Intellectual property and medicine

Module A: Intellectual property of medicine and its sources

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Chapter 4: Categories of intellectual property relevant to medicine

Introduction

Medical industries, research and development depend on a full range of intellectual property rights, but the most important bases for their commercial business models are patents and related rights, trade marks and trade secrets.

Learning outcomes

Having studied this chapter and the related readings, you should be able to:

- explain the basic concept of a patent, including the patent monopoly
- discuss the basic principles underlying the patent system, including the duty of disclosure
- explain in outline how the patent system developed
- identify the basic principles of the UK patent system
- explain what supplementary protection certificates are and how they function
- explain trade secrets and confidential information and their relevance for industries in these fields of technology
- understand and explain trade marks and the system of International Nonproprietary Names (INN).

Essential reading

- Gibson, Chapter 9, pp.185–87.
- Bently, L. and B. Sherman *Intellectual property law.* (Oxford: Oxford University Press, 2009) third edition [ISBN 9780199292042], Chapter 14.
- European Patent Convention (EPC), Part II, Chapter I and Article 83.
- UK Patents Act 1977, ss.1, 2, 3, 4, 4A and 60.
- European Commission Council Regulation (EEC) No. 1768/92 of 18 June 1992 concerning the creation of a supplementary protection certificate for medicinal products.
- *Merck & Co* v *SmithKline Beecham Plc ('Jeryl Lynn' Trade Mark)* [1999] FSR 491.

Useful further reading

- Bently, L. and B. Sherman *Intellectual property law.* (Oxford: Oxford University Press, 2009) third edition [ISBN 9780199292042], Chapters 17 and 31.

4.1 Introduction to patents

A patent is a limited monopoly over an invention – that is, it is a monopoly which persists for a limited amount of time. However, it is a very extensive monopoly, covering almost all commercial uses of the invention. As with other intellectual property rights, patent rights are also territorial and limited to the jurisdiction in which they are granted. Patents are also described as property, and this interpretation of a

monopoly right in what is otherwise a public good is very significant in debates over competing human rights, access to patented medicines and the application of patents in gene-related inventions – as you will learn through your study of this course.

The rationale for patenting is that an inventor invents something new and a monopoly is granted so that the inventor can make some money out of that invention. But this monopoly is granted in return for something: the sharing of the invention with the public. It would make no sense nor would it be fair simply to shut down all competition for the inventor and allow them to keep the specifics of their invention secret. This can be described as a kind of social contract,[1] the benefit to society being the disclosure of the invention (rather than keeping it a trade secret). Additional benefits might include the contribution of new knowledge to the field (a kind of teaching benefit) as well as an incentive to inventors to continue to innovate (for the promise of a patent monopoly for their subsequent invention).

Therefore the state (through an agency such as the UK Intellectual Property Office) grants what is usually a 20-year exclusive right to control the way the patented invention is exploited (TRIPS Article 33). This monopoly is granted in return for the inventor 'sharing' their invention, disclosing it as part of the patent application process so that it can be used (or 'worked') by a 'person skilled in the art' (TRIPS Article 29) – that is, a notional person who has the requisite skill and knowledge appropriate to the type of invention.

So what can qualify for this exclusive right? What should be patentable? Let us look at some basic principles of patent law in more detail.

[1] Social contract theory is largely attributed to the work of Hobbes, Locke and Rousseau. It justifies a political system or action, such as the award of a patent monopoly, as being in the rational self-interest of ordinary citizens. In other words, the argument might be that without a patent monopoly, innovative activity would decrease and dissemination of information would end, with inventors relying on secrets rather than patents to protect their invention. Social contract theory is similar to utilitarian theory but is characterised by the reliance on arguments of a 'dismal alternative' to the proposed system.

4.1.1 What is an invention?

An invention must provide a new technical solution to a problem. Therefore, it must not already exist in the literature or common practice (even if not protected by a patent); it must be **novel** (EPC Articles 52, 54).

