

# Introduction to Intellectual Property Rights and their Relevance to the Pharmaceutical Industry

'Intellectual Property' is a generic term covering assets that are created from the exercise of the human mind and have no physical existence as such hence the reference to "intellect". These assets are often referred to particularly by accountants, as 'intangible' assets and although frequently do not appear on a company balance sheet, can be extremely valuable. The assets generally belong to the creator, or a third party such as an employer by virtue of a contract, and can be used in business to protect a market or to generate revenue by licensing, sale (by assignment) or even by being mortgaged.

As one might imagine, intellectual property rights are by their nature very diverse, and with the relentless march of technology and the appetite of human beings to create, the list is increasing year on year. The strongest form of rights are those which must be registered such as patents, registered designs and registered trade marks. The statutes which are in force to provide the framework for their protection set out clear standards and criteria for registration and procedures for enforcement. Unregistered rights such as copyright, design right and database rights still benefit from the existence of a statute providing for their enforcement, whilst the rights of 'passing off' and protection for valuable know-how must rely upon common law for their protection, in the latter case by breach of contract. New forms of operational or technical rights such as domain names which are not strictly intellectual property rights, have stretched the legislators, as they require their own form of regulation and do not merely 'fit' one of the existing statutes.

In many cases a combination of rights building up a complex web through which the competition find it increasing difficult to navigate, can be a powerful deterrent, even where each particular right is not necessarily as strong as might be desired. This is a perfectly valid strategy; just as one does not rely entirely on either doors, guard dogs, locks or alarms to protect ones home, but often use all means available, so should a company look to all aspects of intellectual property to protect its products and its position in the market.

The rationale behind creating these rights is to provide appropriate recompense and reward for the investment of time and resource on the part of the creator. If society wishes to benefit from the fruits of an individual's 'intellectual' labour, they should be as prepared to pay for it as they are any other commodity. The problem for the creator or owner is the 'copycat'. The risk of plagiarism depriving the owner of any exclusive reward, diminishes interest in making the investment in the first place, and nowhere is this more apparent than in the pharmaceutical industry, where the investment is huge and the returns a long way off.

Striking the appropriate balance to achieve a form of monopoly appropriate to the investment made, is perhaps one of the hardest for the legislators. With this comes the need of these forms of protection to be regularly reviewed as technology advances, and the regulatory environment and markets evolve. This was becoming a

very significant problem for the pharmaceutical industry, who until fairly recently, was seeing the term of protection under patent law being rapidly eroded by the increasingly complex and drawn-out regulatory requirements it faced in getting its products to market. The legislators rose to these complaints and most developed countries have now enacted new legislation providing for extension of patent term commensurate (to some degree) with the loss of patent life resulting from regulatory delays. This has helped to restore that vital balance and maintain the incentive for companies to continue to invest in research and development.

This chapter will look to introduce each of the intellectual property rights that impact on the pharmaceutical industry as follows:

- [Patents and Supplementary Protection Certificates](#)
- [Trade marks \(including passing off and unfair competition\)](#)
- [Domain Names](#)
- [Registered Designs and Design Right](#)
- [Copyright](#)
- [Database Rights](#)
- [Regulatory Data Exclusivity/ Orphan Drug Protection](#)
- [Know-How/ Trade Secrets](#)
- [Plant Varieties](#)

It will also provide an insight into the procedures and costs of their creation, how they can be policed, and in view of the focus of this publication, make reference to how they impact on the pharmaceutical industry.

Patents and Supplementary Protection Certificates

## **Introduction**

A patent is a document issued, usually by a government (originally by the monarch) in respect of a specifically described invention, granting to the inventor or his successor in title, the right to stop others from making, using, selling, keeping or importing the invention for a specified time. The patent is awarded in recognition of innovation and more particularly the investment required to foster technical advance and the development of new ideas. This was also a means of supporting trade and generating revenues in the form of taxes (or renewals) paid to maintain the monopoly.

Patents can only be granted covering inventions for which there is a utility, or in the words of the European legislation 'an industrial application'. In a land-mark decision in the USA (known as *Diamond v Chakrabarty*) Chief Justice Warren Burger decreed that US Congress intended statutory subject-matter for which patents could be granted to include anything under the sun 'made by man'. This comment has proven very controversial particularly in view of the success of the human genome project where the term 'made by man' has been argued by antagonists not to cover entities discovered or extracted by man which were existing in nature already. However, isolation, purification and characterisation of genes and proteins have all required investment of time and money and although this information was in existence within the human body, it was not available to mankind prior to the labours of the individuals involved. Therefore, sound counter arguments for the granting of patents

to such subject-matter can also be made. It should also be noted that many of the drugs relied upon for many years, and which are on sale today, had their origins in plant extracts; it would appear hypocritical therefore to treat modern drug technology differently when what is actually underpinning the science and therefore the intellectual property rights has not changed- at its most simple level it is merely chemistry.

At present, patent monopolies are territorial rights, enforceable through the national courts of each state to prevent competitors commercially exploiting the invention. Enforcement remains the last aspect of law to escape the grip of the European legislators. Thus, for example, a US patent would not be infringed by commercial activities carried out solely in the United Kingdom . In order to obtain patent protection in different countries throughout the world, separate patents must generally be pursued in each country. Increasingly international trade and the global economy have seen the formation of treaties and pacts designed to reduce the costs and to harmonise the laws but most of these cover only the early stages of life of a patent application and the resultant patents have to be effected on a national basis.

The European Patent Convention came into effect in 1977 and the European Patent Office (EPO), as an independent body has effectively replaced much of the patenting activity which used to take place at the national patent offices of the member states. The World Intellectual Property Office or WIPO was established in 1974 to facilitate the filing and early examination of patents on a near global basis. The PCT or Patent Co-operation Treaty that forms the legislation behind WIPO now extends to 177 member states with only a few notable exceptions and the EPC or European Patent Convention now extends to twenty six states including some Baltic nations.

