

# **THE ASSOCIATION OF THE BRITISH PHARMACEUTICAL INDUSTRY**

## **RESPONSE TO THE GOWERS REVIEW OF INTELLECTUAL PROPERTY CALL FOR EVIDENCE**

### Summary of ABPI position

- ABPI welcomes the Gowers review of intellectual property
- The pharmaceutical industry's involvement with IP lies primarily with patents in relation to development of new medicines, but trade mark protection, copyright and design protection are also important.
- ABPI takes the view that the current IP systems in both the UK and the EU (for the UK system cannot be viewed in isolation) generally achieve the aim of protecting innovation and promoting the development of new concepts
- Any proposals for change to the IP system which emerge from the review should be made subject to detailed evaluation and consultation prior to implementation to ensure that change is beneficial and well understood
- IP can play a significant role in attempts to limit or prevent counterfeiting of medicines, and thus obviate risks to public health which might otherwise arise through such unlawful practices

### General Questions

#### **Question 1 – How is IP awarded?**

##### **1(a) and 1(b)**

As the question posed suggests, the IP system can appear a complex one. Large companies whose staff deal with IP on a regular basis are unlikely to find the complexity a barrier to obtaining IP rights. However, SMEs and private inventors may find the system daunting at first instance and feel obliged to call upon professional advice.

For the pharmaceutical industry, it is generally the case that patent rights are obtained on a European or even international basis. Our members have generally not encountered serious and regular problems in relation to either of those routes and the systems tend to work efficiently on the whole.

The website of the UK Patent Office (PO) is a very informative tool for both large and small companies alike and the assistance which the PO staff are able to provide is welcomed. Generally speaking the trade mark system is straightforward, and so too is obtaining design rights in the UK.

Difficulties can arise, however, if a company wishes to obtain design rights in a number of countries since the position can vary and ascertaining the differences can be time-consuming and costly.

ABPI takes the view that those organisations which do not regularly apply for IP rights will not always be aware of the importance of obtaining rights not just domestically, but internationally as well. UK plc would benefit if this advice could be stressed to prospective inventors, and this could be done using the PO website and through periodic publicity campaigns.

### **1(c) and 1(d)**

ABPI members do not consider that there are barriers to obtaining UK IP rights on the grounds of costs. Any reduction in the level of cost is likely to lead to a cut in the service provided by the UK Patent Office and this is not felt to be desirable.

### **1 (f)**

For a system to be perceived as trustworthy users must be satisfied that applications are properly evaluated and scrutinised and that enforcement is robust.

In terms of patents, ABPI members are satisfied that the standard of search and examination of applications in both the UK Patent Office and the European Patent Office (EPO) is quite high. In assessing whether the subject matter of an application is considered 'non-obvious', ABPI is of the view that the standard should not be set so high that meritorious applications are denied since this would have the effect of deterring development and investment. The current standard applied in this regard by the Patent Office appears to be broadly correct.

In terms of trade marks, ABPI is aware that the Patent Office is currently consulting on whether to move towards the standard adopted by the Office of Harmonisation for the Internal Market. The test applied by OHIM appears to be less onerous than that applied by the Patent Office and ABPI would see such a move as a retrograde step since the PO examination of new trade mark applications on the basis of their potential conflict with earlier trade mark applications/registrations is generally seen as providing a high presumption of validity.

In terms of design rights ABPI notes that there is no formal means in the UK for conducting a substantive examination of an application for a registered design and this means that the Patent Office is unable to endorse validity. This is a weakness in the system. Looking towards the EU, a further problem arises because some jurisdictions award a design right but do not limit it by indication of a product or classification with the consequent effect that to determine a position with any certainty requires engaging specialists, at cost.

### **1(g)**

Although more closely related to retaining, rather than obtaining IP rights, a number of ABPI members have reported that where they wish to have an article published in a prestigious peer review journal they will usually be required to assign any IP in that article to the journal concerned. In some instances that IP will then be licensed back to the company concerned by the journal, but the need to part with title in the IP at all is questionable.

### **1 (i)**

ABPI members' view is that the PO and the EU system generally work well.

In relation to patents ABPI would express some concern about the time which is taken in the EU procedure in relation to Oppositions, where patents are argued to be wrongly granted, and any appeals from such proceedings. Member companies have experienced periods of 4 to 5 years for such matters to be determined which gives rise to considerable commercial uncertainty for all involved.

In relation to trade marks ABPI is content with the way in which the UK Trade Mark Registry operates, being both helpful and efficient in its processes. Its EU counterpart, which operates through OHIM, does show signs of inconsistency from time to time in the way in which it deals with unusual trade marks which can cause uncertainty for applicants moving forward.