The concept of invention incorporates the understanding that the solution is inventive, that is, it is not already obvious to a person skilled in the art. In relation to inventiveness, you may also hear the term 'non-obviousness' used – this is the term used in the United States and some other jurisdictions. In English law, we refer to this criterion as **inventiveness** or **inventive step** (EPC Articles 52, 56).

As well as novelty and inventive step, the invention must have **industrial application** in order to justify the monopoly of a patent (EPC Articles 52, 57).

Finally, if an applicant fails to disclose the patent sufficiently, it is in effect not a patent in that the basis for the monopoly is not evident in the patent documents. Therefore, a patent may also be declared invalid for lack of **sufficiency** in the documentation (EPC Article 83).

If an invention is not new or lacks an inventive step or has no industrial application or the application is insufficient, then the patent can be declared invalid by the court and all rights revoked.

4.1.2 Basic principles of the patent system

It is possible to identify three basic principles underpinning the patent system:

- privilege for the individual
- duties that they must perform in order to enjoy the privilege
- benefits to society.

First, consider the concept of a patent as providing a privilege for the individual. A patent provides **recognition** of the inventor as the creator of the invention (Paris Convention Article 4*ter*; EPC Article 62). A patent also provides **property** in that invention, subject to the fulfilment of certain criteria (as discussed above: novelty, inventiveness, industrial application).

In return, the patentee owes certain duties to society at large. Importantly, the patentee must **disclose** the invention in a useful way (that is, provide **sufficient** information for the invention to be understood by the person skilled in the art).

The benefit to wider society can be understood as the underlying rationale and basis of the system. This benefit is usually argued to be the generation of more and more innovation because the patent system:

- ensures a useful disclosure of the invention (for further innovation and teaching);
- rewards useful inventive activity; and
- thus provides an incentive towards further innovation.

In other words, the usual argument for the current patent system is that further innovation is facilitated by building upon the information set out and disclosed to the public in patent applications. Further innovation is encouraged by the system in several ways, but all based upon the disclosure of the invention in the patent documentation. Disclosure provides for the opportunity for innovation based on incremental improvements on what has gone before, teaching (access to information), rewards and incentives for further innovation and benefits to greater society as a result.

4.2 A general history of the patent system

4.2.1 Founding principles of the patent system

The first general statute dealing with patents is usually considered to be that passed by the Venetian state in 1474. This law granted 10-year privileges to inventors of new arts and machines. The principles behind the law were very similar to those set out earlier:

- to recognise the inventor;
- to encourage innovation; and thus
- to achieve greater social benefit.

4.2.2 Twentieth-century developments

Although the principles of patent law have their origins in the fifteenth century or earlier, the modern system of administration and examination of patents, including patent requirements such as novelty and inventive step, was not really established until the twentieth century.

Of the various statutory revisions that occurred in 1907 and 1919, it is of particular note that product patents on chemicals were abolished by a 1919 revision of the law so as to make it possible for industrial companies to copy the technical advances of their competitors and thus to develop greater capacity. As we noted in the previous chapter, this is particularly interesting in the context of contemporary debates over the application of TRIPS minimum standards in developing countries which are still trying to build their industries and expertise, particularly in the area of pharmaceutical research and development. Critics of the international intellectual property law system often argue that it is unfair of industrialised countries to deprive developing countries of the same opportunities they enjoyed during their economic and technological development. The 1919 revision also allowed for freer granting of compulsory licences for medicines. Compulsory licensing is a critical facility in realising access to medicines in times of emergency, particularly in developing countries, and this policy of 1919 (which was not changed until 1977) is very relevant to that debate.

Finally, in 1977, the modern UK Patents Act was enacted and remains in force today, albeit amended several times.

4.3 Modern patent law

For this course, you need a working knowledge of the basic concepts and principles of UK patent law. We will introduce patent law to the extent that it is useful for the understanding of its relationship to medical research, access to medicines and other areas of public health.

