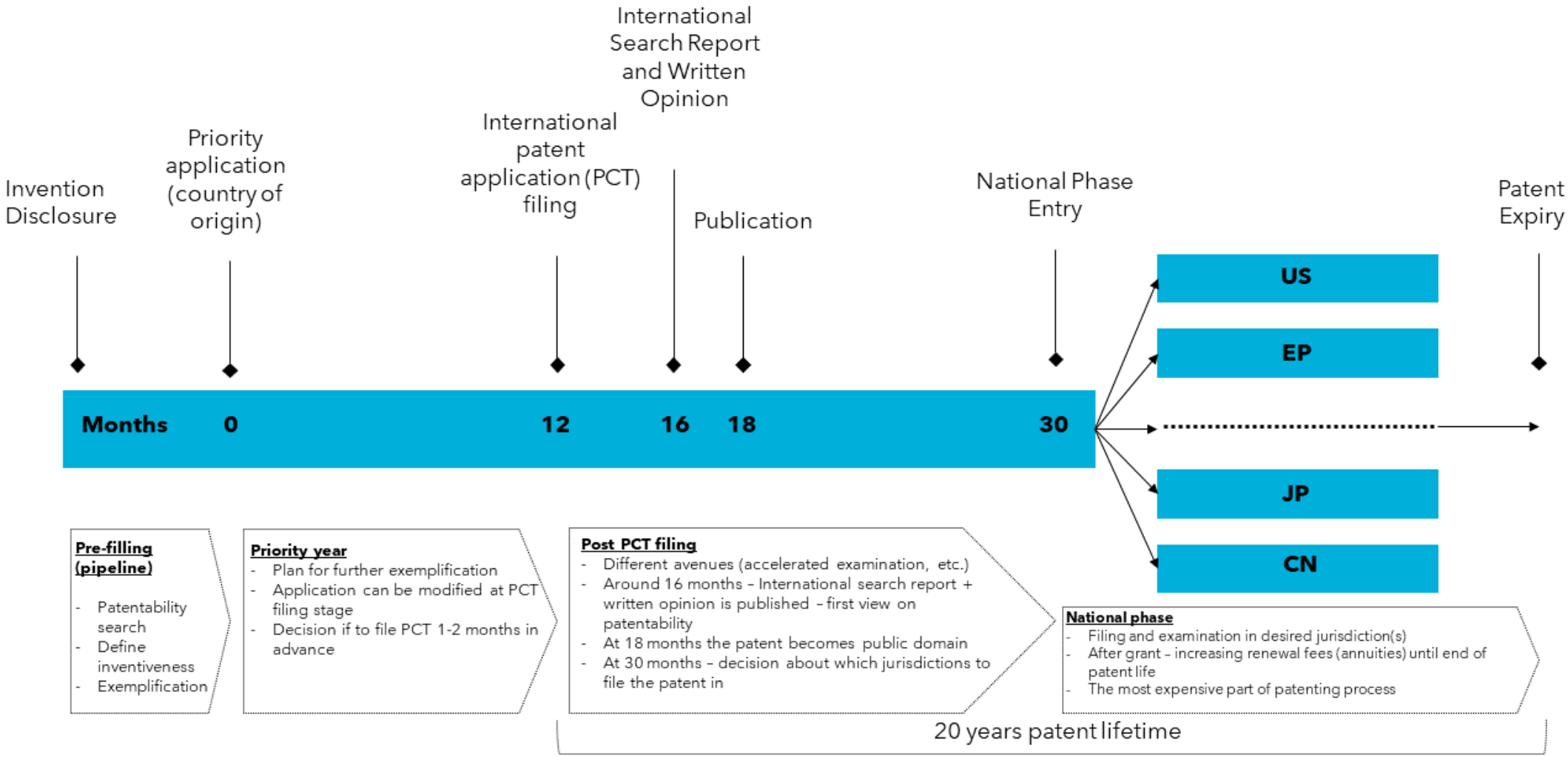
Costs/Budget constraints

- Efficient process with Patent attorneys
- Decrease official filing fees

Filing strategies



Most common filing strategy



Prosecution of patents

- Speed/Delay
- Examiner
- Keeping application live
- Objections

67% of life sciences patent attorneys encounter a patent eligibility subject matter objection frequently or very frequently.

