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Research scientists are increasingly being forced to seek and secure funding from alternative sources to the research grants upon which reliance has traditionally been placed. Commercialisation of the fruits of research is the most obvious avenue of alternative funding available. In the area of medical research, where commercialisation involves enormous risk to investors and long lead times before products make it to market, it is particularly important for researchers to protect their intellectual property and to thereby be in a position to offer investors a period of market exclusivity. Patents offer the most effective means of securing this desired market exclusivity.

While there are numerous international conventions in place which outline basic requirements of national patent laws, patents are granted and administered by national governments and therefore separate applications must be made in each country or region of commercial interest. The basic principle behind these various patent systems is, however, consistent throughout the world. This basic principle is that in return for full disclosure of an invention by an inventor, the national government will grant to the inventor in the form of a patent a period of market exclusivity. This term is 20 years in most countries. During this period the inventor, or someone to whom the inventor’s rights are transferred, will be able to bring an action in the courts to prevent others from commercially exploiting the invention. The intention is that research and development will be encouraged, at the same time as ensuring technical details of inventions are made public and can be used as a basis for further research. In this regard, it is important to emphasise that further non-commercial research in relation to a patented invention should not constitute an infringement of the patent owner’s rights.

In the field of medical research there is a wide variety of subject matter which may be the subject of patent protection. Apart from pharmaceutical compounds and compositions it may also be possible to obtain protection in respect of methods of medical treatment, diagnostic methods, methods of preparation of compounds or compositions, medical instruments, medical research tools, such as drug targets, screening methods and related computer software, for example. In addition to falling within the scope of what is generally understood to be patentable subject matter, a number of other requirements must also be satisfied to qualify for patent protection. These include that the invention must be novel, it must be inventive, and a detailed written description of it must be provided. These requirements will be discussed in further detail below.

**Novelty**

The requirement of novelty is relatively straightforward. It simply means the invention must be different from anything that has previously been published or
patented (the prior art). This is established during examination, which involves a
detailed search of patent and technical literature.

Although there are some differences in the novelty requirements between
countries due to the divergence of national laws, it is generally the case that
disclosure or publication of an invention before lodgement of a patent
application will destroy novelty. The main exception to this rule which exists in a
few countries, such as the United States, is where a grace period is provided
during which publications by the inventor are allowed. In the United States the
grace period is the twelve months prior to the filing of a patent application in the
United States. Reliance upon this grace period is usually not recommended as it
is likely to jeopardise the prospects of obtaining patent protection in other
countries.

Inventiveness

The requirement of inventiveness is more complicated. Again it requires a
comparison between the invention and the prior art, and again there are
differences between countries in relation to the standard required. In the case of
inventiveness though, it is not sufficient for there just to be differences between
the “invention” and the prior art. Rather there must have been either some
ingenuity involved in conceiving the invention or some unexpected result
observed.

A test often adopted for inventiveness is to pose the following question: if a
person skilled in the relevant area of technology (a person equipped with all the
skills and knowledge routinely used in the field) was to attempt to solve the
same problem intended to be solved by the invention, would the skilled person
routinely and without ingenuity arrive at the invention? In other words, would the
invention be considered obvious to the skilled person? If the answer is in the
affirmative, then it is also considered to lack inventiveness.

Clearly, the test for inventiveness is a subjective test which leaves much open
for argument.

Written description

A patent application must include a written description of the invention which
provides detailed information to the extent that would enable a person skilled in
the relevant field to make and use the invention. In the case of medical research
related inventions, patent applications usually take a format somewhat similar to
a scientific publication, and indeed it is becoming more prevalent for patents to
be considered as publications for the purposes of reviewing researchers’
performance. The patent application will usually include some background to the
problem which the invention intends to solve, a disclosure of how the invention
can be made and used which includes description of possible modifications,
some examples of how the invention has successfully been implemented as well
as a set of claims. The claims are of particular importance as it is these that
define the boundaries of the invention and will be closely considered by a court if
a third party is accused of patent infringement.

If the invention relates to a peptide and/or nucleic acid sequence it will be
necessary to include sequence listing information within the patent application.
Other specific requirements apply to microorganism related inventions where it
might not be possible to adequately describe the invention in a written manner.
In this case it may be necessary to deposit a sample of the microorganism with a
recognised depository institution. In this way third parties who wish to conduct
research in relation to the invention or work the invention after patent expiry will
be able to do so by obtaining a sample of the deposited microorganism.
Overview

It is not the intention of this article to provide detailed information in relation to the many complex issues you may be confronted with in seeking patent protection in respect of commercial development arising from medical research. Rather, the article is intended to provide a brief overview of some of the opportunities associated with patent protection and the major requirements of novelty, inventiveness and filing a written application. The most important message to understand is that prospects of obtaining patent protection may be destroyed if there is disclosure of the invention before filing a patent application. You should therefore consult a patent attorney before publishing in relation to research with commercial potential.

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