The important aspects to understand include:

- the principles behind the privileges to the applicant and the duties and benefits to greater society (of teaching and of greater innovation)
- the key requirements of patentability (novelty, inventiveness or non-obviousness, utility, and internal requirements of sufficiency)
- exceptions to patentability.

We will also briefly consider some other forms of protection that may apply to patentable material, such as trade secrets and supplementary protection certificates (SPC), and we will look at protection through trade mark law (including International Nonproprietary Names for drugs).

4.3.1 Public benefit justifications for patents

The notion of the public benefit may be broadly understood as incorporating the 'information function' and the 'innovation function':

- The **information function** is, in effect, the duty to publish and disclose the patent in a useful way (to 'teach' the invention, as it were), thus disseminating the information to the public. Remember that disclosure must be **sufficient** so that a person skilled in the art can work the patent. Furthermore, the patent must add knowledge to the field; it must not just 'disclose' inventions already in use or published elsewhere in the literature. So the other key term here is the **novelty** of the invention.
- By **innovation function**, we mean the way in which the patent system may be seen as providing an incentive to ongoing innovation and investment in innovation. The promise of a patent to protect an inventive innovation that provides a useful solution to a technical problem is argued to provide greater incentive to invest in innovation. In other words, the patent system provides greater certainty for costly research and development enterprises. The patentee has a competitive advantage in the market for the period of the patent, thus enhancing the commercial value of the invention and making the patent a potentially valuable asset to transfer to other parties, or to encourage the investment of other partners during the development and commercialisation process (something which might otherwise be beyond a single inventor).

Activity 4.1

List some of the reasons why the information function may be important to the knowledge economy.

Feedback: page 54.

4.3.2 The Patents Act 1977 and the European Patent Convention (EPC)

Patent law in the UK is found in the Patents Act 1977, which implements the European Patent Convention (EPC), including accommodating the procedures of the European Patent Office (EPO).

The principles that have developed over the history of patents can be interpreted in this Act and the modern patent.

The key provisions for the purposes of this course are:

- section 1: patentable inventions
- section 2: novelty
- section 3: inventive step
- section 4: industrial application
- section 4A: methods of treatment or diagnosis
- section 60(5): exceptions to infringement.

We will look briefly at each of these.

4.3.3 Patentability

The basic requirements for patentability are set out in Article 52 of the EPC and s.1 of the Patents Act 1977. The definition of a patentable invention is important because it defines the scope of patentable subject matter.

Section 1(1) sets out the grounds for patentability (in other words, it sets out what **is** patentable):

> (1) A patent may be granted only for an invention in respect of which the following conditions are satisfied, that is to say—
>
> (a) the invention is new; [**novelty**]
>
> (b) it involves an inventive step; [**inventiveness**]
>
> (c) it is capable of industrial application; [**industrial application/utility**]
>
> (d) the grant of a patent for it is not excluded by subsections (2) and (3) below;
>
> and references in this Act to a patentable invention shall be construed accordingly.

Section 1(2) deals with what is **not** patentable subject matter. Importantly for the present discussion, a patent is not available for a mere discovery, scientific theory or mathematical method (s.1(2)(a)). Section 1(2)(b) excludes works ordinarily covered by copyright and s.1(2)(c) excludes business methods and computer programs (though computer programs may be patentable if they are shown to have technical effect, which is why we have software patents). Section 1(2)(d) excludes the mere presentation of information.

Section 1(3) provides for circumstances where a patent may not be available because the grant of a patent would be contrary to the public order or morality (the *ordre public* exception is found in Article 53(a) of the EPC). The fact that a working of an invention may be contrary to law (for instance, a domestic security system designed to kill intruders) does not preclude it from patentability on this ground – that is, it is by definition an invention – but the grant of a patent may be refused by virtue of an exception.

4.3.4 Novelty

Section 2 of the UK Patents Act 1977 deals with novelty in detail and sets out the definition of novelty. An invention will be new when it does not form part of the state of the art, that is, when it is not known to those in the field and has not been previously published or used or otherwise made available to the public before the application for patent protection has been made.

