

Gowers Review of Intellectual Property – Call for Evidence

AstraZeneca is one of the world's leading pharmaceutical companies, dedicated to the discovery, development, manufacturing and marketing of high quality, effective prescription medicines that bring benefit for patients and wider society.

We employ around 12,000 people in research and development at 11 R&D centres in seven countries including two major R&D centres in the UK, three major R&D centres in Sweden, two in the USA and one in France. In total, we employ over 65,000 people worldwide with over half of these in the European Union.

Our R&D Budget for 2005 was \$3.4 billion. The vast majority of this is spent in researching for new medicines and bringing new medical entities through the long development process of typically 10-12 years to market.

With such a major commitment to R&D, we value Governments which put in place frameworks including a well-functioning patent system, that will serve to stimulate and foster an environment of innovation and competitiveness. Simply, without an effective IP framework to support and protect innovation, our business would not exist to provide life-enhancing pharmaceuticals to patients.

Our responses to the general and specific questions set out below are given from our perspective as a major pharmaceutical company. Pharmaceutical research requires substantial long-term commitment to continued investment in R&D and infrastructure. It takes over 10-12 years to develop a new medicine and the patent system is an essential underpinning to the necessary innovative and creative R&D process which provides these new medicines.

Whilst we do not specifically comment on areas of less relevance to AstraZeneca, we do support provisions to support creativity and innovation in all industry sectors.

GENERAL QUESTIONS

1. How is IP awarded?

1(a) : Are there barriers to obtaining IP rights due to system complexity? What could be done to improve this situation?

Intellectual Property law and practice has evolved over hundreds of years, on a national, regional and global scale. The IP system has shown itself to be sufficiently flexible, by and large, to cope with dramatic changes in technological advances in society over the centuries. There are complexities, as with any law, but these are not a barrier to us.

1 (b) : How easy is it to find out about obtaining IP rights? What could be done to improve awareness for businesses and innovators? Is there sufficient awareness of the need to protect IP internationally?

We are very aware of how to obtain IP rights internationally. We believe that continuing efforts need to be made to encourage SMEs, academia and individual innovators to be aware of the benefits, both national and international, of the IP system for them. The UK Patent Office is particularly active in this regard and we encourage greater resources for them to continue to take the lead in this important respect.

1 (c) : Are there barriers to obtaining UK IP rights on grounds of cost? What drives these costs?

We seek IP rights on an international basis and costs in the UK are not a significant factor.

1 (d) : How do these costs compare internationally in your organisation's experience?

We are content with the comparative position of the UK.

1 (e) : Do you have any comments on the UK Patent Office fees structure for obtaining and renewing IP protection?

We are content with this.

1 (f) : Is lack of trust in the system a barrier? To what extent do you rely on other tools to bring innovation to the marketplace, such as being first to market, maintaining trade secrets, or using an open innovation model to generate value through reputation or network effects?

Trust in the system is absolutely fundamental for our industry. We have very long lead times between innovation and marketing. The typical investment to get a compound from test tube to market is quoted to be over \$800 million with the investment for some newer medicines predicted to be as much as \$1.5 billion. These enormous investments are only justified if there is the confidence of generating a return on the investment. The return on investment is protected by the IP system.

Therefore we need to trust the system. We have two paramount needs:

- a good quality system that provides good quality IP rights in the first place
- a good quality system for enforcing those IP rights

We do rely on trade secrets. We do rely on government regulations preserving confidentiality, and granting exclusive use, of commercially sensitive data for example that provided to support marketing approval. We do not believe that open innovation models are helpful in our sector.

1 (g) : Are there specific barriers to obtaining IP rights in your sector?

Not in general. Specifically, the patent law excludes the patentability of methods of medical treatment. Some innovations are directed to a new way of using a known medicine. To develop these innovations safely to the market can require considerable investment. The law constrains the manner in which we can protect such innovations.

We enclose a link to an article from the internet that reports comments from Mr Justice Jacob in the case of Teva et al. v. Merck et al.

www.olswang.com/pdfs/patent_protection_jul03.pdf

1 (h) : Are there specific barriers to obtaining IP rights for small businesses or individuals?

No specific comments

1 (i) : How well does the national system for awarding IP, administered by the Patent Office perform? How well do the international and European systems work?

We generally obtain IP rights via the European Patent Office (EPO) and OHIM (the European Trade Mark Registry). We are generally content with the performance of the EPO but wish to make the following points:

- Examiners must not sacrifice quality for speed. There are political pressures to speed up the granting of rights. These pressures must not lead to any lessening of quality. In fact, the EPO should be striving to increase quality.
- Competitors can challenge granted patents at the EPO via an Opposition procedure often followed by an Appeal procedure. Whilst this works quite well, in general, decisions are too slow and efforts must be made to speed up the procedures whilst maintaining quality.

2. How IP is used?

2 (a) What types of IP does your organisation use and why?

We use most types of IP, in particular patents, trade marks, designs and copyright.

2 (b) To what extent do you seek multiple overlapping forms of IP protection?