### **Patentable Entities of relevance to the Pharma Industry**

The following classes of invention are of relevance here:

- **Compositions of matter** - whether new chemical or biological entities including for example isolated cells, genetically engineered animals and plants, combinations and formulations.
- **Processes** - for the preparation of compositions of matter whether new or old. New processes for manufacturing known drugs can radically reduce cost of production and therefore viability.
- **New uses** -many compounds exist on the shelves of pharmaceutical companies and provide new leads when screened against targets for which they were not originally prepared. Screening libraries of known compounds to identify new uses and therefore new leads is big business.
- **Devices** - physical devices for the administration of compounds can also turn otherwise non-viable treatments into a realistic proposition, in some cases new means of delivery can radically improve treatments and devices for depot delivery, sustained delivery, transdermal delivery etc can all provide useful protection.
- **Business methods** - as the Internet takes over even the pharma industry have to consider whether the traditional ways of marketing and distributing their products and services will need to evolve. Business methods, which

have traditionally been granted only in the USA , are being considered as potential subject-matter warranting protection in Europe and elsewhere.

- **Enabling technologies/ research tools** - these bridge a number of the categories above but cover for example the host cells, vectors and vector components as well as methods for biological production of chemical and biological entities. Research tools patents per se have been controversial in protecting and therefore potentially blocking the very basis of research. However protection on a particular target for example, whether the receptor or the gene could be important in justifying the expense of the investment in the research to have identified in the first place.

## **Criteria for Patentability and Patent Claims**

In order for a patent to be granted the invention must be:

- Novel i.e. not have been disclosed to the public orally, in writing or in any other way.
- Unobvious to a person skilled in the art.
- Be capable of industrial application i.e. be useful.
- Be described sufficiently in the specification to enable one of ordinary skill to repeat the invention.

The scope of the monopoly conferred by a patent is determined principally by the claims. The claims define, in clear technical terms, the subject matter embodying the invention. Novelty and inventiveness of the claims are assessed on the basis of the prior art, which comprises all information relevant to the invention which was available to the public prior to the date at which the patent application was filed or, where relevant, the priority date.

## **Routes to the filing of a Patent**

The routes that may be used to file and obtain grant of a patent include the following:

- The national UK patent system operating in the United Kingdom and governed by domestic legislation. An application for a UK patent is made to the UK Patent Office and, once granted, will establish a monopoly right in the United Kingdom alone.
- The European patent system established by the European Patent Convention and administered by the European Patent Office. A European patent application will be examined by the EPO as a single application but once granted it becomes a bundle of separate national patents in any or all of the following states: Austria , Belgium , Cyprus , Denmark , Finland , France , Germany , Hellenic Republic , Ireland , Italy , Liechtenstein , Luxembourg , Monaco , Netherlands , Portugal , Spain , Sweden , Switzerland , Turkey and the United Kingdom . A European patent may also be extended to certain Baltic states which are not parties to the EPC including Albania , Lithuania , Latvia , Macedonia , Romania and Slovenia .

- The international patent system established by the Patent Co-operation Treaty and administered by the World Intellectual Property Organisation (WIPO). An international application can be made under the PCT, and applicants may currently designate one hundred and seventy seven member states, either separately or by way of regional designations such as a European patent application. An international application will be treated as a single application, and is subject to a search and if requested, an examination of patentability by way of International Preliminary Examination (“IPE”). International Preliminary Examination is an initial examination of the patentability of an international patent application which gives the applicant a chance to assess the likelihood of grant and therefore the value of proceeding with the next expensive stage of prosecution. Although it is not binding on the national offices, a favourable International Preliminary Examination may be very persuasive in later prosecution. The PCT application is ultimately converted into a number of national and/or regional patent applications, which are then examined again to meet national/ regional requirements for the purposes of grant.
- The various national patent systems of individual countries administered by their respective national patent offices throughout the world.

### **Procedures and costs of filing a Patent**

To obtain grant of a patent in one or more territories the typical procedure for a UK resident is described in more detail below. There are other routes as described above and alluded to below, which can lead to different scenarios, but to describe them all would be overly complex:

- The first filing to be made which is called the ‘priority’ or ‘basic’ application will be at a national patent office, in the case of a UK resident, usually at the UK Patent Office. The basic cost in the UK is just the cost of preparation by the attorney as there are no official fees; the cost is therefore in the order of a few thousand pounds depending on the complexity of the drafting.
- Within twelve months of the basic filing, a decision must be made as to whether protection is required elsewhere in the world. Assuming it is, further filings will be required. These filings may be international, regional and/or foreign national applications claiming priority from the basic application, i.e. benefiting from the earlier date of that filing. In the typical example, a single PCT application designating all states should suffice. This will cost several thousands of pounds depending on whether further data needs to be added and the attorney must spend more time drafting.
- Whilst the filing is in the international phase (i.e. is still a PCT filing), a literature search will be carried out automatically by a designated Patent Office on behalf of WIPO (the organisation which administers the PCT), to determine the extent of the prior art. The cost of this is included in the fees paid on filing.
- Still in the international phase, publication of the application which is also an automatic activity (unless you take steps in time to prevent it) will occur eighteen months from the earliest priority date. This publication may be the first opportunity for interested third parties (including competitors) to study the

invention and the scope of the claims. There is no cost to the applicant at this stage as these costs are also built in to the filing costs.