4.3.5 Inventive step

Section 3 defines the criterion of inventive step. An invention will involve an inventive step where that invention is not obvious to a person skilled in the art, that is, that particular solution to the particular technical problem addressed by the invention is not immediately obvious. In other words, in devising this particular solution, the inventor must truly have taken an inventive step.

4.3.6 Industrial application

Section 4 provides that an invention will be deemed capable of industrial application when it can be made or used in any kind of industry. The definition includes agriculture, which is significant for patents on plant varieties.

4.3.7 The methods of medical treatment exclusion

Section 4A implements the changes brought about by amendments to the European Patent Convention in the year 2000 ('EPC 2000') which changed the rules for methods of medical treatment. Previously, methods of medical treatment were deemed to be incapable of industrial application and therefore not patentable. However, the new provision explicitly excludes methods of medical treatment rather than going via a deeming provision.

4.3.8 Exceptions to infringement

Section 60 defines acts of infringement and s.60(5) provides for exceptions to infringement in specified circumstances. This provision is especially important in medical research and development. The following exceptions are particularly relevant in the course of research and development as well as clinical trials:

(a) private, non-commercial use

(b) research (experimental purposes)

(c) extemporaneous preparation in a pharmacy (making a mixture from constituent ingredients)

(h) breeding of patented animals.

4.3.9 Purpose/Swiss-type claims

Of particular relevance in pharmaceuticals is so-called purpose or 'Swiss-type' protection. This type of protection arose in recognition of the fact that some products, particularly pharmaceuticals, will have more than one effect.

One of the best-known examples of a medicine with multiple applications is Acetylsalicylic acid (acetosal), commonly called Aspirin, which was originally used for its analgesic, antipyretic and anti-inflammatory qualities (pain relief, fever reduction and reducing swelling), but was discovered many years later to also have antiplatelet qualities (thinning the blood).

Although there is no patent on the original analgesic application, the issue at stake is whether it would be possible to obtain patent protection for the later identified antiplatelet qualities (a second medical use for a known substance). There is therefore an important policy decision as to whether it should be possible to patent acetosal for blood thinning despite the fact that the substance was in the public domain (i.e. not subject to any patent protection) in relation to its analgesic, antipyretic and anti-inflammatory qualities.

This sort of claim is also sometimes called a **second medical use** claim (or 'Swiss claim'), but where it does not relate to medicine it is called a **use** or **purpose claim**.

In the context of gene sequences, the common term is 'purpose-bound protection'. In this case, if protection is bound to the use disclosed in the patent then the gene sequence remains available as a resource for other types of use; if not, then the identification of one use may give a de facto monopoly over the gene sequence itself. This may have important ramifications for developments in pharmaceutical patents in that the prescription and application of a medicine for a use not disclosed or claimed in the original patent may not constitute infringement (however, this is a developing and speculative area of the law). An additional concern in this context is that the protein for which a gene sequence codes must be identified and disclosed (along with its function in the body) in order for a patent to be available to this type of invention.

We will look at IP issues in relation to gene sequences in more detail in Module C of this course.

4.4 Supplementary protection certificates

Supplementary protection certificates (SPCs) are special kinds of intellectual property rights that are applied only in the fields of pharmaceuticals and plant protection.

Before new drugs and plant products can be put on the market they must be subjected to clinical trial and regulatory approval. This inevitably delays the use that the patentee can make of the product because it cannot be marketed. Thus, the monopoly that can be exploited is in effect shorter than the usual 20-year patent term, and so full advantage of the period of the patent grant is not possible.

SPCs are intellectual property rights that are based on, and similar in nature to, patents. They operate to extend patent protection where it has not been possible for the patent owner to take full advantage of their patent rights over the period of the grant. They are especially relevant where the owner has not been able to market the patented product because of delays in obtaining regulatory approval, as in drug approval.

