

Patents and pharmaceuticals

In the first of two articles on intellectual property, **Rachel Graham** introduces the topic and sets out the general rules relating to patents

Pharmaceutical companies generally try to protect their technological innovations. They also try to build up brands. It might also be important to them to prevent others from copying pieces of software (or other “literature”) they have created and databases they have put together, or to receive royalties (ie, licence fees) from others to carry out certain scientific processes or to make some of their drugs. In doing any of these, companies will be using their intellectual property rights (IPRs). IPRs include patents, trade marks, domain names, copyright, databases and designs. Of these, patents are, arguably, the most important.

Patents

Patents protect inventions. For pharmaceuticals, the invention is often a new molecule or family of molecules for the treatment (or prevention) of a particular disease (protected by what is known as a “product” or “substance patent”), or a method of producing a drug (protected by what is known as a “process” or “methods” patent).

A patent gives the owner a monopoly over the invention, usually for 20 years. During this period, no one can reproduce it, regardless of whether they copy the methods of the patent owner or come up with the invention independently. The trade-off is that the patent document itself (known as a “specification”) becomes a publicly available document. Hence, while the patent is in force, others are able to read about the invention and understand how it works, and have the information to exploit it as soon as the patent expires.

Whether to apply for a patent or to try to keep an invention secret so that others can potentially never exploit it is a commercial decision. For the pharmaceutical industry, where a product is generally expensive to research and develop but relatively inexpensive to manufacture and where its constituents can be fairly easily analysed so that it is difficult to keep their composition a secret, patent protection generally makes sense. However, fees will need to be paid to patent offices for the life of the patent.

If, as can be the case in other industries, development costs are low and reproduction costs high, or if a product is of such a nature that it can be put on the market without enabling people to reverse engineer or otherwise analyse it, then patents may not be the best form of protection.

Requirements for patentability

In order to be patentable, an invention must meet certain requirements. The invention must be new, involve an inventive step, be capable of industrial application and must not expressly be excluded from patentability.

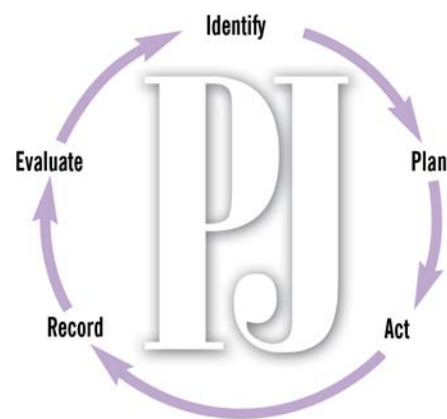
New Newness or “novelty” is relatively easy to assess. An invention is new if it does not form part of the “state of the art”. The state of the art includes, for example, products, processes and information about them (such as research papers) known or published anywhere in the world, in any language, before the “priority date” of the patent (usually the date it was filed). The information available must contain enough detail for a person “skilled in the art” (someone with a knowledge of the particular area in question) to carry it out — it is not good enough to hint at the invention.

Importantly, the state of the art includes the inventor’s own publications, products and processes that are available to the public. This includes research about an invention presented at a conference before a patent is filed. There is no equivalent in European or UK patent law to the provision in US law that allows inventors to speak or present research papers at conferences and events up to a year before a patent is applied for without jeopardising the grant of a patent.

Inventive step Whether or not an invention involves an inventive step (ie, is not “obvious”) can be more difficult to decide. Essentially, an invention is obvious if a person skilled in the art would have considered the step between the state of the art and the invention an obvious one to make. Hence parts of the state of the art that merely hint at an invention may well result in the invention being considered obvious. Obviousness is determined on a case-by-case basis. Some rules, however, have been established in the courts. For example, an invention can still be considered obvious, if a person skilled in the art would have thought it an option worth trying, even if they would have tried other options first.