- If the applicant chooses to do so, he/she may elect for the PCT application to be examined in a second stage of the international phase. This is International Preliminary Examination or IPE as described above and is the start of what is often referred to as “prosecution” of the application. The official fee for the examination of a PCT application is about one thousand pounds, but there may be additional cost if the attorney is requested to review and respond to any objections which are raised. At the end of the examination, the applicant will receive an International Preliminary Examination Report or IPEA which will be sent to the Patent Offices of any countries which are pursued in the next stage as a basis for any further examination as described below.
- The next stage is the Regional and National Phase entry from the PCT. If protection is to be maintained in for example Europe (Regional), USA (National) and Japan (National), each of these must be specifically elected and certain requirements met including the payment of fees. If the decision was taken not to seek International Preliminary Examination of the PCT application, then this must be effected within twenty months of the priority date. If an IPEA was undertaken, this deadline extends until thirty months from the priority date. Failure to act at this stage is fatal to the application as it is not possible to re-instate rights at a later date. The cost of this stage is one of the most expensive and hard to generalise, but may be in the tens of thousands if a significant number of territories are involved, in particular those needing translations.
- The National Patent offices in most countries (or in the case of a European application the Regional office which is the EPO) then carry out substantive examination. This may refer to the International Preliminary Examination but often raises further objections. The examination aims to determine the scope of protection to which an applicant is entitled, having regard to the prior art, and the extent to which the applicant has effectively described the invention, in accordance with National/Regional, as opposed to International laws. In most cases, applications are filed with relatively broad claims which are narrowed by way of amendment in the course of substantive examination. The cost of this prosecution, bearing in mind any translations required of the office actions and cited documents, etc. can be extensive.
- Following what may be several years of prosecution in each country, by now following its own timetable and acting independently of the others, the application(s) will hopefully be granted. It is at this point that the patent owner actually receives his/her ‘monopoly’ and right to stop others through enforcement of the patent in the territory. Part of the grant procedure is publication of the patent in its granted form i.e. including any amendments made during prosecution. The cost of the grant stage varies enormously on a territory by territory basis but may be a few hundred pounds or more if translations are involved again. Thereafter there will be fees, often annual, to maintain the patent in force. These fees at least in the UK start at a few tens of pounds and rise to several hundred by the 20<sup>th</sup> year.
- European patents may be opposed within a nine month opposition period which runs from the date of grant. This opposition term provides a mechanism by which all patents arising from the European application can be challenged together before the EPO. Granted patents in any territory may be challenged

for validity by a third party before the National courts at any time throughout the life of the patent. However, in general a granted patent carries a presumption of validity, and good evidence and/or arguments must be presented to revoke the patent or to force a limitation of the scope of the claims.

## **Ownership of a Patent**

According to UK Law, the right to apply for and be granted a patent primarily accrues to the inventor or inventors, but by act of law or agreement that right may belong to another. This provision includes employee inventors whose inventions are generally considered to belong to the employer, in particular where their duties are such that they can reasonably be expected to invent, or where they are in such a position within the company (such as a managerial position), that they can be expected to further the interests of their employer by the making of an invention.

## **The Right granted to the Patent Owner**

A granted patent gives the patent holder the right to stop others from making, using, selling, keeping or importing the invention in the territory in which the patent is held. What the patent does not grant is the right of the patent holder to do these things and that distinction is of critical importance. The fact that an invention can be described generically means a patent may be granted to a first inventor which albeit does not disclose a specific embodiment, covers that embodiment just the same. That specific embodiment may itself be independently patentable and a subsequent 'selection patent' could be granted to a second inventor. What this means in practice is that the second inventor will be unable to practice his or her invention without a licence from the first inventor, and the first inventor will be precluded from practising the specific invention claimed by the second inventor absent a licence back. In these circumstances the parties will need to collaborate either by the grant of a licence to one party for the purposes of exploitation or by a cross-licence to enable both the second and first inventors to practice the specific embodiment. Unless such a licence explicitly states that the second inventor can exploit anything else falling within the first inventor's claims, his right to exploit will be limited to the specific embodiment he has devised.

## **Patent Term**

In Europe and now the USA , a patent is granted for the term of twenty years from filing. By virtue of a convention called the Paris Convention, a year prior to this called the 'priority' or 'convention' year will be recognised for the purpose of establishing the date of first filing in most territories. This first year is not used in the calculation of the twenty-year term. Patent filings on pharmaceuticals are generally made when the chemical is still on the laboratory bench. As a patent is awarded (at least in Europe ), to the first to file (rather than the first to invent as in the USA ), many years will elapse whilst the product progresses through the various stages of development towards the market place. All this time patent life is being used up. The effective patent life therefore remaining for a product post launch and before patent expiry, has decreased markedly. An average effective patent life of a pharmaceutical

product has these days reduced to about eight years. Bearing in mind the cost to develop a drug to market, which has increased to several hundreds of millions of pounds, and the fact that most development projects fail to result in product, the cost of research and development has increased as patent life has decreased.

To deal with this problem many countries including most developed countries have enacted legislation to restore (at least in part), time lost from the effective patent life due to regulatory delays.

### **Supplementary Protection Certificates**

Supplementary Protection Certificates (and in the USA Patent Term Extensions which will not be discussed here) are the mechanism by which governments have attempted to return to the patent holder something nearer the twenty year monopoly he/she once enjoyed. These Certificates or Extensions do not provide the same breadth of cover; they are usually restricted to the active chemical entity or a combination of active ingredients contained in the marketed product (and sometimes close derivatives). They do not therefore restore the broad monopoly otherwise enjoyed by the patent holder in the first twenty years.

#### *Requirements for a Supplementary Protection Certificate*

In order to apply for a UK Supplementary Protection Certificate the following requirements are necessary:

- A patent must be in force in the UK covering the product as such, a method for its production or the use of that product.
- There must be a valid marketing authorisation in UK for the product as a medicinal product.
- The product must not already be the subject of an SPC
- The marketing authorisation must be the first one issued in any EU country.

#### *Procedures for obtaining an SPC, Duration and Costs*

Even though the legislation covering SPC's is European, the SPC must be filed with the National Patent Office as follows:

- Within six months of the date of the first marketing authorisation in that country, and
- Where authorisation is obtained prior to grant of the patent in that country, the application must be filed within six months from the date of grant of the basic patent.

The term of the SPC is calculated based on the earliest marketing authorisation and is effectively the delay between the date of the patent application in that country and the date on which marketing approval is first granted, less five years. In any event the Certificate cannot exceed five years.