In 1990 a formal Proposal by the European Commission led to two EU Regulations which created new rights relating to patents for medicinal products (Council Regulation (EEC) No. 1768/92 of 18 June 1992) and for plant protection products (Regulation (EC) No. 1610/96 of 23 July 1996). The former forms the basis for SPCs in the EU.

4.4.1 SPCs and extension of monopoly term

The right is characterised as distinct from that of patents in order to avoid the apparent conflict under Article 63 of the EPC (term of the European patent). Nevertheless, SPCs do in effect provide pharmaceutical patents with an extended monopoly.

4.4.2 Limited coverage of SPCs

SPCs are limited in coverage compared to the broad coverage of patents. Products protected by an SPC are usually defined by reference to their chemical or other ingredients and physical form or intended mode of delivery. A patent, on the other hand, would usually be much broader in coverage, and could in fact extend to a chemical per se or a combination of chemicals, a method of production, or a new medical

use of a known product. So where a single patent could in fact cover a range of individual medicinal or plant protection products, this would not be the case for a supplementary protection certificate.

4.4.3 Administration of SPCs

SPCs are administered in the UK by the Intellectual Property Office. Applications must be made within six months of receipt of authorisation to market the medicinal product or plant protection product. An SPC can provide protection for the 'product' covered by the authorisation and any use of the product as a medicinal or plant protection product that has been authorised before expiry of the SPC.

Limitations and obligations governing the rights granted under an SPC are the same as those applied to a basic patent. In consequence, an SPC may also be subject to compulsory licences (compulsory licences are examined in more detail in Module B of this course).

An SPC will come into operation at the expiry of the patent, subject to the requirement that the patent is maintained until the end of its potential term. If the patent is permitted to lapse or is declared invalid or is revoked, the SPC will not come into effect. The duration of protection will vary depending upon the time it took to receive regulatory approval. In other words, it will depend on the kinds of delays suffered by the applicant. The maximum time extension is five years.

In 2006 the European Commission revised the law on approval of paediatric medicine and one change made was to allow an additional six months of SPC protection for medicines in this area. Again, this protection would be awarded on the same basis as the standard SPC. These changes were introduced by Regulation (EC) No. 1901/2006 (see in particular Article 36).

Activity 4.2

Consider the intellectual property 'balance' in the context of SPCs. What arguments might support the effective extension of monopoly for patented medicines and what might be the possible issues for consumers and competitors?

Feedback: page 54.

4.5 Trade secrets and confidential information

The law of confidential information, or trade secrets, or breach of confidence, aims to protect owners of confidential information against unauthorised disclosure. The protection of trade secrets is required by Article 39 of TRIPS, which is based on the rationale that protection of trade secrets is part of the law on unfair competition. In some jurisdictions, particularly civil law countries, trade secrets are protected under unfair competition law. However, in common law countries trade secrets tend to be protected under a regime which is separate from unfair competition.

As one might expect, there will be many circumstances in the development of an invention in which the unauthorised disclosure of confidential information (such as testing information, or plans, or so on) would cause serious detriment to the inventors and possible loss of

the opportunity to patent the developments.

Confidential information can be relevant in a range of circumstances, but in all cases the disclosure of the information may result in a commercial or developmental loss. For example, confidential information or trade secrets may protect:

- mere information that would otherwise be unpatentable but is valuable as long as it is confidential
- patentable subject-matter (i.e. not mere information) that is nevertheless not patentable (for instance, small improvements may lack an inventive step but are otherwise valuable if protected by trade secrets)
- patentable subject-matter whose value if kept as a trade secret outweighs that offered by patent protection (e.g. the composition of a perfume)
- know-how (could be part of research and development or with regard to the current patent portfolio).

Other information, such as business information and methods, may also be treated by data protection laws (under EU law).[2] For example, these would be relevant if dealing with customer lists.

