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Medtech Tips: Expert Pointers For Protecting IP In The Medtech Space

by

In this edition of Medtech Tips, Ilya Kazi, a partner at intellectual property firm Mathys & Squire LLP, provides top tips on what medtech businesses should do in order to help protect their IP and avoid risks to their inventions.

For small companies in the medtech space, the most usual exit is to be acquired by a larger corporation. Having seen this process from both sides, through advising a vast number of startups and multi-nationals, I cannot overemphasize how important spending a small amount of time in order to look ahead and get the intellectual property (IP) strategy right at the outset can make a big difference both to the likelihood of a successful acquisition and the sale price.

Following are some top tips on what medtech businesses should do in order to help protect their IP and avoid risks to their inventions.

Think about IP from the outset and start protecting it early on.

If you are successful with your product, potential larger acquirers will want to know:

- (a) is it protected, or can it be copied; and
- (b) is it free to use or does it infringe someone?

You cannot patent an invention once it has been disclosed publicly, whether in a press release or to potential investors unless those investors are under a non-disclosure agreement (NDA). You should be aware even of teasers which may not go into full detail but make it public enough to render a later patent application obvious. Therefore, it is important that you apply for patent protection prior to disclosing the technical details of your technology. Be wary of including too much speculative information early on as you may reduce the chances of protecting future advances, which could be considered obvious if you hint towards them in earlier applications.

Check that you can show you own the IP.

This is particularly important when you have research and development collaborations or where tech comes from university research/work with healthcare providers. The default in the UK is that the right to patents or designs is owned by the employer of the inventor(s) or designer(s), although this can be altered by agreement. Make sure it is clear from the outset who will own the IP from any collaborations and ensure this is clearly reflected in the IP clauses in the agreement.

Some universities have standard procedures for transferring or licensing the IP, whilst it is harder at others. Ensure you know the terms of your contract and your options before entering into any discussions about who owns the IP and how to transfer it out, if necessary.

Know what IP your competitors have and make a plan for dealing with it.

Third-party IP rights can block you from getting your product to market, lead to potentially lengthy and uncertain litigation, costly settlements or simply make you less attractive to investors. There is a delicate balance as an almost limitless amount of money could be spent searching for and analysing third parties' IP, whereas doing nothing may result in being surprised by something that really should have been identified before and may have been a simple work-around or might have been effectively neutralised, had it been identified earlier.

Consider third-party observations or oppositions (in Europe) which are much cheaper than litigation or Inter Partes Review (in the US) to help prevent competitors getting IP that may be an issue. Gaining protection which may interfere with competitors' commercial activities, even if such IP does not directly cover your own, may improve your negotiating position and provide a disincentive for competitors to assert their own IP against you.

Tie in your IP strategy closely to your funding and business plan.

It is not essential to apply for worldwide protection for everything from day one. Work out what you need to protect early on - the key concept is anything you have to disclose publicly to obtain funding - and file a national application with little or no official fees. Defer costs by filing an International PCT application a year later, which puts off the decision on which countries you eventually want to pursue protection in for two and a half years after the initial filing. Include several concepts in one application; you are likely to get an objection that the application relates to multiple inventions but can file divisional or continuation applications later to protect separate concepts, reducing the initial cost of official fees and prosecution.

It is normally quicker and easier to obtain protection for narrower concepts, so if there is a difficult battle and funds are tight, one strategy is to focus on getting something useful protected early on, while ensuring you have basis to protect the broader idea in a divisional or continuation later when you hopefully have more funding. Investors often want to know you have registered IP and showing a few early grants for patents that read directly onto your products can be very

helpful.

Aim to achieve good protection in key territories rather than weaker protection everywhere.

Think about the key markets for yourself and your competitors; where your competitors are based and manufacture; and where - normally as a last resort - you would litigate if needed. It would be very unusual to fight litigation in every possible market. The US, Europe - particularly Germany and the UK - and, increasingly China, are normally key territories. But this very much depends on the marketplace and your commercial strategy.

Beware that IP protection differs throughout the world. For example, there are restrictions on patenting medical methods of treatment or diagnosis in Europe. Although, the devices can be protected as can related methods, as long as they do not involve the actual treatment or diagnosis. Taking a strategic view early on may give you better outcomes.

Don't overlook registered designs and trade mark protection.

Registered designs are relatively cheap; a few hundred to a few thousand pounds, and fairly quick; a few weeks to a few months to obtain as they do not require substantive examination prior to grant. Designs cover products which are novel in appearance (i.e. design), rather than technical innovations.

If you have spent time and money getting your product to look right, whether a web/app interface or a hand-held device, then it is normally worthwhile to obtain registered design protection. If you are successful, your brand may become your biggest asset so set your brand strategy early and don't do things to weaken it.

Finally - a little good strategic advice early is generally much cheaper and more valuable than scrabbling to resolve problems after they have become serious enough to get your attention.

About the author

Ilya has more than a decade of experience in providing IP management and strategic advice to clients ranging from large multinational corporations to lone inventors. Named in the IAM Strategy 300 as one of the world's leading IP Strategists, Ilya has been widely recognized for his commercial, client-focused and strategic approach. He has spent time in California working directly with some of the leading clients he now represents. Ilya's technical specialisms include medical device technologies, information technology, communications systems and electronics, as well as subject matter of a more mechanical nature. He has a Master's Degree in Natural Sciences from Cambridge University, where



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