

MedTech BEST:

Business and Entrepreneurial Skills Training

Wednesday 7 December 2016

Intellectual Property and Freedom to Operate

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Introduction to IP

IP is a set of legal rights, in categories such as

- confidential information / know-how
- patents
- copyright
- computer programs
- databases
- designs
- passing off & trade marks

Confidential information / know-how

- The law of confidence says that where:
 - you have information that is (a) important and (b) not in the public domain; and
 - you impart it to someone in conditions of confidence; and
 - they misuse it, i.e. publish it or make use of it; you have a cause of action against them.
- To bolster this legal right, we get people to sign NDAs (contracts). These set out the position in more detail.

Structure of an NDA:

- Parties
- The ‘Confidential Information’ means [E.G. INFORMATION RELATING TO THE PROJECT KNOWN AS ...]
- Purpose of the disclosure [E.G. TO HELP THE RECIPIENT DECIDE WHETHER TO COLLABORATE WITH ME]
- Duration
- Law and jurisdiction
- Signatures

Patents

- Patents are 20-year monopolies
- Available for inventions (new ideas, which are inventive)
- The deal is you disclose the idea in detail, in return for the monopoly, and you pay fees

Copyright

- Authors have long-lasting rights to prevent the copying of their original works (such as original text, drawings, photos, or compilations of data)
- To enforce this right, you have to prove copying or publishing, of a ‘substantial’ part of the work
- Use of a copyright work for criticism or review, where you acknowledge its source, is permitted

Computer programs

- Copyright protects the source code, but not the underlying ideas
- The Software Directive sets down special rules, but still does not prevent the copying of the ideas behind the program, only the literal copying of lines of code

Databases

- The Database Directive protects against substantial amounts of data being extracted from a database, provided substantial investment went into gathering the data

Designs

- The novel shape or appearance of your product can be protected
- Protection is better for aesthetic designs

Designs which are solely dictated by technical function

- Protected in the UK automatically, for 15 years
- Protected by the copyright in your design drawings in most countries of the world

Designs with aesthetic appeal

- Protected across the EU automatically, but only for 3 years from publication date
- Better protected across the EU when you register the design, for up to 25 years, which you can do cheaply and easily

