IP in the digital age: a tricky path ahead for pharma companies?

"The pharmaceutical industry needs to adjust its expectations of the scope of IP protection available in the digital age"

The pharmaceutical industry is becoming increasingly interested in digital health and serious money is being invested in the technology. Pharmaceutical companies are used to an established commercial formula for bringing new products to market, with product development involving a significant up-front investment including research and development costs and generating the requisite quality, safety and efficacy data.

Recovering these costs and generating a profit depends on how successfully the company can navigate the marketing authorisation (MA) process, data exclusivity and intellectual property.

In the pharma model, regulatory data exclusivity gives some protection for the expensively-generated data required to obtain MA, barring generics from relying on the data.

Patent protection provides monopoly exclusivity for inventions including new active ingredients and new medical uses. When digital health products are concerned, how much of this is true?

The term ‘digital health technology’ covers a wide range of products with different functionalities and objectives.

Two examples are used to highlight some of the issues a digital health product developer would face when bringing a product to market.

Product A is a cloud-based system linked to an app on a smartphone that monitors a patient’s chronic condition and uses that data to help the patient make the best use of his or her medicine.

Product A also provides key data to the patient’s doctor so that the patient can control his or her condition better with fewer unscheduled hospital visits.

Product B is an app that teaches the user techniques such as cognitive behaviour therapy to improve mental health or improve sleep patterns.

Protecting your invention

Patent protection is important if the core functionality of a digital health product or service is to be protected.

But obtaining patent protection can be difficult, as the technological areas to which digital health relates are excluded from patentability in many countries.

Contacts

Stephen Bennett
Partner, London
stephen.bennett@hoganlovells.com

Elisabethann Wright
Partner, Brussels
ea.wright@hoganlovells.com

Mark Marfe
Senior Associate, London
mark.marfe@hoganlovells.com

hoganlovells.com
limegreenip.com
limegreenipnews.com
In Europe there are exclusions for computer programs, presentations of information and therapeutic or diagnostic methods, while in the US, recent Supreme Court decisions have created even broader exclusions, the scope of which is still being mapped out.

Patents can be obtained in the field of digital health, depending very much on the type of product or service.

For novel devices and remote monitoring systems, such as product A, the exclusions from patentability may not apply. Apps, such as Product B, may present more of a problem but this depends on their functionality.

The app may make use of sensors in a mobile or wearable device, such as a camera or heart rate monitor, and process the sensor data in a novel way, so that the app is more than just a computer program that presents information. The processing of the sensor data may not amount to a method of diagnosis, so this exclusion can be avoided as well.

Even if a digital health invention seems at first sight to fall entirely within an excluded area, it is sometimes possible to avoid objections with careful drafting to emphasise the technical aspects of the invention.

Examiners are human, and can be swayed by the overall ‘feel’ of the patent application. Choice of patent office is also important: national patent offices in Europe may be more lenient on excluded subject matter than the European Patent Office.

Of course, the invention must also be novel and inventive for a patent to be granted and this can be a challenge in many areas of digital health, which are already crowded with proposals.

It is worthwhile carrying out patentability searches before filing patent applications; even a quick web search can bring up similar ideas. The results may suggest that a patent would not be worthwhile, but may result in a patent application that is more focused on the novel aspects, and more likely to succeed.

Computer programs and the preparatory design material for a computer program are protected by copyright. Artistic copyright may subsist in logos or other visible elements that appear when the computer program is running.

It is also possible to file a trademark application for the name of the product as well as for any logos or images used.

The bottom line for copyright and trademarks is that others can compete provided they don’t copy your code and they keep a sufficient distance from your trademark. Where being first to market is important, that may be enough—the need to write new code buys time and the trademark helps to distinguish your product.

**Being exclusive**

A new, active medicinal product substance will enjoy eight years of data exclusivity and ten years of market exclusivity in the EU; eight years of data exclusivity during which generics (or biosimilar applicants) may not file an application for authorisation that refers to the data in the originator’s MA dossier, plus two years
of market exclusivity during which generics authorised on the basis of the originator’s dossier may not be placed on the market in the European Economic Area.

“Even if a digital health invention seems at first sight to fall entirely within an excluded area, it is sometimes possible to avoid objections with careful drafting.”

Apps for medical applications can be regulated as medical devices if they fulfil the cumulative criteria laid down in the European Commission MEDDEV 2.1/6 Qualification and Classification of standalone software.

There is no authorisation procedure for medical devices, which must be CE marked by their legal manufacturers before being placed on the EU market or put into service.

The regulatory requirements applicable to a medical device in the EU are quite different from the requirements applicable to a medicinal product for which an MA is required.

Medical device legislation provides no form of data exclusivity for the data generated by the legal manufacturer to support the safety and performance of its medical device. The result is that the first to market with a medical app regulated as a medical device has little to rely on in the way of barriers to entry for competitors, at least from a regulatory perspective.

**Adding value**

If the product is an app then an obvious way to add value is to have the end-user pay for the app through an applications store offered by the user’s mobile device.

There are issues with that model including persuading end-users to pay for healthcare items when they are used to having these reimbursed (through national health systems or health insurers).

An alternative is to have the product paid for by a reimbursement system. The organisations that administer the various reimbursement systems are used to paying for medicinal products that have been through a series of clinical trials to establish quality, safety and efficacy.

Pursuing reimbursement in this way from the National Health Service or other reimbursement body brings with it the likelihood that it will want to see clinical data showing the product is safe and effective.

That increases the up-front cost to the digital health developer which, in turn, underlines the need for some sort of IP protection or regulatory exclusivity to help in recouping that investment. Given the limits on regulatory exclusivity, the burden currently falls on IP.

**Difficult times ahead?**

The focus so far has been on the digital health provider establishing its own exclusivities. But digital health also brings with it a range of IP issues that typically don’t bother pharma.
The first is wireless technology (necessary in remote monitoring devices) which is, on the whole, standardised technology. Bluetooth, used for short range radio communication, is a prime example of a standardised technology.

But just because the technology is standardised, that doesn’t mean it comes free. The sheer number of patents that need to be licensed to use some wireless technologies may surprise pharma companies used to a manageable number of patents that can be individually assessed in freedom-to-operate exercises.

The good news is that buying wireless hardware from suppliers who have the right licences can deal with that headache, but you need to make sure your supplier is licensed.

The bad news is the other problem that applies particularly in the tech sector: non practising entities (NPEs).

The story so far with NPEs, in the tech sector predominantly, has been that their preferred target is well-funded new entrants to the market and, preferably, the seller of the end product.

Where standardised technologies are involved, and frequently they are, the interface with competition law means there is a right and a wrong way to deal with a demand from a party owning patents essential to that technology. Established tech sector manufacturers know this but it will probably be news to those launching their first connected products.

IP protection and regulatory exclusivity represent unique challenges for digital health in establishing market exclusivity.

It's clear that there is scope for IP protection including patents, but that the expectations of the scope of protection available may need to be adjusted for those coming from other healthcare sectors.

First published here in Life Sciences intellectual Property Review (LSIPR), 13 September 2016