## **Question 2 – how is IP used?**

### **2(a)**

Pharmaceutical companies rely on all types of intellectual property rights to protect the investment which is made in the development of medicines, currently in the order of £9m per day. As such companies use patent, trade mark, registered design, unregistered design and copyright.

### **2(b)**

Different IP rights provide different forms of protection. In the pharmaceutical industry companies will often apply for several different types of IP protection in respect of the same product. A typical list might be:

- A patent application for a specific formulation
- A design right in respect, for example, of the shape of the tablet, or appearance of the product, or an aspect of a delivery device
- A trade mark application to protect the name of the product, and possibly other aspects of the appearance of the packaging
- Copyright in relation to packaging and patient information leaflets

### **2(c)**

Companies will determine which IP to apply for dependent upon the particular circumstances of the product. Companies will ensure that their applications are sufficient to cover all appropriate aspects of the product.

### **2(e)**

The duration of an IP right is something which companies take into account in considering investment decisions. Given the cost, and the risks, of development of pharmaceuticals the duration of IP rights is a key factor.

### **2(f)**

ABPI takes the view that the UK IP system generally works well and that both it and the EU system promote a healthy balance between promoting innovation whilst at the same time not preventing the dissemination of knowledge.

IP, however, is not the sole factor which promotes innovation, which can be influenced by a number of other factors ranging from education and research to political climate.

### **2(g)**

ABPI members encourage innovation through a variety of government funding schemes, including

Faraday Partnerships  
Knowledge Transfer Partnerships  
DTI Technology Programme

### **2(j)**

ABPI members report that defensive use of patents and other IP rights is rare in their experience and companies are aware of provisions in the UK Patents Act and the Trade Marks Act 1994 that prevent such activity.

In the pharmaceutical sector it is not uncommon for a company to file a number of patent applications early on in a research programme due to the uncertain nature of how a drug may be developed during research. However, as research progresses the number of options will necessarily be reduced. The industry will then protect the specific medicine and any appropriate back-up compounds.

Whilst members have not raised concerns in relation to trade marks, they are aware that this is due in large measure to the standard of vetting which is applied by the Patent Office and similar bodies. Any weakening of that process would render easier for questionable applications to be processed.

### **Question 3 – how IP is licensed and exchanged**

#### **3(a)**

In general terms, ABPI members report that negotiation of IP licences are treated like other commercial negotiation transactions and that they do not give rise to any greater or lesser difficulties. However, negotiations with small organisations can give rise to problems, particularly where (due to lack of understanding or commercial insight) IP rights are taken out in fewer jurisdictions than appropriate, which means that issues arise in relation to the cost of extending that protection; and assessing the value of only limited patents.

In order to ensure that companies do not inadvertently breach a third party's copyright, pharmaceutical companies do encounter some administrative difficulty. Companies can choose to approach publishers direct for permission to use their materials (which can be a costly and time-consuming process) or they can approach a collecting society, such as the Copyright Licensing Agency, which represents multiple (but not all) publishers for a suitable licence. As the CLA licence will often be taken out by companies as a 'fail safe', it can often prove to be the case that publishers will enjoy multiple revenue streams for the same content.

#### **3(c)**

Members do not report issues in relation to the research exemption. Although this has given rise to additional cost in many instances, the nature of the exemption is relatively clear cut. ABPI would not be in favour of any change in the law in order to try and clarify the exemption since it believes that any such attempt is likely to adversely affect the ability of the courts to judge matters on the facts presented on a case by case basis.

#### **3 (d)(e)(f)(h) and (i)**

ABPI members report that the greatest barrier to licensing occurs where multi-jurisdictions are involved. This is because:

- Different jurisdictions (whether inside or outside the EU) do not always operate the same legislation in respect of IP protection which can give rise to the need for specialist advice, and hence cost
- Competition law, which is applicable to collaborative research, can be applied in different ways in different jurisdictions, giving rise to uncertainty about the likely impact on proposed relationships

In terms of collecting societies, it is ABPI's experience that because the scope of licences of collecting societies in the USA and in the UK are different, mutual recognition and licencing of materials is rendered more difficult, and sometimes impossible.

### **3(l)**

Whilst ABPI is aware of legislative provisions which allow for compulsory licensing, it is not aware of any recent instances when compulsory licensing has been called into play. This would indicate that the IP system is working as was intended, and that recourse to compulsory licensing is not required.

## **Question 4 – how IP is challenged and enforced**

### **4(a)**

The main means of enforcing IP rights is by litigation. There is no aspect to IP litigation which presents particular barriers to enforcement of rights

### **4(b) and (f)**

IP litigation, like any other form of litigation, can be both time consuming and costly. IP litigation varies from other counterparts in that the content will be factually complex and the potential gains/losses arising from such litigation can be commercially very significant given the costs of medicine development; the number of medicines which never reach the market; and the value of the product should it reach the market.