Trade marks

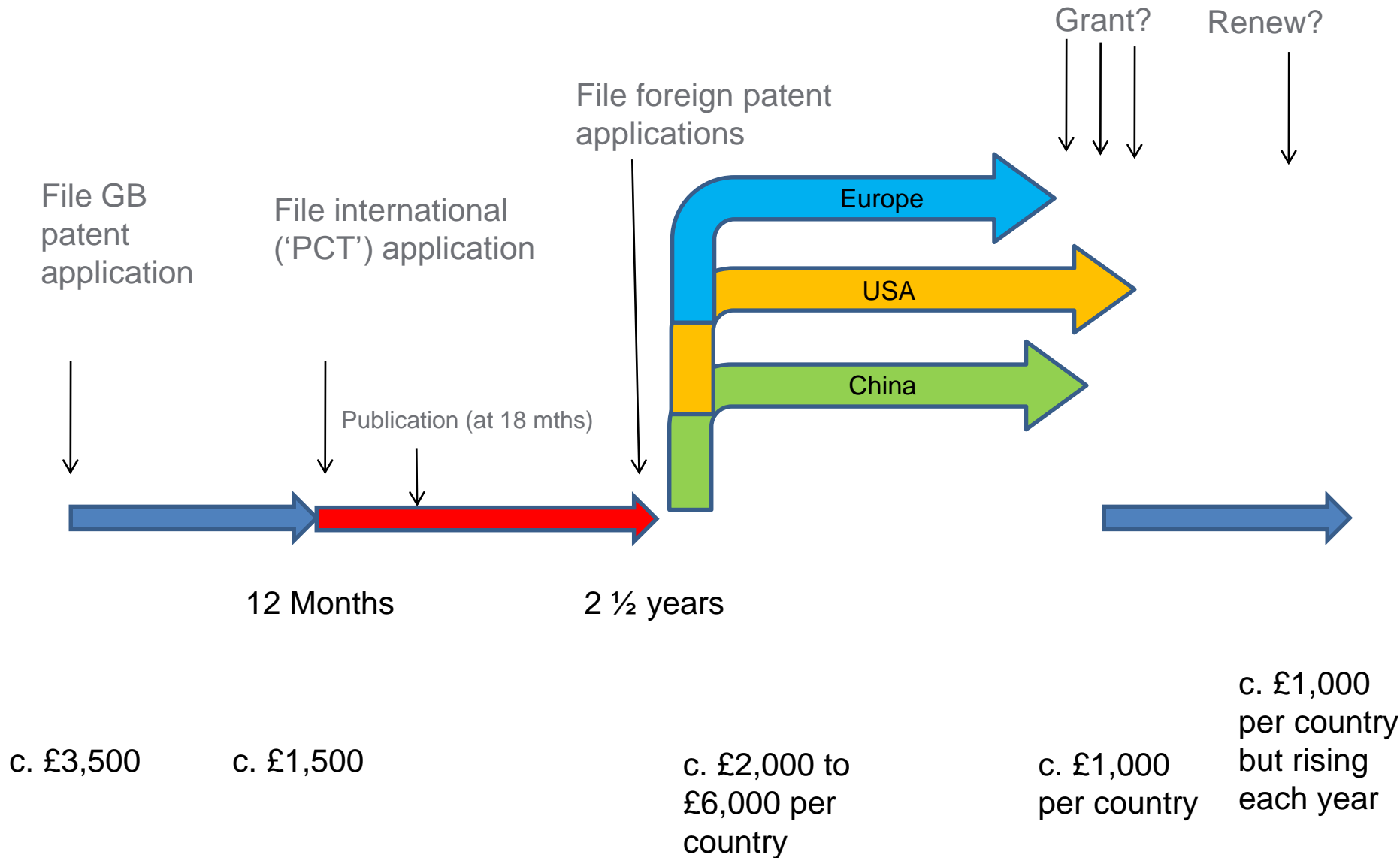
- You can protect IP rights in the name, colour, shape, etc. of your product, where you've built up a reputation
- If you register your trade mark you get a strong right to prevent use of it, in the classes of goods/services for which you register it
- Registered trade marks last indefinitely, as long as you pay the renewal fees
- Unregistered marks are protectable under the law of passing-off

More on patents...

- the patenting process

- File 'priority' application in home country, and request a search
- You'll get a search report after about 6 months, indicating what the UK examiner thinks about novelty and inventiveness
- Within 12 months, file 'PCT' international application (adding in any improvements)
- Your application is only published 18 months after first filing (it's wise to keep its contents confidential until then, if possible)
- Within 2.5 years of first filing, file in whichever countries you want to cover (hopefully, you will have interest from investors by this point and they will direct where to file, and fund these 'national' filings – this is called 'national phase entry')
- The patent examiners in each country will raise questions for you to counter, or perhaps you will agree to amend or delete claims
- 3 or 4 (maybe more) years from filing, once the examiner is happy, your patent will be granted (country-by-country)

