

Energising medical devices

How to use your IP to get ahead of the game

By Rebecca Baines and Christopher Leung

Product design and innovation are more important than ever for medical device companies. To stand out from the crowd, successful companies are focusing on patients' needs to develop new and improved products delivering faster, cheaper and more efficient care. They are also using their IP, strategically, to maximise the rewards flowing from these innovations.

What can IP do for me?

The key to successful IP planning is working out which of the various IP rights outlined in the chart overleaf will be of most assistance in achieving your commercial goals. Each IP right has a different purpose.

Medical device companies typically use such rights to do one or more of the following:

1. Secure early stage investment
2. Achieve freedom to operate (eg through cross-licensing IP with a competitor whose rights they would otherwise infringe)
3. Force a competitor to exit the market or design around key patents or designs
4. Obtain royalties through IP licensing
5. Prevent copycat products and/or misuse of brand names and trade secrets.

Set a budget and involve key decision makers

Start planning your IP at the concept stage. Speak to key decision makers in your business to explain how IP can be used to maximise product revenues and agree an initial budget for IP protection. You will need to keep this under review as you develop your device.

Speak to an adviser

Speak to a specialist IP adviser to maximise your chances of forging a successful IP strategy. Most advisers will provide an initial consultation without charge. Critically, you could lose your ability to obtain certain



forms of IP (such as patents and designs) if you disclose your ideas before applying for protection. If you need outside expertise to take your idea beyond the concept stage, or early feedback from potential users in order to tailor your device to specific customer needs, ask those third parties to sign confidentiality agreements before discussing your proposed device. Any employees should be similarly bound by appropriate clauses in their employment contracts. You should also agree in writing with collaborators, particularly contractors, who will own the IP resulting from your joint efforts and on what terms.

Take a portfolio approach

Investing in a range of IP rights will provide more robust protection for your device and can bring licensing opportunities. Which aspects of your device give the greatest value to users and/or are most likely to be imitated? Invest in protecting those areas. Infringement claims against medical devices are often based on a combination of IP rights. Consider a patented mechanism in an inhaler whose shape is also protected by design rights. In the event of a dispute, a claim based on multiple rights will bring greater pressure to bear on your opponent increasing your chances of a favourable outcome.

Has it been done before?

Before rushing to patent your device, ask your adviser to assess whether it is new and inventive over existing devices. If it is, it may well be patentable. Patents are powerful rights, offering up to 20 years' market exclusivity in return for publishing full details of the way in which your invention works. However, they can also be difficult to obtain and expensive to apply for and renew.

If your product will have a short shelf life and is difficult to reverse engineer you could save money by relying on trade secrets instead. These unregistered rights are protectable for as long as the product's workings are kept secret.

If your product's value lies mainly in its appearance, design protection may be preferable, coupled with a strong marketing campaign and registered trade mark protection.

Does your product infringe existing IP rights?

Your adviser should carry out patent, trade mark and design searches to determine whether anyone else has already worked or patented your invention or acquired rights in the proposed name or appearance of your device. Any pre-existing rights which read onto your device could block your path to

market. Take advice on how to overcome any obstacles; can you design around a patent or design, rethink your branding to avoid a conflicting trademark, license-in the relevant IP or apply to revoke or oppose the right? Repeat freedom to operate searches before launching your device; much can change in the time it takes to transform your idea into a marketable device.

Consider a clean room design

If you plan to improve an existing device and/or you intend to launch a device into a crowded market, you will want to avoid claims that you have copied your competitors' products. To reduce the risk of a successful IP claim against you, and strengthen your negotiating position in any dispute, consider implementing a 'clean room' design process. Create an independent technical specification for your device and ask your design team to implement it without reference to any existing devices. Provided the process is well documented, this could afford you a defence to any claims of copyright or unregistered design right infringement, which require proof of copying.

Keep records

Keep dated records showing who created the technical specifications and design drawings for your device at each stage of the design process. If a competitor claims you have copied their device, this may well strengthen your negotiating position and in the event of litigation could act as crucial evidence that you created your device independently.

Review periodically

Regularly review your IP portfolio to ensure it keeps in step with your current and future business plans. If you improve your device during the testing phase, you may be able to seek additional patent protection for these improvements. Many medical device companies practise patent portfolio optimisation or 'pruning' to make the most of their patent portfolios while reducing unnecessary costs. If you decide not to pursue, or to discontinue sales of, a particular device, consider licensing associated patents to others as an additional income stream or allow them to lapse to save on renewal fees.

IP rights at a glance

| IP right | What does it protect? | For how long? |
|-----------------------------|---|--|
| Unregistrable rights | | |
| Trade secrets | Confidential information disclosed to a person who knows or ought reasonably to know it should be kept secret. eg: a secret chemical formula and process for adding insecticide to fabrics to produce mosquito nets. | Until the information enters the public domain |
| Copyright | Original (ie non-copied) creative works. Infringement claims require proof of copying. eg: <ul style="list-style-type: none"> • Instruction manuals, website text and images • Graphics on user interface of MRI scanner • Surface decoration e.g. animal drawings on children's plasters. | Typically life of the creator plus 70 years |
| Unregistered designs | UK: shape of the whole or part of device. EU: similar to registered designs (see below). Infringement claims require proof of copying. eg: shape of a foldaway bath chair or thermometer. | UK: 10-15 years EU: 3 years |
| Registrable rights | | |
| Patents | New and inventive technical products and processes (but not methods of treatment or diagnosis performed on humans such as surgery). eg: <ul style="list-style-type: none"> • Bandages and dressings incorporating medicaments • Electronic control system for prosthetic hand • Mechanism in an insulin auto-injector pen to administer varying doses of a drug. | Up to 20 years |
| Registered designs | Device appearance such as shape and decoration (but not if prescribed by technical features). e.g.: comfortable grip used on a toothbrush, textured pattern on hospital bath mats. | Up to 25 years |
| Trademarks | Branding including names, logos and jingles. | Renewable every 10 years |

Be prepared to enforce

IP rights can lose value if they are not enforced when infringed. Poor enforcement can lead to infringing goods entering the market which may decrease your market share. It can also send a message to competitors that they will not face any consequences if they infringe your IP.

A range of enforcement tools (varying in cost and complexity) are available to IP owners to help them achieve their commercial goals. Low-cost enforcement options include online detection and takedown programmes (to block online sales of infringing goods) and customs monitoring applications (resulting in the detention of infringing goods at national borders by customs authorities).

IP litigation is sometimes unavoidable.

Starting court proceedings will often provoke a settlement offer and the majority of IP claims settle long before trial. Litigation is similar to any commercial project: at an early stage, you will need to engage key decision makers in your business, identify your objectives and set a budget for achieving them. In consultation with your IP advisers, give your business clear expectations as to the timetable, costs and exit strategy for the case and keep these under review. Speak to your adviser about the best ways of controlling the cost and speed of court proceedings. Ⓞ

Rebecca Baines is a partner, Intellectual Property and Christopher Leung is a solicitor, Intellectual Property at FieldFisher