Protecting intellectual property in pharmacy

Richard Hough, a practitioner in pharmacy law, advises on securing the products of hard work and invention

An entrepreneurial outlook and innovative thinking are not uncommon traits amongst pharmacists. I represent a number of pharmacist clients whose innovative thinking has enabled them to explore new business opportunities. One, in particular, was frustrated by what he experienced as the limitations of the medicines compliance aids on the market. Not one to let frustration get the better of him, he sought to improve upon them through innovation, dedication and investment. Having thought through his innovative concept, he concluded that there was a market for it that could give him a return on his investment. So, he designed a new product, built a prototype and investigated the routes to market.

But all this hard work would have been for nothing if the appropriate intellectual property (IP) protections in the innovation had not been sought, the absence of which would have allowed a competitor to claim my client's innovation as its own. In order to maximise the potential for commercial exploitation it is vital that the IP in the innovation is protected to the fullest extent possible. IP rights either protect innovation or build up brands.

Patent protection

A patent, which protects innovation, may be granted for either a product or a process. If a patent is granted, the inventor obtains a monopoly over the use of his invention for (generally) 20 years (ie, he can stop anybody else using it within this period). The trade-off is that the patent document becomes publicly available. Hence, while a patent is in force, others may read about the invention, how it works and have the information to exploit it upon expiry of the patent.

In order to be patentable, an invention must meet four basic requirements. It must be new, involve an inventive step, be capable of industrial application and not fall into one of the exclusions.

A patent is infringed if someone makes a patented product or uses a patented process without the permission of the patent owner. 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 product) to look for documents to show that the invention was obvious (and not new) and that the patent should be revoked on grounds of invalidity. The scope of the claims (and how to interpret them) may also be the subject of litigation.

Patents are generally a good means of protecting inventions and once granted they confer a very strong monopoly right.

Brand protection

It is advisable to give careful consideration to the brand of the product that will eventually be marketed. The most cost-effective way to protect a brand name is by seeking registration of a trade mark.

Trade marks are signs which indicate the commercial origin of goods or services. Consumers should be aware that goods sold under a trade mark come from the same company as other goods sold under that brand. Trade marks, which may be registered® or unregistered™, are therefore used to build reputations.

> **"It is advisable for innovators to identify, protect and exploit all their intellectual property and to have a coherent IP strategy"**

It is preferable to be the proprietor of a registered trade mark rather than an unregistered one. Ownership of a registered trade mark is more easily proved and litigation is generally quicker and cheaper than for those involving an unregistered trade mark.

A trade mark gives the proprietor an exclusive monopoly right to use the mark in relation to the specific goods and services for which it has been registered within a particular territory. If used and renewed, a trade mark can potentially last indefinitely upon payment of a 10-yearly renewal fee and is a cost-effective form of protection.

Only signs that are capable of being represented graphically and which are capable of distinguishing the goods or services of one entity from those of another may be registered. The trade mark, which is often made up of a word or logo, must have a distinctive character, not be descriptive nor merely indicate the intended purpose of the goods. In other words, a mark such as "cough medicine" could not be registered as a trade mark, whereas everyday words unusually combined could support registration, eg, "Baby Dry" nappies. Less common trade marks include those for colours, sounds, smells, 3D shapes and slogans.

Passing off

Where it is not possible to register a trade mark, owners of unregistered marks can seek redress against infringers through the common law action of passing off, though this can be difficult to prove. The brand owner must establish that its product has established goodwill in the course of trade, the infringer has made a misrepresentation in relation to the product and that this has caused damage to the brand owner. Unregistered trade marks arise automatically through use over time and can exist indefinitely as long as goodwill exists in the mark.

Registered design

Another IP right worth considering is registered design. This is concerned with the appearance of the whole or part of a product and protects new designs that have individual character (eg, lines, contours, colours, shape, texture, materials or ornamentation). It is a monopoly right that is protected by registration for up to a maximum of 25 years (renewable every five years) and is also used to protect the appearance of the packaging of a product.

In order for the design to be protected, it must be new at the date of application. The novelty of the design is judged against prior art available anywhere in the world that could reasonably have been ascertained in the relevant trade sector.

It is relatively straightforward to seek protection, both in the UK and in the European Community, for a registered design.

The examination procedure is not stringent, which makes designs easier to register than patents. It is also a relatively inexpensive process. However, registered designs may be vulnerable to claims of invalidity.

Copyright and other rights

Other forms of IP rights not considered in detail in this article are copyright, unregistered design rights and database rights. However, these can offer some protection and can arise automatically without the requirement for registration (although in other territories such as the USA, registration may be required for adequate copyright protection).

Often overlooked, the law of confidentiality protects trade secrets or know-how. All employees of a business involved in innovation should be signed up to strict contractual confidentiality provisions (dependant on their role within the business) and all dealings with third parties should be subject to confidentiality undertakings. This should help to avoid any prior publication of any innovation, which could be fatal to any patent application for instance.

To be protected by the law of confidence, information must be confidential in nature, must not be publicly known and must be disclosed in circumstances importing an obligation of confidence. Confidential information can continue to be protected for as long as the information remains confidential. This could significantly outlive the length of a patent. Therefore, know-how and trade secrets which are not disclosed within any patent or promotional material, but which are essential to the success of any particular product, are of intrinsic value to a business.

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Confidential information should therefore be identified and marked as confidential and anyone becoming party to such information should do so only under suitable undertakings (eg, non-disclosure agreements). While common law confidentiality rights exist in the UK, it is preferable to rely upon contractual obligations, as these are much easier to identify and enforce.

It is advisable for innovators like my client to identify, protect and exploit all their IP and to have a coherent IP strategy. This can be achieved by reliance upon several layers of IP protection, including registered, unregistered and contractual rights. IP strategies should be constantly reviewed and expert legal advice should be sought for their implementation.

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Corrections

In the January issue of the *Independent Community Pharmacist*, in the Pharmacy Product of the Year cough and cold/flu category, Almus Codeine Linctus was listed incorrectly as a "GSL category" product. It is a Pharmacy Only product. Also Alvita TENS in the pain relief category was wrongly labelled Alvita Tenscare. The errors are regretted.