

Introduction to Intellectual Property

Oliver Sexton

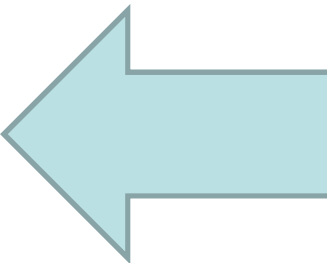
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Introduction

- Who am I?
- Types of Intellectual Property
- Patents – what, why, who, where, how?
- Other forms of IP and their uses

Forms of IP relevant to Surgery and Medicine

- Patents
- Data exclusivity
- “Know-How”
- Design Rights
- Copyright
- Database Rights
- Trade Marks



**Collectively
“Intellectual
Property
Rights”
(IP or IPR)**

Patents

- Provide broadest protection for invention / discovery
- Prove ownership AND inventorship
- Usually required to obtain external investment
- Vital for any business involving lengthy and high risk product development
 - e.g. health products
 - must protect investment from unfair competition

Patents – what are they?

- Monopoly right to inventor(s)
 - Maximum 20 years
 - Restricted by territory
 - Restricted by details and claims of patent document
- Can patent products, processes, methods
- Cannot patent ideas, theories, “laws of nature”, animal and plant varieties
- Patent law always lags behind technical advances
 - Regular need to “adjust” legal practice with progress in science and technology

Patents – what are they not?

- No absolute right to use, sell patented process/product, only to prevent others from doing so without permission
- **May require permission(s) from other patent holders**
- Not a licence to print money!!
- >95% of patents don't pay for themselves...
- But a few do, many times over

Patents – who invents?

- Anyone who makes an “inventive contribution”
- Not necessarily person who carries out work
- May not be same as authors of paper
- Must get it right according to patent law
 - wrong inventorship may invalidate patent, esp. U.S.

Patents – who owns?

- Any invention made during employment is normally property of the employer
- May have shared ownership
- Rule applies to academics – the University owns your invention
- Student inventors – IC policy depends on who contributes

<http://www3.imperial.ac.uk/researchsupport/contractsandip/ippolicy>

<http://www3.imperial.ac.uk/researchsupport/contractsandip/intellectualpropertyip>

Patents – where?

- A national right
- Costs limit patenting to countries where commercially important
- Generally file application in one country initially e.g. UK (“establish priority”)
- Need to decide on other countries after 12 months

Patents – requirements

- **Three essentials**
 - **Novelty**
 - **Inventiveness / non-obviousness**
 - **Practical/industrial application**

Patents - novelty

- Must not be part of the “state of the art”
- **NO PRIOR DISCLOSURE!!!!**
 - *Any* non-confidential written or spoken disclosure. Papers, talks, posters, abstracts, chats in the pub
- State of the art. Everything that is available to the public prior to the patent filing date
- A few countries allow patenting after disclosure, but rules complex. Commercially important countries are
 - USA* and Canada (12 months)
 - Australia, Brazil (12 months)
 - Japan (6 months)

* **BUT** USA rules change in 2013 to “First to File”

Patents – inventiveness

- Legal, not “scientific” definition
- Not obvious to “person skilled in the art”
 - Does not mean Nobel prize-winner!
- Unexpected result helps
- Patent not written like scientific paper