[2] *The Data Protection Directive: Directive 95/46/EC of the European Parliament and of the Council of 24 October 1995 on the protection of individuals with regard to the processing of personal data and on the free movement of such data.*

One of the distinct advantages of trade secrets is that the information can potentially enjoy protection longer than any patent term as long as it remains confidential. However, if disclosed, all commercial or other benefit may be lost and damages may never be adequate to recover the loss if such a disclosure occurs.

Another advantage is that, unlike patents, which require application and renewal fees to be maintained, there are no administrative costs as such in maintaining confidential information.

Importantly, it is not possible to enjoy dual protection as patents and trade secrets are diametrically opposed to each other in principle – patents must be disclosed and trade secrets must be kept secret. In the UK, if a person has been using an invention secretly for 20 years they may subsequently apply for patent protection and be granted the full term; secret use will not defeat the novelty of an invention. However, in the United States an applicant must elect between trade secret and patent protection: if an invention has been used for a period and then the inventor chooses to apply for patent protection, the application will deemed to be not novel.

4.6 Trade marks and public health

4.6.1 What is a trade mark?

The trade marks used by an organisation to identify its goods or services are one of its most important and valuable assets because they suggest to the world the source and the quality of the organisation's goods or services. Some commentators suggest that a trade mark reassures customers. In other words, when a customer makes a subsequent purchase of goods carrying the same mark, it is sometimes said that this reassures the customer that those purchases will be

of a similar quality and from the same source. This can be especially relevant in the area of pharmaceuticals, where customers will learn to 'trust' a particular product so that they maintain their loyalty to that product long after the expiration of the patent (for example Panadol as distinct from a generic paracetamol).

Therefore, it is undesirable for a competitor to start using one's mark – this can have implications for the customer information not only as to source but also as to quality if the competitor's goods are of inferior quality. Again, this can raise very particular issues in medicines, where counterfeit products appropriate the authentic product's mark in order to deceive the consumer.

A trade mark can therefore be defined as a means of identification. It has five primary functions:

- source
- quality
- distinction
- promotion
- competition.

In other words, a trade mark may be taken to mean that all goods bearing that trade mark come from a particular source. The trade mark therefore acts as a form of identification, for example that the goods are identified with a particular manufacturer.

Secondly, a trade marks implies a particular quality. This kind of function of a trade mark is something which will increase with subsequent purchases; it builds along with the goodwill in a product. To an extent, in this sense a trade mark provides some sort of information about the product. However, as we will see, in the area of medicines proprietors cannot incorporate generic names into trade marks as it would be inappropriate for this important information to be unavailable when describing generic versions of the patented product. Trade marks are important tools of marketing and branding, but they are not substitutes for labelling of goods and informing the public about other things that might influence their choice (such as active ingredients). We will come back to this point later, in the discussion of International Nonproprietary Names – that is, the generic name that cannot be subject to the private right of a trade mark.

Thirdly, trade marks are also important tools by which to distinguish one product from another, not only for consumers but also for competitors.

Fourthly, trade marks are important for promoting products. As will be seen, this can be significant in the area of over-the-counter medicines in particular as companies build goodwill in their product during its period of patent monopoly so as to enjoy a greater market share after the expiration of that monopoly. Where brand loyalty has been built in a particular product during the period of the intellectual property monopoly, that loyalty can continue to protect market share beyond the expiration of that monopoly. This is particularly apparent when looking at pharmaceuticals. Where the patent monopoly protecting a

drug has expired, the established reputation of its trade mark during the time when the monopoly was effective may well mean that it will continue to enjoy an advantage in the market even after the expiration of patent protection. Trade mark reputation can slow or, in some cases, even prevent the erosion of market share that usually follows the end of a patent's life.

Finally, and related to the functions of distinction and promotion, trade marks are important in ensuring competition in the market. Trade mark law assists in ensuring that customers are not confused or misled, and confusingly similar marks can be removed from the trade mark registry. Thus, trade marks can be important in ensuring against unfair trade practices.