Industrial application Methods of treating the human or animal body by surgery or therapy or methods of diagnosis are expressly not capable of industrial application. This preclusion from patentability is, however, interpreted narrowly and diagnostic procedures that do not take place in or on the body can be allowed (ie, *in vitro* tests on tissue removed from the body during a diagnostic procedure can be patented). Similarly, substances used in methods of treatment or diagnosis can be patented.

Not excluded from patentability Some things are expressly not patentable. For example, discoveries cannot be patented, but a product based on a discovery can be. Many pharmaceutical patents rely on this distinction. For example, the discovery that substance X



Identify knowledge gaps

1. What is required for a patent to be granted?
2. How long does a patent last?
3. What is a supplementary protection certificate?

Before reading on, think about how this article may help you to do your job better. The Royal Pharmaceutical Society’s areas of competence for pharmacists are listed in “Plan and record”, (available at: www.rpsgb.org/education). This article relates to “legal considerations” (see appendix 4 of “Plan and record”). Competencies for pharmacists in industry or academia are to be published by the end of the year.

(which either occurs naturally or is otherwise already available) can be used to treat disease A is not in itself patentable, but a medicine made from substance X to treat disease A can be. These are known as “Swiss claim” or “second medical use” patents.

Some things are excluded from patentability on public morality grounds. An example of an invention likely to be excluded on these grounds would be a drug designed to enable motorists to give a negative breathalyser reading despite being over the limit.

The public morality ground was widely (but usually unsuccessfully) cited in the past by those seeking to prevent the patenting of biotechnological inventions. In this context, it has largely been superseded by specific rules (set out below).

Biotechnological inventions Processes for cloning human beings and modifying the genetic identity of human beings cannot be patented. Processes for genetically modifying animals, for example, to be susceptible to

Rachel Graham, DPhil, MRPharmS, is staff editor on *Hospital Pharmacist* and previously worked as an intellectual property lawyer

cancer, or the modified animals themselves (eg, the Harvard mouse — a transgenic mouse that is predisposed to developing cancer at an accelerated rate), can be patented, depending on the balance between the suffering of the animal and the benefit its use in research is likely to bring to human or animal health. The sequence of a gene or part of a gene can no longer in itself be patented, but if the function of the gene in the body is known so that there is a likely practical application of the gene sequence, then a patent can result. Some of these rules are different in the US.

Obtaining patents

Patents are territorial — having a UK patent will not prevent other people or companies from exploiting an invention, for example, in the US. That said, it is not necessary to apply individually to the patent office of each individual country where protection is required. Various treaties (eg, the Patent Co-operation Treaty) mean that applications can be passed from one patent office to another (eg, the US to the UK, or vice versa), after a preliminary examination of the application has been carried out.

For protection in Europe, the European Patent Office system (based in Munich, Germany) can be used. It is important to note, however, that this system just centralises the application procedure so that a bunch of national patents (ie, a European patent UK ["EP UK"], an "EP Germany" and an "EP France" patent) is granted.

Once granted, EP patents come under the control of the courts in the relevant country. Long-term plans to bring about a community patent system (where only one patent covering the whole of the EU is granted and a community patent court deals with all cases about the patent) are in jeopardy because of disagreements over the status of translations into the various European languages.

Period of protection As mentioned, most patents are granted for a period of 20 years (from the date of filing). The fact that it is necessary to keep an invention secret until a patent is applied for means that unless confidentiality can be guaranteed, the time taken to carry out the experiments and clinical trials necessary to obtain regulatory approval for pharmaceuticals effectively eats into the 20 years' monopoly conferred by a patent. To compensate for this, a supplementary protection certificate (SPC) can be obtained. These apply only to a marketed product and not the whole invention disclosed in a patent.

The term of an SPC depends on the period of delay between the date of the patent grant and the date marketing authorisation is received — a delay of six years gives a right to a year's supplementary protection with each additional year's delay giving a further year's supplementary protection up to a maximum of five years.