The cost of applying for an SPC in the UK is a few hundred pounds, but if objections are raised, the attorney time may increase this to several thousands. The annual

renewal fees start at several hundred pounds and rise to a thousand or more by year five.

### **Policing the Patent Rights**

Obtaining the grant of a patent is the first step to creating the monopoly. In order for it to have real value it may be necessary to enforce the patent against 'would-be' and actual infringers. This requires the financial ability and willingness on the patent holder to pursue litigation.

In order to enforce the patent through an infringement action in the courts it is necessary to identify those who are infringing. There is no simple way to do this as infringers, particularly those who are infringing knowingly, will cover their tracks. Vigilance and monitoring by reviews of publications, attendance at conferences and meetings, searches on-line and general awareness of all employees, are some of the key measures necessary to identifying those who are not respecting a company's rights. A mere suspicion will not be enough, however, to start litigation and no contact should be made with the alleged infringer without considered advice from patent counsel and/or an intellectual property lawyer. Evidence will need to be amassed and this alone may take months to obtain before action can be taken.

### **Introduction to Freedom to Commercialise**

As mentioned in the introduction, merely owning a patent does not grant a company the right to commercialise free from any threat of infringement of third party rights. As part of any development plan for a product, infringement clearance analyses should be undertaken on each and every aspect of the product, its production methodology, its formulation and its use. Carrying out these analyses early in development can help to avoid costly development being wasted on products that are the subject of someone else's patents. It also gives the company an opportunity to devise non-infringing processes and formulations of the product which is free from problems itself but in respect of which the enabling technology is patented.

### **(Sub-) Identification of Third Party Patents**

Third party patents should be identified by specific patent searches undertaken by a specialist with expertise in searching the relevant databases. Searches may focus on company and scientist names known to be active in the field, keywords, classification and even sequence searching where sequences of proteins or nucleic acids are involved. The databases used are of great importance as they need to be comprehensive and not merely representative if all potentially relevant documents are to be found. Consideration should be given to whether the searching should be geographically limited; a search covering UK , EP , USA and PCT publications will generally identify all potentially relevant families as these key territories are almost always designated. The searches will require analysis, sometimes by both patent attorneys and scientists, to determine whether any documents warrant further scrutiny for claims that might pose a threat. Prior to any detailed analysis, the status of any patent should be checked to see if the patentee has allowed it to lapse, to see if it has expired and to check whether or not it has been granted. At the same time

territorial scope should be checked to see if patent filings cover the territories of interest. If the patents potentially cover, for example, targets the company wishes to use in screening, it is possible that it will have completed its screening activities before any patent grants, or the company may decide it can move its screening activities to a non-patented territory, thus possibly avoiding infringement. It will always be important to know in this circumstance, whether the patent contains basis for any sort of 'reach-through' claim to the products of that screening process; if so attempts to work outside territorial scope may ultimately be thwarted by such claims, assuming they are valid.

### **(Sub-) Assessment of Third Party rights and dealing with the Threat**

If there is deemed to be a risk of infringement, an assessment of the validity of the claims should be the next stage. If the patent is flawed the company may feel comfortable to ignore it on the basis that should it be sued it is confident of its ability to counter-claim for invalidity. However this strategy carries the risk of litigation. If the patent is still pending, simply monitoring through to grant and then challenging validity may help pre-empt any infringement suit.

Following a thorough analysis, the company may determine it wishes to cease those activities as the risk of infringement is too great; it may however identify a way in which to 'work around' the claims.

Two other options are available to the company in the event that the claims pose an infringement threat and are considered valid. Turning the threat into an opportunity by acquiring the patent and making it part of the company's own portfolio may be an option, as may acquiring an exclusive licence under the claims. Failing that, a non-exclusive licence giving the company the freedom it needs to commercialise, but no exclusive protection, may be adequate for its needs and free it from any further threat.

## **Trade Marks Passing Off and Unfair Competition**

### **Introduction to Trade Marks**

Although trade marks are included in the introduction as a registered right, unlike patents, (at least in the UK, although this is not typical of the rest of Europe and elsewhere) it is not mandatory for a mark to be registered for rights to accrue, as those rights can exist under common law and will be addressed under the section on passing-off. The first part of this section will therefore deal with registered trade marks, how they are obtained in the UK and their relevance to the industry.

### **Registered Trade Marks in UK**

The UK Trade Marks Act of 1994 (as amended) governs the requirements for obtaining and enforcing a trade mark in the UK . A trade mark is defined in the Act as being any sign which is capable of being represented graphically and which can in

the course of trade distinguish the goods or services of one undertaking from those of another. Unlike patents, globalisation of the economy has not caused quite the same level or need for harmonisation of trade marks possibly because the effects of language and culture often mean that different trade marks are required in different territories for the same product. However the Community trade mark (CTM) does provide for a unified registration system which applies to all member states of the European Union. Just as with the patents system this system is an alternative; national trade marks may still be registered independently in each state. The Madrid Protocol, an initiative of WIPO, also exists to provide a centralised application procedure as with the Patents Co-operation Treaty, the result being a bundle of national trade marks.

### **Ownership of a Registered Trade Mark**

Trade marks belong to the proprietor, who is essentially the applicant for the mark. Proprietorship can be determined prior to a trade mark being generated by virtue of contract or it may transfer after creation by assignment. With device marks it is essential that the underlying copyright in the mark is also owned by the trade mark proprietor and where outside designers are used, the company should ensure that the copyright is assigned if the entire title is to vest appropriately. Failing to ensure that copyright in any designs created at the time the trade mark is created, can leave a company vulnerable as the designer may realise the opportunity to charge again or may just refuse. Copyright infringement may also form an important element of any enforcement strategy but without ownership of the copyright, such action will prove impossible or at least very complicated and costly to sort out whilst preparing for litigation. In some countries, such as the USA , it may be advisable to record the copyright as well as registering the trade mark.