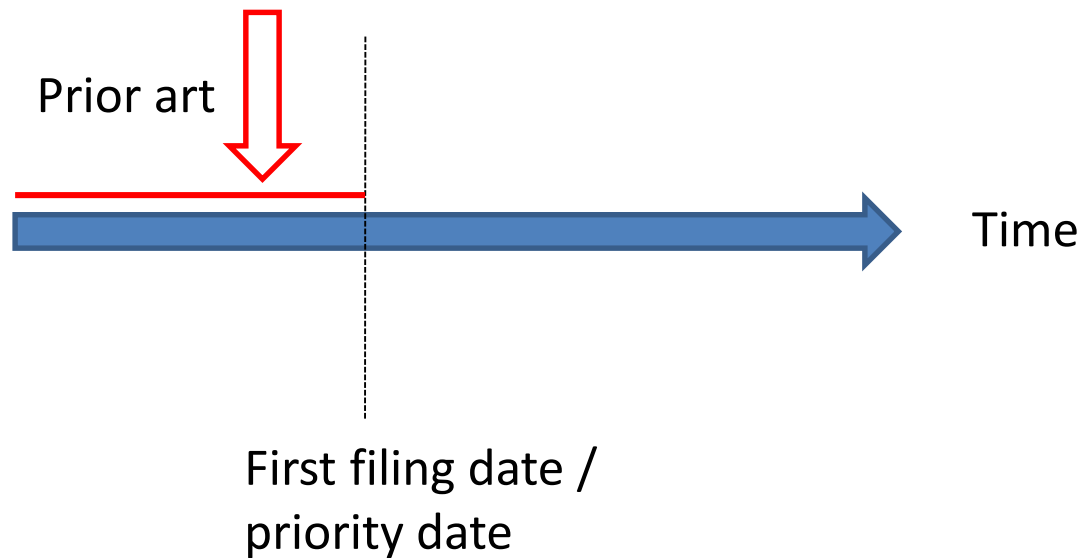
A typical filing strategy



More on patents...

- novelty

- Inventions must be novel (not in the prior art)
- The prior art is everything made available to the public prior to your priority date (first filing date)



More on patents...

- the skilled person

- The hypothetical ‘skilled person’
 - is involved in the field of technology of the invention;
 - may be a team of people if more than one field is involved;
 - is aware of all material that is in the public domain in that field and ‘common general knowledge’ relating to the field; but
 - has no inventive capacity – so will not, for example, combine ideas from two different published sources unless they cross-refer.

More on patents...

- what is prior art (when might something not be in it)?

- Disclosures (e.g. papers) place in the prior art that which they enable the skilled person to put into effect
- A non-enabling disclosure is one which does not give enough information to the skilled person to work the invention
- The skilled person can use his common general knowledge, and trial and error, to try to work the invention, but should not have to go to great lengths
- For some inventions, simply showing the product is an enabling disclosure (you can work out how it is made); but for others, e.g. a compound, only giving its formula, and perhaps even method of manufacture, is an enabling disclosure

More on patents...

- inventive step
- Obvious advances are not patentable, and obviousness is judged from the point of view of the skilled person, at the priority date

More on patents...

- international differences
- Europe, the US, China, they all have different patent laws
- Some things are not patentable in Europe, but patentable in the US (e.g. a method of treatment practised on or in the human or animal body)
- Naturally occurring products are patentable in Europe if they are isolated from their natural environment; whereas in the US they need to be 'significantly different' to the natural product

More on patents...

- how much does it cost?

- Costs are initially small but can get very high as time progresses
- £3,500 to file, maybe an extra £2,000 in 12 months, then another £1,000 in 1 ½ years....Perhaps budget £10,000 for the first 2 ½ years
- Costs leap at the 2½ year deadline, which is when you decide which countries to cover, and vary depending on the countries chosen (NB for most non-English speaking countries, there will also be patent translation costs)
- Aim to have a definite commercial plan by then
- You cannot put an application on hold

Freedom to operate ('FTO')

- FTO is the ability to sell a product, or carry out a process commercially, without infringing IP rights
- IP rights include patents, designs, etc., anywhere you might sell the product
- It is difficult to be 100% sure – full FTO searches take many man hours and so cost about £30,000 to £100,000
- Initial FTO checks you can carry out include searching the patent registers worldwide (e.g. using Espacenet.com)
- If you find a patent, but are not sure whether you would infringe it or not, you may decide to consult a patent attorney
- Prior art you are aware of should be notified to the patent office, when you file a patent

Why is it important to have IP in your idea?

- IP gives you exclusivity on the market: it forms a barrier to entry
- Companies aren't likely to invest in ideas which can easily be copied; they tend to look for at least three years' exclusivity on the market
- A patent, for example, gives you up to 20 years' exclusivity on the market in the country it is granted in
- Some patents are easy to work around, but a good patent covers all embodiments of your invention, and improvements to it, or 'second generation' products
- Consider various types of IP: trade secrets, trade marks, copyright in design drawings, etc.; maybe you can rely on one of these, and getting first to market