The introduction of the 'Woolf Reforms' has led to better and more prompt case management systems which have served to ensure that litigation costs generally are better controlled, without distorting the court's ability to consider all necessary facts and other evidence in coming to a determination of the issues.

The litigation system generally works well as a means of enforcement. ABPI would not be in favour of any change in the litigation process which reduced a court's ability to have full facts put before it, or reduced the parties' ability to examine and respond to the opposition case in full. A would-be litigant who is unable to fund litigation, but nevertheless has a reasonable case, should be given access to an appropriate funding channel.

### **4(h)**

ABPI members believe that the greatest barriers to efficient and successful challenge and enforcement internationally will be:

- cost (especially relevant for SMEs) and quality of enforcement litigation in the United States; and
- the quality of enforcement processes, and the available remedy

## **Specific Issues**

### **1. Pharmaceutical Supplementary Protection Certificates (SPCs)**

Pharmaceutical companies, including ABPI members, make use of SPCs.

It can take up to 12 years for a pharmaceutical product to be brought successfully to market. As such, a company's return on its considerable investment may not materialise until late into the patent term. SPCs are a necessary part of IP protection for pharmaceutical products. SPCs are granted to extend the term of protection on the active ingredient in the patented product and compensate for the time required to obtain regulatory approval for the product. Without SPCs some products would not make a return.

ABPI suggests the following improvements to SPCs:

- Deletion of the cap of 5 years, and allow a compensatory period equal to the full period of delay between grant of IP rights and regulatory approval.
- Allow active ingredients to benefit from more than one SPC. This approach is adopted in a number of countries, and a flexible approach was recently recommended in a case before the European Court of Justice at Opinion stage. Policy should clearly encourage innovation and maximise incentives.
- Rationalisation of the basis for calculating the term of SPCs would provide business certainty in Europe. Adoption of the Swiss MA as the basis for this calculation has served to erode the effective term of protection for products across all 28 EEA States. An example is a product approved by the EMEA 8 years after its patent application is filed – the product would receive a 3 year SPC throughout the EEA. However, if the Swiss health authorities approve the product after only 5 years, no SPC will be available. Since the system was designed to compensate for EU regulatory delays, this is inappropriate.

The EU is currently considering a proposal in respect of paediatric medicines. Under that proposal, most new medicines will need to be assessed by studies to ascertain if they are suitable for children. A 6 month extension of the SPC is proposed by way of incentive. Whilst the proposal is welcomed in principle, it suffers from two serious flaws: (1) the SPC extension would only be available if there is a current SPC, and is not to be available for products which have no SPC (namely where they have been brought to market quickly); and (2) the extension will only be available if the product has been authorised in all Member States, despite the fact that current SPCs are granted on a national basis without a need for total EU authorisation. ABPI continues to lobby for change in both areas, but has not been successful to date.

## **2. Trade Marks – international issues**

The trade mark system generally works well both at UK and EU level. However, there remains inconsistency in the way EU law is applied and steps to reduce this would be welcome.

## **3. Legal Sanctions on IP infringement**

ABPI is of the view that the sanctions available for infringement of IP rights are generally acceptable, but that enforcement of those sanctions can present issues. ABPI would **not** support the introduction of criminal sanctions for patent infringement.

## **4. Parallel imports and international exhaustion**

EU case law recognises parallel trade as a legitimate form of commerce where parallel importers do so within the bounds of the law. Parallel trade arises where national governments fix the prices at which pharmaceutical companies may place prescription medicines on their national markets, and parallel traders trade products which are cheaper on one market onto another, higher priced, market. The business is in effect an arbitrage but:

- In the UK market does not provide a benefit to the patient or purchaser, only to the parallel trader
- Leads to lost sales revenue for UK based pharmaceutical companies which then reduces the amount of money available for research and development of new products
- Can give rise to safety concerns about medicines (complexity of product recalls should that be necessary; imports of foreign-language packs from abroad giving rise to possible misunderstanding by the patient; risk of counterfeit products entering a supply chain which is no longer controlled by the manufacturer,etc.)

ABPI is opposed to any switch from Community exhaustion of trade marks to international exhaustion.

## **Other Issues**

### **1. Archiving**

ABPI is concerned about the cost which can be incurred by companies in seeking archive copies of journals and other materials when a publisher has gone out of business. Such copies can be obtained from the British Library, but for a fee. ABPI believes that publishers should be obliged to keep their own archive and to make this available in the event of the demise of their business to any subscriber for the period of the subscription concerned.

### **2. Digital Rights Management**

ABPI is also concerned that application of digital rights management can serve to take away the rights which might be held under another licence. For example, if the British Library sends an applicant a copy of an article, the rules of the British Library mean that it can only be printed off once before it is lost from the recipient's computer system. This is in contrast to the CLA model licence, which would allow such a licensee to make further use of that copy.