4.7 Generic names or International Nonproprietary Names

In the area of pharmaceuticals, the system of International Nonproprietary Names (INNs) for pharmaceuticals shares similar principles of denying registration of information that is necessary to all competitors in the field and is necessary for all customers to make their decisions. All names are unique, nonproprietary, universally recognised and available as public property. INNs are also known as 'generic names'.

The modern INN system was established in 1950 by a World Health Assembly resolution WHA3.11. In 1953 it began operations and the first list of INNs for pharmaceutical substances was published. The cumulative list of INNs now includes around 7,000 names designated since that time. The list of names grows by around 120–150 every year, indicating also an increase in the utilisation of the system.

Activity 4.3

Read *Merck & Co* v *SmithKline Beecham Plc ('Jeryl Lynn' Trade Mark)* [1999] FSR 491. Consider the implications of this case in relation to INNs and attempts to register an INN as a trade mark.

No feedback provided.

4.7.1 International consumer safety and information

As with the general underlying principles of trade mark law, similarly the INN system is concerned with consumer information and safety and ensuring against confusion. The INN system means that each pharmaceutical substance is identified by a unique and universally available name. Each name must be genuinely unique, distinctive in sound and spelling and not likely to be confused with any other names in common use.

INNs for pharmacologically-related substances also indicate that relationship by using a common 'stem'. Pharmaceutical products sharing a common stem can then be recognised by pharmacists, medical practitioners and others as belonging to a group of substances with similar pharmacological activity.

Medical practitioners and other healthcare workers have access to this basic information on every product. As an international nomenclature

for pharmaceutical substances, the INN system makes it possible to prescribe and dispense medicines safely no matter which branded product is used. This also assists in the clear identification of generics which enter the market and compete after the expiration of the patent on the original product. Importantly, as an international system it assists with the delivery of safe and effective information worldwide.

To facilitate international availability, the names are designated as nonproprietary – in other words, they are genuinely in the public domain to be accessed as universally available public property. To achieve this objective, the WHO formally places the names in the public domain to be used without any restriction whatsoever to identify pharmaceutical substances in pharmacopoeias, product labelling and information, drug regulation, scientific literature, advertising and of course for generics.

4.7.2 INNs and trade marks

> The procedure for selecting INNs allows manufacturers to contest names that are either identical or similar to their licensed trade-marks. In contrast, trade-mark applications are disallowed, in accordance with the present procedure, only when they are identical to an INN. A case for increased protection of INNs is now apparent as a result of competitive promotion of products no longer protected by patents. Rather than marketing these products under generic names, many companies apply for a trade-mark derived from an INN and, in particular, including the INN common stem. This practice endangers the principle that INNs are public property; it can frustrate the rational selection of further INNs for related substances, and it will ultimately compromise the safety of patients by promoting confusion in drug nomenclature.
>
> (Fifth Report of the WHO Expert Committee on the Use of Essential Drugs, 1991)

The relationship between the INN and the trade mark on product labelling is very important. Furthermore, the distinction between trade marks and INNs or generic names must be preserved in order to maintain the utility of the INN. Measures in various jurisdictions have included mandating a minimum size for the INN which must be printed under the trade-mark labelling and advertising; requiring the INN to be at least half the size of the proprietary name on the labelling; and requiring the INN to be larger than the proprietary name. Most importantly, in all cases the trade mark cannot be derived from the INN and must not include the common stem. This is critical in order to guard against confusion and so protect the safety of consumers. In Europe the relevant legislation can be found in Directive 2001/83/EC of the European Parliament and of the Council of 6 November 2001 on the Community code relating to medicinal products for human use as amended (the Medicinal Products for Human Use Directive).

The rights of existing trade mark owners are given due regard in the process of selecting new INNs, and interested persons are entitled to file formal objections during the selection process of a new INN if they believe that the proposed INN will conflict with an existing trade mark. The WHO will not recommend an INN in the face of such an objection,

and will try to resolve the objection or reconsider the name.

4.7.3 The selection of INNs

The WHO is responsible for determining INNs in consultation with experts from the WHO Expert Advisory Panel on the International Pharmacopoeia and Pharmaceutical Preparations.