### **Types of Marks which are registrable**

As stated above any sign, which serves to distinguish a company's goods or services from those of others can in theory, be registered as a trade mark.

- Letters, numerals, words, names and slogans.
- Designs or logos.
- Shapes of goods or packaging (in this regard see particularly the section on registered designs).
- Colours, sounds or smells
- Combinations of the above.

### **Criteria for registration of a Trade Mark**

In order to be registrable, certain criteria are set out in the Trade Marks Act and include the following:

- The mark should not directly describe the goods or services to which they will be applied, otherwise they will not distinguish the company's goods from those of others.
- The mark should not be misleading.

- The mark should not conflict with any other users' rights (registered or in common law).
- The mark should demonstrate distinctiveness

Registration alone is insufficient to maintain a mark. The statute provides that unused marks may be removed from the register. It is therefore important to consider what use is to be made of a mark and when, in order to devise an appropriate strategy for protection. The use itself must also be appropriate. It should not be used as a substitute name for a product or service; this type of use risks the trade mark becoming the generic term for an article or activity rather than distinguishing the goods or services of the company. Aspirin is a registered trade mark of Bayer in Germany but it is used generically in the UK through failure of Bayer to prevent misuse of its trade mark.

### **Procedures and Costs of registering Trade Marks**

For each new mark it is advisable to conduct clearance searches before filing. The costs will vary depending on the territory searched and the extent of the search undertaken. When carrying out appropriate searches consideration should be given to which markets i.e. the geographical extent of the searching.

- An application for the registration of a trade mark needs to be made at an appropriate office or Registry such as the UK trade marks registry, which is part of the Patent Office. The registration will need to specify one or more of the 42 classes (of goods or service), for which the mark is to be protected. The cost for this at the UK Registry is currently a couple of hundred pounds for the application with a small additional fee for each additional class. There will also be the professional time associated with the preparation and filing of the application; typically a few hundred pounds.
- The mark is then examined to ensure it meets the requirements set out above. This examination will usually take place within about two months of filing, and the procedure for responding to any objections may take up to six months.
- Six weeks after acceptance of the trade mark, i.e. after all objections are dealt with, the trade mark is published to allow for a three month period of opposition by third parties.
- Following expiry of the opposition period without opposition or successful defence of an opposition, the trade mark will be entered on to the Register. The cost of defending an opposition may be anything from a few hundred to many thousands of pounds.

### **Foreign filing of Registered Trade Marks**

It is possible to claim priority from an earlier trade mark filing as with a patent filing. The period for doing this is six months. Filing national applications can be an expensive business and on average will be several hundred to a thousand or more per country for new filings and the same again in prosecution costs. If the foreign filing is in the form of a CTM it alone may be several thousands of pounds. In most countries it is possible to obtain registration within about two years.

## **Duration of a Registered Trade Mark**

In the UK a trade mark can last indefinitely subject to payment of the appropriate fees. The initial period is 10 years renewable thereafter in perpetuity for further periods of ten years.

## **Freedom to use the Trade Mark**

As well as assessing what marks may conflict for the purpose of registration it is also important to ensure freedom from the threat of litigation, by checking for marks filed by others which might be infringed by the company's use of a proposed mark. This may also assist the company in creating alternatives which will be more effective in distinguishing its goods and services from those in the market already.

## **Policing Trade Marks**

As with patent rights, merely owning the registration will not provide protection, it is the steps the company takes to monitor the activities of others and to be prepared to enforce those rights, if necessary, which provides protection. Monitoring new registrations being made at the Registries, reviewing publicity material of competitors and others in the field, attendance at tradeshows, conferences etc., will all help in ensuring that use of the company's marks will come to its attention promptly. Embarking on action to enforce the company's rights requires appropriate legal advice, particularly as the recent Trade Mark Amendment Act now provides for action to be brought against a party who is threatening another with action inappropriately.

## **Relevance of Trade Marks to the Pharma Industry**

Trade marks are of very significant importance for the pharmaceutical industry not only to identify the goods as being goods deriving from a particular company, but to try to protect the market for a therapeutic, post patent expiry. Patient recognition of a particular brand of pharmaceutical preparation is strong and reluctance to change from a treatment which is working, is high; trade marks therefore play an extremely important role in maintaining brand loyalty and therefore market share when patent protection is lost and generics enter the market.

# **Passing-Off and Unfair Competition**

## **Introduction Passing-Off and Unfair Competition**

Passing-off and unfair competition are aspects of English common law which deal with the fact that goodwill and reputation can be built up in a mark during the normal course of trade. For these rights to accrue no registration need have been made but trade mark infringement actions may well be combined with an action for passing-off,

if it is felt that there is more likelihood of such an action succeeding where marks are not identical or are not for identical goods.

## **Establishment of Passing-Off**

In order to establish before a court that goodwill exists, there will necessarily have had to be a reasonable amount of use made of the mark in the course of trade. Many passing-off actions fail because the plaintiff is unable to demonstrate adequately that goodwill has in fact been established.

Another element required by the courts in the demonstration of passing-off, will be the need to demonstrate misrepresentations to the public by the defendant.

Finally, there will need to be some damage to the plaintiff resulting from the misrepresentation.

The value of this aspect of common law has come to the fore in dealings with domain names where allegations of trade mark infringement and passing-off have frequently succeeded in a positive decision for the trade mark holder, particularly in cases of cybersquatting as described in connection with Domain Names.

# **Domain Names**

## **Introduction to Domain Names**

Domain names are an essential element of the Internet, as they are the unique identifiers of each 'individual' presence on the Internet in a form which is meaningful, and therefore useable in everyday communication. Underlying each of these unique names is a numeric address recognisable to the computers (domain servers) that underpin the service. The domain name is made up of different parts; in their simplest form the name comprises a sub-level domain (or name) 'smiths' separated from a top-level domain 'co.uk' or 'com' by a dot. Sub-level domains may also be separated to comprise the individual's name 'jobloggs' and the 'escargot' as the French so endearingly call the '@' sign which separates the two, to give [jobloggs@smiths.co.uk](mailto:jobloggs@smiths.co.uk) This e-mail address is being protected from spambots, you need JavaScript enabled to view it as the full email address.