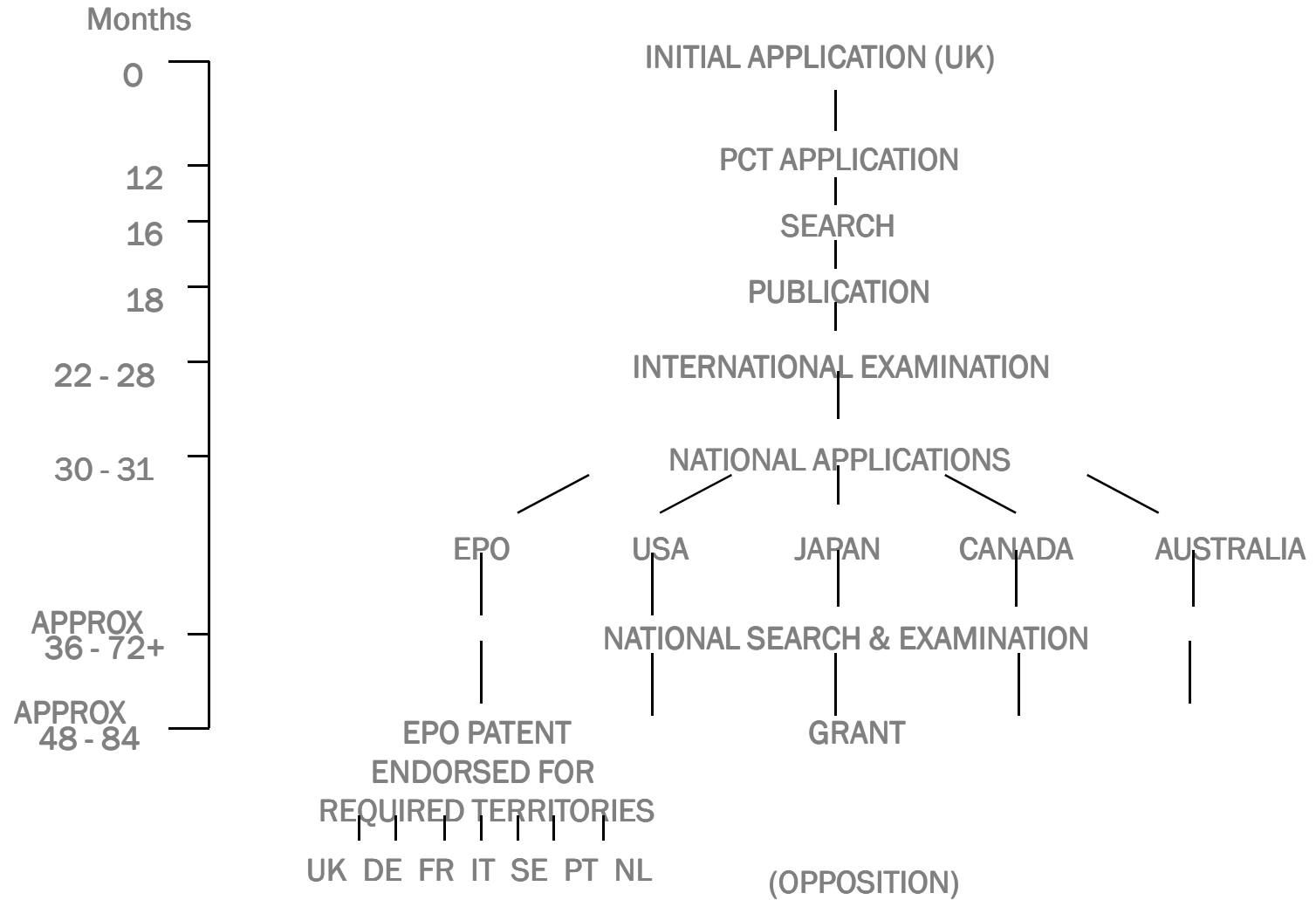
Patents - utility

- Industrial/commercial application (“utility”) required
- Best means (US requirement – *being relaxed in 2013*)
- Complete (“enabling”) disclosure needed
- Certain areas blocked –
 - **surgical procedures**
 - anything against “public order”

Patents – how much?

- (Fairly) low cost start
 - Initial national application few £1000s
- Costs mount after 12 months
 - International application several £1000s
- “National phase” after ~ 30 months
 - £2500-4000 per country plus translation costs
- Renewal costs increase towards end of patent life
- Typical total cost over patent life £150-500K

The patent process





(12) EUROPEAN PATENT APPLICATION

(43) Date of publication:
14.03.2001 Bulletin 2001/11

(51) Int. Cl.⁷: A61M 16/18

(21) Application number: 00116625.5

(22) Date of filing: 01.08.2000

(84) Designated Contracting States:
AT BE CH CY DE DK ES FI FR GB GR IE IT LI LU
MC NL PT SE
Designated Extension States:
AL LT LV MK RO SI

(71) Applicant: Siemens-Elema AB
171 95 Solna (SE)

(72) Inventors:
• Pessala, Tom
01100 Östersundom (FI)
• Emtell, Pär
16247 Vällingby (SE)

(30) Priority: 09.09.1999 SE 9903193

(54) Anaesthetic vaporiser

(57) An anaesthetic vaporiser (1) for dosing a liquid anaesthetic (10), comprising a liquid container (8) for the anaesthetic (10), and outlet tube (12) from the liquid container (8) to a dosing point (14), a first regulating means (18) for regulating a flow of anaesthetic (10) from the liquid container (8) towards the dosing point (14) and a control unit (36) for controlling dosing are described. To improve dosing and safety, the anaesthetic vaporiser (1) according to the invention is devised with a return tube (28) connected in parallel across the first regulating means (18) by a first connection point (30), downstream from the first regulating means (18), and a second connection point (32), upstream from the first regulating means, a second regulating means (34; 52) is arranged in the return tube (28) and a third regulating means (22) is arranged in the outlet tube (12), downstream from the first connection point (30). The control unit (36) controls at least one of the regulating means (18, 34, 22) in dosing the anaesthetic (10).

