

Patenting research outputs – medical and pharmaceutical inventions

Before making the leap into patent law as part of WP Thompson's chemical and life sciences team, Dr Ian Wilson worked and studied in academia for over a decade. In our continuing series highlighting the key considerations for researchers thinking about patenting an invention, Ian investigates patentability in the medical and pharmaceutical fields.

A Matter of Morality

Last time, we looked briefly at the types of subject-matter that are excluded from patentability. Among them were methods of diagnosis, surgery and treatment relating to humans or animals. Importantly, however, this does not include equipment and substances for use in those methods. The reason for this difference is considered a matter of morality. To illustrate, if a hospital lacked certain necessary equipment, this would be unfortunate but, under the relevant policy considerations, would not be viewed as immoral as hospitals may have access to different facilities. Conversely, if a doctor working at a hospital could not treat a patient simply because they were not permitted to employ a necessary method, this would be viewed as immoral. Yet methods not involving diagnosis, surgery or therapy may still be patentable if a monopoly on their use would not prevent patient access to medical treatment. Notwithstanding this caveat, medical equipment and substances are the more commonly patented and are our focus here.

First and Further Medical Uses

As we have seen previously, a product must be capable of industrial application to be patentable. Any patent application for a medical device, substance or composition must disclose how it is to be used but do so carefully so as to differentiate between the use of the product in a treatment and the method of treatment to which it may be applied. Often, medical compositions and substances have more than one beneficial effect and therefore more than one industrially applicable medical use. Thus, a previously-unknown new use of a known substance may be patentable (a so called second medical use). Indeed, there is no limit to the number of new medical uses of a single substance for which one could theoretically acquire patent protection.

Alternative Medical Uses

Often, innovation comes in the form of different applications of a product to a single known use. For example, a novel dosage regime of a drug, or use of a drug in a specific patient group, may yield unexpected

benefits in the treatment of the disease for which its use is already known. Alternatively, a new and beneficial method of administration might be invented. Sometimes, a unique combination of previously known drugs might lead to unexpected beneficial therapeutic effects. Evidently, despite the unpatentability of medical methods, considerable protection is still available within the medical and pharmaceutical industries.

Supplementary Protection Certificates

Acquiring market authorisation to sell a medical substance or composition can be a lengthy process, and with good reason. Following the thalidomide scandal in the 1950s and 1960s, substances and compositions for use in humans and animals must undergo rigorous safety checks before being granted market authorisation. This can take many years, eating into the period of patent protection available and so too the considerable financial reward it may represent. Supplementary Protection Certificates (SPCs) exist to compensate patent owners affected by this process. They can extend the period of protection available for a particular product by up to 5 years. In addition, if investigations are conducted for potential paediatric uses according to an agreed Paediatric Investigation Plan, then an additional six months of protection may be available, bringing the SPC protection to a maximum of 5 and a half years. This system rewards a safety orientated approach by ensuring proprietors of such patents are not disadvantaged compared with owners of non-medical inventions.

Understand your invention

As we saw last time, knowing the inventive concept of your invention can help you avoid excluded matter objections from the Patent Office. This is particularly important in the lucrative but treacherous waters of medical and pharmaceutical inventions. Understanding precisely what extent of protection you seek will help direct your research, aid in drafting a patent application, and potentially direct your filing strategy, which we will discuss in more detail next time.

To find out more, including how IP could benefit your work, please visit <https://www.wpt.co.uk> or contact Stuart Forrest at sfo@wpt.co.uk