83% of life sciences patent attorneys encounter a written description objection frequently or very frequently.

75% of life sciences patent attorneys encounter an added matter or intermediate generalisation objection frequently or very frequently.

Understating timelines – important for innovation process & strategy

Understanding cost implications – better control of budgets

Patent/IP Strategy

Patent/IP strategy overview

Best protection for innovations – Moat (defensibility) – Exclusionary right!

- Filing strategy
- Commercialization strategy
- Key for both - communication

Filing strategy

How does one obtain the maximum legal protection for one's invention(s)?

Costs & time constraints

Technology transfer offices (TTOs)

Companies – startup vs corporate

Commercial Strategy

Which markets offer the most financial returns from the sale of the product/service protected by the patent(s)? (Return on investment)

Which countries/jurisdictions would be involved in the supply chain for the product/service the company is selling?

Industrial biotech startup using biomass residues

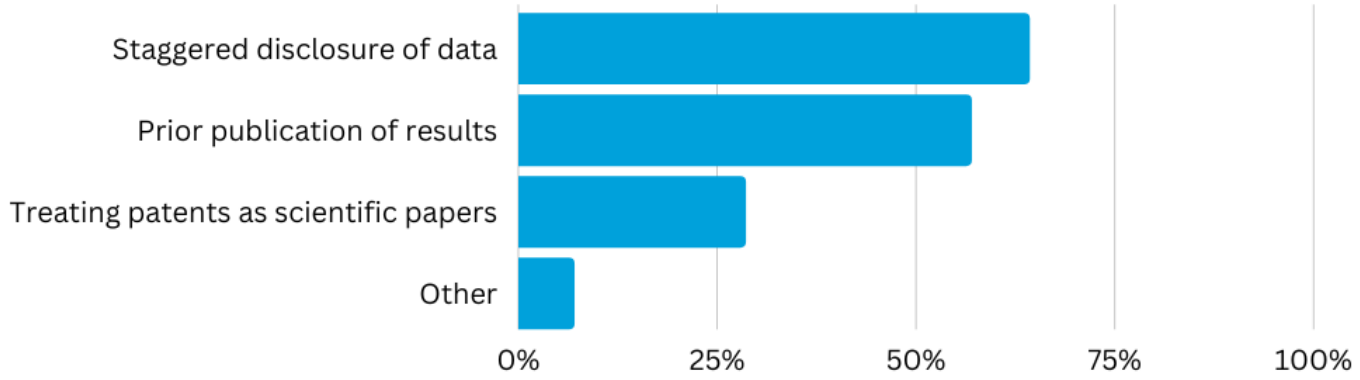
Strategy alignment

Filing & Commercial alignment – Business IP strategy

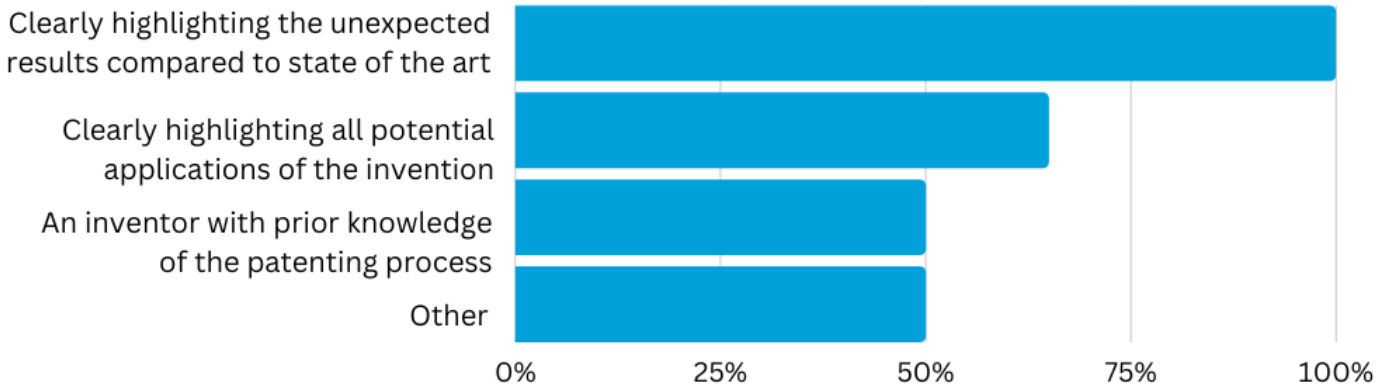
Patent attorneys – can help with the optimal balance for the strategy

Communication approaches

What are the most common elements that hinder communication with inventors when drafting patents?