The top-level domains such as '.com'; '.co.uk', '.net', '.org'; '.edu' etc., have generally been allocated and administered by Network Information Centres around the world. The speed with which the need for domain names has arisen, the administration of them and the apparently unpredicted trade that has arisen in them, has left legislators well behind and having to legislate frantically to catch up.

Allocation of domain names is really a first-come, first-serve system of 'you pay your money, you get your name'. However the practice of 'cybersquatting' - purchasing popular names with a view to selling them at a premium - and the fact that more disputes over names arose than was predicted, has led to a number of high profile court cases, as well as dispute resolution procedures being put in place, the latter principally by the Network Information Centres.

## **Cybersquatting**

'Cybersquatting' arose when a number of unscrupulous individuals saw an opportunity to acquire, at a nominal price of £5.00 to £100.00, domain names that contained the names of high profile individuals and/or companies. These were then offered to the individuals or companies concerned for tens of thousand of pounds or more. The courts took an extremely dim view of this practice in the UK and in the famous 'Harrods' case in which trade mark infringement, passing-off and conspiracy were all alleged, Harrods were successful, as have many others been since, in demonstrating trade mark infringement and passing-off and having the domain name transferred to them.

## **Dispute Resolution of Domain Names**

Some disputes over domain names are between two parties with a genuine right to be able to use the name, and in these cases someone must determine who will have the right to use it. Many Network Information Centres have created their own procedures to try to resolve such disputes or where resolution involving agreement between the parties cannot be achieved, to decide based upon evidence the parties will present to it, whether one or other party should retain the name or whether its use should be suspended on the basis that it will lead to confusion. Where the disputes have ended up in court, often the decision has been given in favour of the first to have sought to acquire the name.

# **Registered Designs and Design Right**

## **Introduction**

A design can be protected by both registered and unregistered rights. A registered design protects the appearance of an article or set of articles, i.e. its shape and/or surface pattern. It is additional to any design right or copyright protection which may subsist automatically in a design. A design right, on the other hand, is not a monopoly right but a right to prevent copying.

## **Criteria for Registered Designs and Procedure**

At the time of writing this article, to be registrable, the design must be new, have eye appeal and not fall into an excluded class of designs which are not protected under the Designs Act. What is meant by new, in terms of a registered design, is that the design should not have been made available or disclosed to the public in any way whatsoever in the UK, before the application to protect the design has been made. There will be a twelve month grace period for novelty destroying disclosures by the designer or his successor in title.

Significantly, at the time of writing, there are plans to implement the Designs Directive 98/71, to harmonise the substantive requirements for registered design

protection in all EU Member States. The Directive has also been extended to the EEA. Subject to approval, it is intended that the regulations will come into force on 28 October 2001 .

Significant changes to be brought in by the regulations will include a new definition of design to mean 'the appearance of the whole, or part, of a product (not article) resulting from the features of the lines, colours, shape, texture or materials of the product or its ornamentation.' A product is defined as any industrial or handicraft item, other than a computer program, and in particular, includes packaging, get-up, graphic symbols, typographical typeface and parts intended to be assembled into a complete product. The design will need to have 'individual character'.

### **Duration of a Registered Design**

The term of a registered in design in the UK currently and under the new regulations is 25 years renewable in five year terms. As this term is longer than that of a patent, the design protection will invariably outlive the main patent on any drug and therefore has the potential to provide extended protection.

### **Rights granted to the owner of a Registered Design**

The rights granted under a registered design are similar to those granted to a holder of a patent, and that is the right to stop others from making , importing or selling articles with the design applied whilst the registered design is in force.

### **Relevance of Registered Designs to the Pharma Industry**

The design of a tablet (or device) may seem unimportant but as with trade marks, patients can become very wedded to a particular tablet shape and colour. In fact tests have proven that in some cases changing the patient onto a generic form of the drug can adversely affect treatment, particularly if the patient believes they are receiving different drug rather than the one which has successfully been treating their symptoms previously.

### **Design Right**

Design Right is an automatic right which comes into force when a design is first created. The design must be to the shape or configuration of an article. The right offers limited protection to stop others from copying the design, of ten years from marketing or fifteen years from creation (whichever is the shorter). There is no registration procedure and therefore no cost in obtaining the right.

Like copyright, it is wise to keep original works and/or records of when a design is first recorded in material form, and when articles made to the design are first made available for sale or hire.

## **Copyright**

### **Introduction to Copyright**

Copyright is a right which in the UK at least, comes into being upon creation without the need for any registration. However there is a statute which governs what works attract copyright and how they are enforced. An EC directive on 'Copyright and related rights in the information society', was formally adopted on 9 April 2001 and must be effected under National laws by 22 December 2002 . The main changes the directive will require that may impact on the pharmaceutical industry will be in providing more comprehensive protection for works of various forms in the technological age.

In the USA there is a registration system but this is not mandatory for the right to subsist and it is not proposed to discuss the registration procedure in the USA in this chapter. Works covered by copyright under the Copyright, Designs and Patents Act 1988 (as amended on a number of occasions since it came into force in August 1989) include:

- Original literary, dramatic, musical or artistic works; literary works being deemed to include computer programmes and databases (the latter also being protect by Database Rights on which there is a separate section.
- Sound recordings, films, broadcasts or cable programmes.
- The type or graphical arrangement of published editions.

For copyright to subsist, the work(s) must be original; similar works if generated independently, would both benefit from copyright as long as there was no copying involved.

### **Ownership of Copyright**

Copyright in any work belongs to the author or creator first and foremost. In respect of 'literary rights' which are the most relevant to the pharmaceutical industry, works created by an employee will belong to his or her employer. An important point to note is that copyright in a commissioned work remains with the author unless specifically assigned. This can be important particularly in the context of trade marks and designs, where copyright may well need to be assigned in addition to the rights in the trade marks and designs themselves.