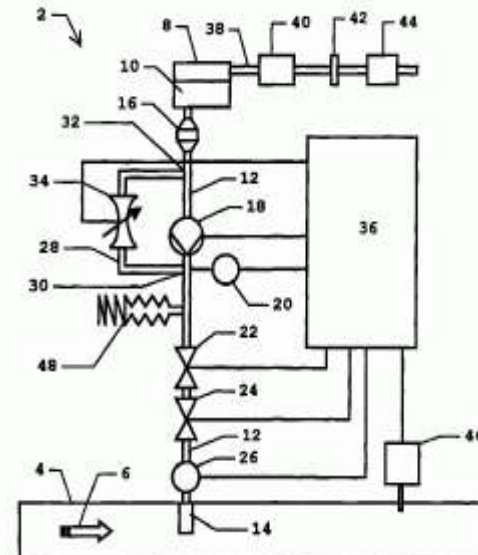


FIG. 1

Using Patent Literature

- Estimated that > 80% of information in patent literature not available elsewhere
- Most patent information that is in the public domain is available free on the Web
- Patent searching can be difficult
- Commercial patent databases available – more user friendly

Patent searching and info

- Espacenet <http://gb.espacenet.com>
- USPTO www.uspto.gov
- UK patent office www.ipo.gov.uk
- EU-funded site www.ipr-helpdesk.org
- <http://www.google.com/patents>
- <http://www.patentlens.net/>
- <http://www3.imperial.ac.uk/library/find/patents>
- www.en.wikipedia.org/wiki/Patents
- [www.en.wikipedia.org/wiki/Software patent](http://www.en.wikipedia.org/wiki/Software_patent)
- http://www3.imperial.ac.uk/entrepreneurship/archives/starting_a_new_venture/ideas/protecting_your_idea
- <http://www.freepatentsonline.com/>

Patents and Research

- General rule
 - Patents do not block “pure” research
- But
 - Rules vary with country
 - Anything related to future application / commercialisation may be blocked
 - Any research in companies likely to be considered “commercial” and hence infringing

Data Exclusivity

- Protection of clinical trials (testing) data required to obtain marketing approval for new drug
 - Generation of such data very costly and time consuming
 - Unfair if prospective generic competition can use such data to get their own marketing approval (product licence)
- Data exclusivity periods (years) for human drugs:
 - US NCEs 5, New Indications 3, Biologics 12, Orphan drug 7
 - EU NCEs 8 + 2, New Indications 1, Orphan drug 10
 - Japan 6, Orphan drug 10

Know-How

- “Trade secrets”, methods, processes, skills
- No registration needed, no formal protection
- Depends on controlling access, confidentiality agreements
- May be material – e.g. monoclonal antibody cell line, “knock-out” mouse
- May be very valuable – e.g. Coca-Cola® recipe, clinical trials data
- Manufacturing methods, processes
 - Less scope to keep secret in pharma than in most other industries because of regulatory requirements

Design Rights - 1

- Protects appearance, not function
 - Shape, colour, texture, materials, contours, ornamentation
- Unregistered design right automatic in EU (cf. copyright)
- Lasts
 - 3 years from first public disclosure (EU)
 - 10 years from first marketable product (UK)
- Prevents copying, “passing off”



Design Rights - 2

- Design can be registered
- Through patent offices
- Prompt, inexpensive
- National right (cf. patents)
- Protection up to 25 years
- Design patents in US



Copyright

- Automatic BUT offers no protection against use of ideas by third parties
- Protects
 - Original literary, dramatic, musical, artistic works, Audio and video recordings, broadcasts, Web pages, blogs. May be used to protect software
- Author is owner unless work produced as part of employment
- Life of author plus up to 70 years

Copyright

- Academic journals often demand assignment of copyright
- Others only require first right of publication
- Check contract – assignment must be in writing
- If required, reserve rights such as
 - Copies for your teaching/research
 - Copies for teaching/research by colleagues
 - Revision and publication for book, conference paper etc.
 - Posting on your web-site

Database Rights

- Automatic, no registration needed
- Maker must be European EA resident
- Protects
 - Investment in obtaining, verifying, sorting, presenting contents of database
 - Against unauthorised use or copying of large parts of database and/or repeated use of small parts
- Lasts 15 years

Trademarks

- Protects distinctive identifying marks used in business
- Usually word(s) or logo or both
- Complex rules (e.g. may not be descriptive)
- **TM** - can be used by anyone
- **®** - registered trademark, gives legal protection



Software issues

- Software can be protected narrowly by copyright or broadly by patents
-IF the software is patentable (“technical effect”)
- Track contributors
- Look after your source code
- Easily copied!

Copyright and Software

The following software-related items **are eligible for copyright protection**:

- The computer program, in both human-readable form and machine-executable form, and
- the related manuals

BUT

- the methods and algorithms within a program are not protected

Source code and object code are protected against copying.

Patents and Software

In Europe software may be patentable if it has a "technical effect":

- Software for controlling an engine - patentable
- Software for text review – probably not patentable

- Software that emulates a mathematical algorithm may not be patentable in Japan and USA

Key Points

- Pharma industry active user of all forms of IP
- Relative importance of forms varies with type of company and within different divisions of company
- Research – Know-How, Patents, Database Rights
- Manufacturing – Know-How, Patents
- Development, Regulatory Affairs - Copyright, Data Exclusivity
- Marketing and Sales – Trade Marks, Design Rights, SPCs, Copyright, Patents
- Patent before you publish!

Thank you!

Any Questions?