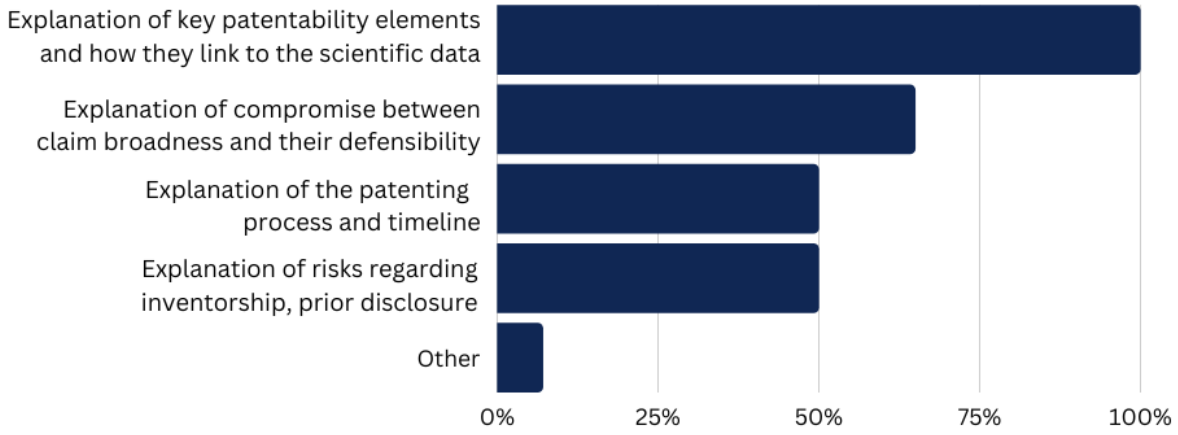


What are the main elements that would improve communication with inventors when drafting patents?

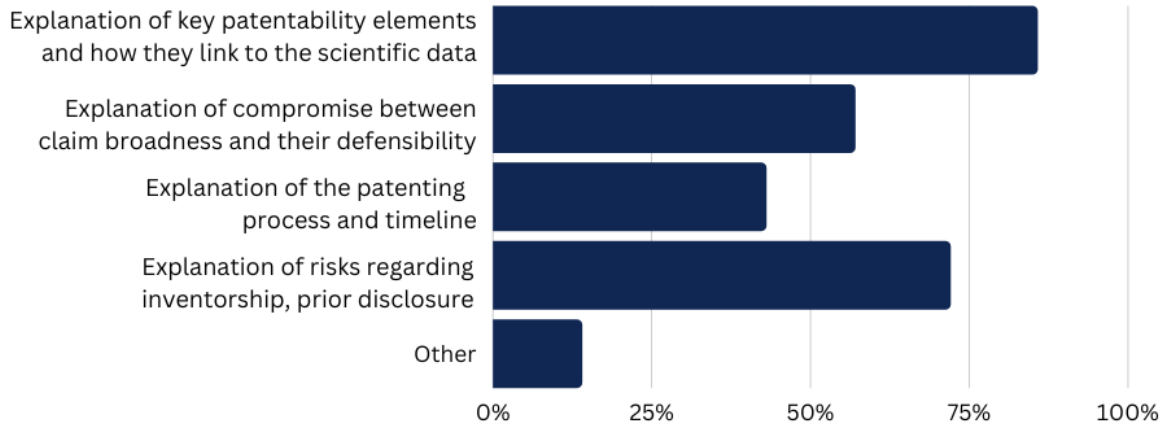


Communication approaches

What communication strategies would you recommend to a less experienced attorney when speaking with an inventor?



What communication strategies would you recommend to a patent attorney when speaking with an inventor/scientist?



Alignment is key – strategy, participants

Great communication acts as a catalyst!

Conclusions

Focus on inventive step, novelty & sufficiency of disclosure

Balancing act; data & date of filing | exemplification & breadth of claims

Understating timelines – important for innovation process & strategy

Understanding cost implications – better control of budgets

Alignment is key – strategy, participants

Great communication acts as a catalyst!

Thank you for your attention!

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