For a new INN, a request or application is made by the manufacturer or inventor. The request is reviewed according to a strict procedure examining for similarities with published INNs and trade marks and then forwarded to the INN experts for comment.

Once a name is agreed, the applicant is informed and a proposed INN is then published in *WHO Drug Information* for comment or objection for an objection period of four months. In case the name has to be reviewed or modified after this period, the proposed name is not to be used until it is given the status of a recommended INN.

If at the end of that period no objection has been made, the name will be published with the status of a recommended INN and is unlikely to be modified further. Therefore, once published as a recommended INN it is immediately available for use in labelling, publications and drug information in order to provide universal identification of the active pharmaceutical substance.

INNs are not given for herbal or homeopathic products, nor for products with a long history of used under a well-established name (for instance, morphine) or trivial chemic names. Some of the radicals and groups are given a shorter nonproprietary name which, when used with an INN, is referred to as an International Nonproprietary Name (Modified), or INNM.

4.7.4 The international system

The WHO sends list of proposed and recommended INNs to all 191 member states as well as national pharmacopoeia commissions and other bodies designated by members, together with a note from the Director-General requesting members to take the necessary steps to prevent the creation of private proprietary rights in these names. This of course includes the prohibition of registration of the names as trade marks.

The US, UK and Japan all have organisations to oversee nonproprietary drug nomenclature, each of which publishes national names (for example, British Adopted Names, or BANs). However, these national publications are becoming less relevant and the majority of pharmaceuticals are usually identified by an INN, thus avoiding the problem of different generic names in different countries. The law in Europe is harmonised by the Medicinal Products for Human Use Directive. There has been adoption of INNs across the EU and the Directive means that even those countries with their own national organisations, including the UK and BANs, will generally adopt INNs as published by the WHO.

4.8 Comparing EU and various national systems

A full list and 'map' of the EU Directives and Regulations relevant throughout this course can be found in the set textbook. Comparative discussion will occur throughout the four modules of the course; at this stage, you just need to understand the relevance of comparative discussion and to note the selected jurisdictions and key laws that will require particular attention. More detailed comparative discussion is available in the textbook, but summaries of the jurisdictions selected for comparison are provided here. These jurisdictions have been selected because of their relevance to the selected case studies in various modules of the course and also because of their significance more generally for international debates on intellectual property, innovation, access to medicines and public health. The jurisdictions to be examined in further detail are:

- United States
  - Patents Act 35 USC
  - Patent and Trademark Law Amendments Act 1980 (the Bayh–Dole Act)
  - Drug Price Competition and Patent Term Restoration Act 1984 (the Hatch–Waxman Act)
  - Subchapter A and Subchapter B of Chapter V of the Food, Drug and Cosmetic Act, 21 USC (priority review voucher)
  - Medical Innovation Prize Bill 2007 (prizes for medical innovation).
- Canada
  - Canada's Access to Medicines Regime (CAMR).
- People's Republic of China
  - Patent Law 1985
  - Traditional Chinese Medicine Database.
- India
  - Indian Patent (Amendment) Act 2005
  - data exclusivity protection
  - exclusive marketing rights.
- South Africa
  - South African Medicines and Related Substances Control Amendment Act 1997.
- Thailand
  - Thai Patents Act 1979 (as amended).

These selected jurisdictions will be considered in greater detail in case studies in the other modules in this course. For example, India is an important example of a developing country with significant production capacity in pharmaceuticals and has been the subject of recent challenges in the area of pharmaceutical patents.

Reminder of learning outcomes

By this stage you should be able to:

- explain the basic concept of a patent, including the patent monopoly
- discuss the basic principles underlying the patent system, including the duty of disclosure
- explain in outline how the patent system developed
- identify the basic principles of the UK patent system
- explain what supplementary protection certificates are and how they function
- explain trade secrets and confidential information and their relevance for industries in these fields of technology
- understand and explain trade marks and the system of International Nonproprietary Names (INN).