### **Grants of Rights and Term in respect of Copyright**

The Copyright, Designs and Patents Act 1988 (as amended) provides for the right of the owner of the copyright to prevent others from copying/reproducing all or a substantial part of their work. This right persists for 70 years from the year in which the author dies. If the work is computer generated the term is 50 years from the year of creation. This provides for an extremely valuable right as it is likely to outlive all other rights in any work.

### **Procedures and Costs**

In view of the fact that there is no registration procedure in the UK , there are no formal registration fees associated with copyright and there are no procedures required for its creation. Signing and dating of works and keeping originals safe will however,

make enforcement easier. To ensure that the date is clear, sending a copy to a bank or to the company's solicitors and asking them to date stamp it and hold it on behalf of the company, can be helpful in establishing the date of creation. Ensuring that works are marked copyright followed by the name of the author and the year of publication is advisable and may assist in infringement proceedings. If the work is electronic each page should be marked accordingly.

## **Policing Copyright**

Where copyright does not differ from the other intellectual property rights is the fact that its value is dependent on policing infringements and in a company's willingness to take action to enforce its rights. Monitoring for infringing activities of others will be the responsibility of the copyright owner and should include regular reviews of publications, conference attendance and general vigilance as described for patents. Enforcement of a company's copyright will ultimately be through the courts in an infringement action, if the infringing acts cannot be halted or legitimised through a licence by agreement between the parties.

## **Freedom to use Copyright**

As long as the work is not copied, the owner will be free to use it even if it is identical to a work of another. The only danger here is an ability to demonstrate originality. Where works are commissioned, it will be important to ensure that the designer is aware of the implications if he or she copies someone else's work on the company's behalf. Such a situation can be avoided by clearly stating in the supply contract, that a requirement of the commission is that the work will be entirely original and will not result from the copying of any work of another.

# **Database Rights**

## **Introduction to Database Rights**

Databases are the most recent form of intellectual property right to be recognised as worthy of its own legislation. The Copyright and Rights in Databases Regulations came into force in 1997 prompted by an EC Directive.

## **Nature of the Database Right**

A 'database' for the purposes of the regulation is defined as a collection of independent works, data or other materials which are arranged in a systematic or methodical way and are individually accessible by electronic or other means. The definition was intended to be broad enough to cover all forms of database, whether in the form of a hard-copy or on-line such as on the Internet.

## **Ownership of the Database Right**

As with other rights the 'maker' may be the person who carries out the work or in the case of the database right 'who takes the initiative', but the rights may accrue to the employer if the maker is employed for that purpose.

### **Criteria for the Database Right to Arise**

Database rights are like copyright and come into existence merely upon creation without the requirement of any form of registration, but like copyright there are provisions in the legislation to clarify the requirements a database must meet for the right to accrue. There must be a substantial investment in obtaining, verifying or presenting the contents of the database and the creator or maker must be a national of the EEA or resident in the EEA or a body incorporated or formed in the EEA for the rights to arise under the UK Act. From the first case to be heard in the UK under this new act it became clear that in order for the right to be upheld the proprietor should keep very clear records of the investment made in constructing the database and the uses to which it would be put.

### **Rights granted to the 'maker' of the Database**

The right that accrues to the 'maker' of a database is the right to prevent use in part, or whole of the contents of the database or to extract elements there from. There are however defences to this and that may be;

- That only an unsubstantiated part of the database has been used,
- That although the act is retrospective including databases created as early as 1983 the act alleged to infringe the rights took place before 1 January 1998 which is deemed the cut-off for the transitional provisions,
- That the user is lawful i.e. has the right (by virtue of contract or whatever), or the use is for example not a commercial one.

### **Duration of the Database Right**

The database right will last 15 years from the end of the calendar year in which the database was completed, or earlier if it was made available to the public beforehand, but if changes/additions to the database involve a 'substantial new investment', a new period of 15 years may take effect, thus extending the effective life of the original parts of the database too.

### **Relevance of the Database Right to the Pharma Industry**

The use of databases or collections of information, whether of the output of screening activities such as gene sequences, or the results of chemical screening, will become, if it has not already, a significant part of the business upon which research and development in the industry will rely. Already companies exist on the basis of their databases of information; many genomics companies (and in the future proteomics companies) sell the data they have generated through sequencing and screening the human genome. Companies also exist which compile data on disease

incidence and drug markets and these too, owe much of their business to their databases and the value inherent in the patient data they contain.

Considering what rights a company may need access to, in any deal involving collections of information and to what, if any degree that access could, should or would need to be exclusive, is essential. The holder of such rights must give very careful consideration to the licensing strategy, if premiums are to be charged for exclusive access, and this will need to be well defined and time-limited if overlap in the scope of licences is to be avoided.

## **Regulatory Data Exclusivity and Orphan Drug Protection**

### **Introduction to Regulatory Data Exclusivity**

Regulatory Data Exclusivity is a right which prevents reliance by generic companies on original toxicological, pharmacological and clinical data generated to comply with the various regulatory requirements. It is an added incentive for companies to undertake novel research and development rather than to use the data generated by others to provide more of the same. Clearly any such protection is weakened by publication of the data which is then freely useable by the generic competition. What the protection does not prevent, as with copyright is independent development of the same data.

### **Duration of Regulatory Data Exclusivity**

This form of protection can often extend post patent expiry. The period of exclusivity in Europe is between six and ten years from the date of FIRST marketing authorisation for products approved under most procedures depending on how the member state has chosen to enact the legislation.

