

## Guide Sheet 2 – How to obtain IP Protection

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Thoroughly document your invention, with relevant dates, giving diagrams and photographs, where appropriate. State why you think the invention is new and provide some discussion of why it is “clever” and where it will be of benefit.

To be patentable, an invention must satisfy three basic criteria. It must be **novel, involve an inventive step and be capable of industrial applicability**. The patent specification (the description of the invention) must also contain an **enabling disclosure**, ie it must describe at least one way of performing the invention (in the US there is an additional burden in that the description must describe the “best mode” of performing the invention).

### Novelty

To qualify for patent protection an invention must be new. This means that it must not have been disclosed (in Europe the test is “made available to the public”) anywhere in the world, by any means (ie written oral etc) before the filing date of the patent application.

### Inventive step

In addition, to be patentable, an invention must involve an inventive step. This is usually judged against what is known in the art, in the particular field, and the test is that the invention must not be “*obvious to one of ordinary skill in the art*”. Various tests have evolved over the years as a result of cases coming before the courts in various countries and it is wise to seek some specific guidance on this issue.

### Industrial Applicability

The test in Europe is that the invention must be capable of “*being made and used in industry*”. In the US there is a specific utility requirement, ie the invention must work in the way described. In Europe certain forms of invention are regarded as excluded per se as being incapable of industrial applicability, for example methods of treatment or diagnosis practised on the human or animal body (but note that substances designed to be administered as treatments are capable of industrial applicability and are therefore entitled to patent protection).

### Enablement

Patent applications are published and thus constitute a very important source of scientific information. In return for the rights afforded by patents, the inventor is expected to provide a description of the invention and describe, by way of examples usually, how the invention is to be performed. The description can make use of “*common general knowledge*” such that basic techniques for example need not be described if they are well known and can simply be referred to. In the US, however, the inventor must provide the best mode for carrying out the invention known at the time of making the patent application.

### What are the costs?

Patents can be an expensive business. Even a relatively simple invention will cost some thousands of pounds to protect in the UK alone. If an applicant wishes to extend protection to include Europe generally, the US and Japan, the cost for filing and prosecution of a patent application will run to the order of £25k plus. Of course the grant of such patents may provide a

patentee with an important commercial advantage in very important markets (Europe, US and Japan account for some 90% of the pharmaceutical/medical market). It should also be remembered that once granted, patents attract annual renewal fees in most countries. These increase with each year, so that by the time the patent is nearing expiry, it can cost around £1000 per country to maintain a patent.

### The Patent Process

An initial application is usually filed in order to establish what is known as a “priority” date. Once filed, an applicant has one year to update/add to the application before deciding whether or not to file in other countries. These later applications can then claim the priority date for the purposes of determining what will be prior art against them. All patent applications are subjected to a search by the patent office to determine whether the invention is new and or involves an inventive step. In most countries patent applications are published at around eighteen months after the priority date, usually together with the search report. The applicant is then generally required to positively request that the patent office subject the application to substantive examination. This is generally conducted via written correspondence between the patent examiner and the agent for the applicant. Hopefully, this will result in an agreed set of claims, which the examiner can process for grant. Grant procedures can themselves be time-consuming and involve fee payments, generally of the order of some hundreds of pounds. It should also be noted that for a patent granted by the European Patent Office (EPO), it would be necessary to provide translations of the accepted claims into the other official languages, apart from the one used to prosecute the case. Thus, if prosecuting in English, it will be necessary to provide translations into French and German. If the European patent is to be validated in individual European countries, this will often require translations of the whole specification and claims. Thus, costs at grant can be of the order of £20K-£25k.

Finally, many patent jurisdictions provide an opportunity for opposition at either the pre-grant (ie post acceptance) or post grant stage. Thus, a European patent can be opposed within nine months of its grant and this process effectively allows a reopening of the whole question of whether the patent should have been granted and/or the scope of the granted claims.

### What to do next ?

If you believe that you have a patentable idea, you should discuss it in confidence with a patent attorney specialising in the particular technical field. They will be able to advise on the requirements for patentability and work with you to fully describe and claim your invention. They can also carry out searches to determine if your invention is new and/or involves an inventive step.

For impartial advice and guidance, you can meet patent agents and the Patent Office at the i2 Events ([www.medicalfutures.co.uk](http://www.medicalfutures.co.uk)).