

Dos and don't on the Road to Success in the Biotech world

Staffan Wilow,
Member of Swedish Bar organization, 1085, CEO af Petersens law firm, IPR,
life science, founded 1986

sw@aap.se

info@aap.se

Protection of an idea or a concept

”Idea” = Abstract representation, way of thinking, invention

In Europe no IPR protection for ideas as such.

Ideas may be legally protected – if materialized
– “concretisation”.

IPR

Intellectual Property Rights

European Law Definition

1. Patents

2. Know-How

Utility Models
Trade Secrets

3. Trade marks

4. Industrial design

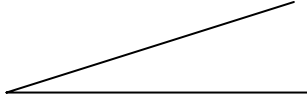
5. Copy Right

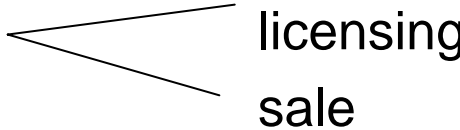
PATENTS	UTILITY Know-how	TRADE MARKS	INDUSTRIAL DESIGNS	COPYRIGHT	TRADE SECRETS Know-how
Technical Inventions: - New - Inventive Step; -Industrial application.	Technical inventions: - New - lower level of inventive activity - Industrial application ((Protectable subject matter can be restricted).	Trade marks for products, services: 2D or 3D pictures, words, names, colours, and/or sounds.	Design: Aesthetic configuration of an object or a specific shape.	Literary, graphic or musical works, software, databases.	Technical information.
Duration of protection: 20 years	Duration of protection (in most of the EU Member States): 10 years	Duration of protection: 10 years, indefinitely renewable	Duration of protection: 5 years, renewable to up to 25 years (according to Directive 98/71 on the legal protection of Designs).	Duration of protection: Author's lifetime + 70 years.	Duration of protection: Indefinite until in the public domain.
Instruments: - National trade marks; - Community Trade marks; -International registration of trade marks.	Instruments: - National utility models (not available in all EU).	Instruments: - National trade marks; - Community Trade marks; -International registration of trade marks.	Instruments: - National trade marks; - Community Trade marks; -International registration of trade marks.		Instruments: No registration
Competent authorities: - National	Competent authorities: - National	Competent authorities: - National	Competent authorities: - National		

Tools and Forms of Protection

- A. Registration
- B. Concretisation
- C. Contractual protection (NDA)
- D. Unfair competition law
(undue advantage of some ones work, parasitic behaviour)

Road to success

- Ideas
 - Concretisation
 - Informal discussion
 - Formalisation of company group
 - Partnership Agreement
 - R & D
 - Clinical trials
- 
- Partners
Finance

- IPR and Tech transfer
- Expending partnerships
- Acquisitions of Know-how
- Manufacturing process
- Exit 
 - licensing
 - sale

- Prime objects:
1. Secure & define IPR ownership
 2. Secure non-disclosure
 3. Secure non-use
 4. (Exit) Secure fair compensation

Acquisition, case study

- Idea, Invention
- Formalised in a Patent Application
- First Round financing
- Additional Know-how, R & D
- Founders deed and agreement
- Acquisition of company shares
- Inventors SHA agreement, IPR transfer
- Constitutory share holders meeting
- Company registration (Swedish AB)
- Additional R & D
- Second Round financing/Exit
- New Co
- Acquisition of all IPR
- SHA

Conclusion: IPR ownership not secured

Exit, Case, study

- Idea, Invention
- Formalised in a Patent Application
- New Co foundation
- IPR transfer of Inventors
- First round financing
- New SHA
- R & D Agreement with third party

Exit

Co-operation, development and licensing agreement

1. Ownership transfer
2. Remuneration terms
 - (1) New products, milestone payments
 - (2) grant of patent, royalty
3. IPR licenses/applications
4. Consultancy services
5. Reps and warranties
6. Indemnifications and warranties
7. Marketing Authorisations
8. NDA
9. Reversion of rights (Tech, Products. Documentation, dossiers, assignments)

REMUNERATION

Milestone payments:

1. Upon commercial launch of a Additional Product
2. Upon tech transfer
3. Upon specified dates

“Use best efforts to commezialise Tech through R & D, marketing and sales.”
Details of R & D program to be agreed.

No detailed agreements made!
R & D Program priority down graded!

- Methods:
- (i) Detailed R & D schdule, time and results
 - (ii) Steering committee with decision taking
 - (iii) Re-transfer of Tech
 - (iv) Compensation for delay

Conclusions

Contractual protection secure:

IPR ownership (note: history)

NDA – procedures

Actual and fair compensation
payment terms.