### **Introduction to Orphan Drug Protection**

This form of protection is intended to provide exclusive marketing rights for a product and to ensure that no generic approval for a drug, regardless of patent status, is granted within a period following first marketing approval, where the disease to be treated by the drug affects a small population. The legislation governing Orphan Drug status in the UK came into force on 22 January 2000 in the form of an EU regulation immediately effective in all member states. The legislation was introduced to provide incentive to companies to invest in the development of drugs which have no potential to become block busters. With a limited market, the ability of a company to recoup its research and development costs are also limited, hence the desire to provide a period in which there is no competition for that product. The grant of rights is usually limited to the specific indications for which the treatment has been approved, and should preclude "similar products", even if developed independently,

from achieving registration. However, the meaning of “similar” could be subject to some debate.

### **Procedure and criteria for obtaining Orphan Drug Protection**

The procedure for obtaining Orphan Drug Protection in Europe is through the centralised EU procedure for obtaining any form of marketing authorisation for a drug. Application can be made at any time prior to the application for marketing authorisation but it is advised to submit the request (which is confidential) as early as possible.

To qualify for registration as an orphan drug product, the drug must be intended for the use in diagnosis, prevention or treatment of a life-threatening or chronically debilitating condition which either affects not more than five in ten thousand people in the EU or is unlikely to generate sufficient return to otherwise justify the investment in development of the drug. A third criterion is that there must be no satisfactory method of diagnosing, preventing or treating the condition already authorised for the market in the EU or if a method exists this new drug must provide substantial benefits to sufferers.

### **Duration of Orphan Drug Protection**

In Europe the exclusivity is granted for 10 years but this may be reduced to six years if the product ceases to meet the criteria or if the product proves sufficiently profitable not to need the benefit of the exclusivity . Exclusivity may also be lost if the holder of the marketing authorisation cannot supply the drug or if a clinically superior drug becomes available.

## **Know- How and Trade Secrets**

### **Introduction to Know- How and Trade Secrets**

Know-how, trade secrets, confidential information are all terms used to describe proprietary information or materials used in the trade which lend a competitive advantage. The information may be held in documents, engendered in people in the form of skills or may be materials such as cell-lines, proteins, crystals, nucleic acids etc. The nature of the information can be extremely varied, it may be process information, analytical methods, clinical data, recipes....the list is endless.

### **Protecting Know-how**

In order for the know-how or materials to retain their value they must remain confidential to the company and release must be restricted. The total loss to industry in general in the USA was calculated some years ago as over \$100 billion. In order for any protection to be effective, a positive decision must be taken that this information or these materials are valuable and should be maintained as secret. Maintaining know how as confidential is actually more difficult in some ways than

pursuing registered rights which are at least lodged and managed. The same degree of management must be applied to the maintenance of trade secrets. It is as important to be aware of partial disclosures as competitors are extremely clever and may be able to reverse engineer the information from what little they are told.

### **Further measures to protecting Know-how**

The first step to protecting know-how is to be able to identify it. Wherever possible information, procedures, ideas, plans etc., should be documented. Reliance on the goodwill of employees to hand back such valuable information when they leave the company is a risky strategy. Even if totally trustworthy, such employees may fail to pass on critical details that leave procedures useless. Undocumented information is impossible to manage and it is much harder to ensure employees understand what is, and what is not confidential, if information is passed freely around the company.

Essential documents should be marked 'confidential; not to be copied', preferably numbered and tracked if circulated, and access restricted to ensure employees understand their importance and the fact that they contain information their employer considers to be valuable. All drafts should be destroyed.

### **Protecting Materials**

All materials should be coded and logged; access to compound and culture stores should be restricted. In the case of biologicals, duplicates should be maintained in equally secure facilities to ensure that if cultures are lost through disease or defrosting for example, the lines are not lost to the company.

### **Employee Awareness**

Loss of valuable know-how through misappropriation by an employee is probably the single greatest risk to an employer. Whether deliberate or unintentional, creating and maintaining awareness amongst employees will help provide problems. Every employee, consultant, advisor to the company should have a written contract containing suitable confidentiality provisions and exit interviews can be used to reinforce the message. Employees should also be made aware of the danger of e-mails and that attachments should be cleared for release as if a publication.

### **Contractual matters**

As important, is to ensure that all dealings with third parties where there is to be a release or exchange of confidential information, should take place under contractual obligations of confidentiality. Such contracts should describe the subject-matter of what is being released, the purpose of the release and how the know-how can and cannot be used by the recipient. As a minimum the agreement should specify the terms over which release to others cannot occur, who if anyone else such as advisors etc., can receive the information and what will happen to that information upon expiry/termination.

## **Protection for Plants**

Plants are often the starting material for many drugs and in some instances the drugs may be produced by extraction directly from a plant, if chemical synthesis is too complex or expensive. Protection of these 'factories' can be important as part of the jigsaw of rights used to create a comprehensive monopoly for a product. As well as the patent system, which can be used to protect plants (though not varieties), there are separate rights to plant varieties.

The Plant Variety Rights Office administers UK plant breeders' rights, and a separate system of EU plant breeders' rights is administered through the Community Plant Variety Office. Plant breeders' rights entitle the holder to prevent others from exploiting the protected variety. The rights last for twenty five years, starting from the date of grant of the right, for all species except trees, vines and potatoes which benefit from thirty years of protection.

The plant variety undergoes a technical examination to ensure it is distinct, uniform and stable. There is a novelty requirement. In this regard, a variety is new if, at the date of the application for protection of the variety, it has not been sold or disposed of with the consent of the breeder either earlier than one year before the date within the EU or earlier than four years before the date outside the EU (six years for trees and vines).

## **Summary**

There are various registered and unregistered rights which can be used in protecting intellectual property arising from drug development. Effective utilisation of the registration systems and legislation available can provide long and effective monopolies, which should ensure adequate return for investment in the research and development necessary to obtain marketing approval for a therapeutic entity. Key considerations in the creation and maintenance of useful intellectual property rights are: to plan the strategy for protection with the routes of exploitation in mind; to ensure that these evolve as product development evolves; and to maintain competitor awareness and evaluate any threats to commercialisation. These simple steps, if executed effectively, should help ensure competitive advantage is maintained.