Content of patents A patent "specification" contains a general description of the invention followed by "claims". The claims essentially dictate the level of protection conferred. Each claim sets out a specific aspect of the invention. How claims are to be interpreted (and, therefore, should be written) has been the subject of much debate, both in the UK and on a European and worldwide scale (see below).

Patents must also disclose an invention sufficiently, such that it can be made by a person skilled in the art. If, for example, constituents need to be added in a particular order to make a product, then this needs to be disclosed in the specification.

Infringement

A patent is infringed if someone makes a patented product or uses a patented process without the permission of the patent owner. If, for example, the other person's (or organisation's) product is exactly the same as that set out in the patent, then infringement can be relatively easy to establish. More likely, however, is that the potentially infringing product will be a variant of what is specifically claimed in the patent. For example, in the context of a drug, the product may well be a derivative of that drug. The question, therefore, becomes: is the potentially infringing variant covered by the patent?

The basic idea is that claims should be interpreted to give enough certainty to other organisations or people working in the area of the invention, as to what they can and cannot do, but should offer fair protection to the owner of the patent, such that those who make insignificant modifications to what is specifically mentioned in the claims are caught by the patent. Courts in the UK and US have traditionally erred on the side of interpreting claims in a strict manner that secures certainty for others although those in, for example, Germany, have tended to adopt a more liberal approach. The international nature of patent law, not to mention the moves towards developing a community patent system, means that greater consensus in claim interpretation is necessary. This is beginning to be found.

Whatever approach to interpretation wins out, it is important to note that patent owners are prevented from having their cake and eating it. If they argue in a court case that their claims should be interpreted liberally (such that a competitor's variant infringes the patent) then the same liberal interpretation applies to assessing the validity (eg, the obviousness and sufficiency) of their patent. A wide interpretation of claims generally gives more scope for an invention to be considered obvious (more material will make up the state of the art) or insufficient (the methods of making the invention disclosed in the patent are less likely to cover all the variants claimed).

Under some circumstances, the law also contains an "experimental use" defence to infringement. This means that third parties

Action: practice points

Reading is only one way to undertake CPD and the Society will expect to see various approaches in a pharmacist's CPD portfolio.

1. Read a selection of reports on the cases and judgments with respect to the patent for Viagra. For example:
 - "Pfizer loses Viagra patent" (<http://news.bbc.co.uk/1/hi/business/1013244.stm>)
 - "Viagra challengers arise" (www.ims-global.com/insight/news_story/0108/news_story_010821.htm)
 - "China challenging drug patents" (www.biomedcentral.com/news/20040820/02)
2. Think about how recent patent expiries have affected your practice.
3. If you work for a pharmaceutical company, find out more about patents by talking to someone in your legal department.

Evaluate

For your work to be presented as CPD, you need to evaluate your reading and any other activities. Answer the following questions: What have you learnt? How has it added value to your practice? (Have you applied this learning or had any feedback?) What will you do now and how will this be achieved?

can produce a patented drug in order to carry out experiments on it. The exception is construed narrowly, however. Research genuinely carried out to discover more information about side effects can potentially be allowed. Research carried out to satisfy regulatory authorities so that a rival product can be launched is unlikely to be.

A patent cannot be infringed if it is invalid (ie, it should not have been granted in the first place). It is, therefore, common for those who are sued for infringement (or those wishing also to produce a patented drug) to look for documents to show that the invention was obvious (and not new) and that the patent should be revoked.

Although patent offices generally carry out literature searches and invite third parties to oppose applications before (or soon after) patents are granted, commercial reality often dictates that more attention is paid to a patent once a successful product based on it is launched.

Conclusion

There are various requirements that need to be met before an invention can be patented. Providing these can be fulfilled, patents are generally a good means of protecting pharmaceutical inventions and are, therefore, sought after. They confer a monopoly on their owners, but require that the invention be disclosed, such that it can be used once the period of protection has ended.

Information about trade marks, domain names, databases and copyright will be covered in the next article.