Most innovations embody different types of IP; eg an inhaler may have a technical patentable, improvement; it may have a distinctive design, it will have copyright protection and typically will have a trade mark associated with it.

We seek IP on almost all aspects of our innovations.

2 (c) To what extent are these decisions influenced by sector-specific considerations?

The pharmaceutical sector is particularly dependent on the know how and technical knowledge needed to invent and develop a new medicine. This involves the collaboration of hundreds of skilled professionals, for example biologists, chemists, biochemists, process chemists, formulation scientists, pharmacists, toxicologists, doctors, etc over 10-12 years of R&D. The ultimate product is relatively easy to copy so we tend to seek IP on almost all aspects of our innovations.

2 (d) How does your company value its IP? Are there problems with raising finance against intangible assets based on IP? What improvements could be made in this area?

IP is fundamental to our business and, as such, is invaluable. The strength of our company and continued investment depends on robust IP protection which is fundamental to innovation for patient benefit.

2 (e) To what extent does the term of IP rights at the margin affect investment decisions?

IP is critical to investment decisions. As mentioned above, from test tube to market can take 10-12 years or more and typically costs \$800 million (and rising). Once patent (or equivalent protection) expires, legitimate competitors can enter the market without incurring anything like the same level of investment. Thus, the term of effective patent rights (including effective patent term extensions such as Supplementary Protection Certificates) is fundamental. If the term is insufficient, the investment is simply not made.

2 (f) : How well does the UK IP system promote innovation?

We believe that the IP system promotes innovation. However this is only one angle. The European Community has professed that it wants to be a competitive knowledge-based society according to the Lisbon Agenda. This aim is increasingly vital as the USA increases its technical and economic lead over Europe and newer Asian economies such as China and India are now world players with vast potential. To succeed, the EU should foster and support underlying research and development allied to innovation-friendly measures.

2 (g) : To what extent does your organisation make use of other methods used by Government to encourage innovation, such as public funding?

The pharmaceutical sector is the one of the highest spending sectors in R&D, if not the highest spending sector, in the UK. We consistently top the DTI R&D scorecard. We participate in, and support, Government funded schemes to encourage innovation eg DTI link programmes; we do not receive direct public funding ourselves.

2 (h) : Are data on the use of patents and other forms of IP useful as a means of measuring innovation?

To a certain extent. However, the main criterion is success in bringing a new medicine to the market.

2 (i) : Do you have any evidence as to the static or dynamic costs that IP rights (as statutory monopolies) impose on the economy?

We believe that a strong, innovative industry, based on IP, brings enhanced economic success and employment to society.

2 (j) : Have you encountered patents or other IP rights being used defensively, i.e. obtained not to develop products, but only to prevent others from doing so? Under what circumstance do you consider this acceptable?

Pharmaceutical companies typically file for patent protection earlier in the R&D process and certainly before publication of the compound through clinical trials, etc. There is a high rate of project termination in our industry; less than 1 in 10 compounds entering development reaches the market 10 - 12 years later. [To put this in even more perspective, many hundreds of compounds are synthesised and tested before one is selected to enter development] This means that the typical patent portfolio contains many patents and applications that are unlikely to cover a marketed product. However, companies tend to allow most of such patents to become abandoned.

3. How IP is licensed and exchanged?

3 (a) : How easy is it to negotiate licences to use others' IP for commercial or non-profit purposes?

We experience no inherent difficulties in negotiating licences and contracts involving IP.

3 (b) : What mechanisms do you use for finding potential licensing partners?

All companies in our sector have global mechanisms; these vary in detail.

3 (c) : How easy is to use others' IP for research purposes? Have you experienced difficulty around research exemptions?

We believe that the law provides sufficient clarity on the first question.

With regard to the second question, we are well aware of the recent introduction of the so-called 'Bolar' exemption into UK law. This follows the EU Directive on Medicines legislation. Before the introduction of the Directive, Member States had differing legal case law on research exemption, for example Germany had a liberal approach exempting many preparative acts by innovators and copiers from infringement. With the introduction of the harmonising EU Directive, different

Member States adopted different legal provisions; some introduced statutory language exempting preparative acts by just copiers, others introduced statutory language exempting preparative acts by copiers and innovators. This has led to an uneven playing field within Europe which does not help innovative industry in the UK.

3 (d) : Are there specific barriers to licensing in the main forms of IP currently used: patents, copyright, trade marks, and designs?

We refer to our answer to 3(a).

3 (e) : Are there barriers to licensing IP on grounds of costs? What drives these costs?

IP licensing may be more complex and protracted than many other forms of licensing and this may lead to higher transaction costs. However, such higher costs are usually understandable in view of the complex legal and technical considerations in settling an agreement which will often last for 10-20 years.

Taxation: On the taxation front, a new tax regime for intellectual property was introduced in 2002. Under the new rules, tax relief is available for amortisation on capitalised intellectual property. The change was designed to simplify the rules in this area and also broaden the scope of intangibles on which tax relief could be claimed, a change that was welcomed by AstraZeneca.

However, in cases where tax relief was available under the old tax regime, the impact of the new rules has been, in a majority of cases, to delay the time at which a tax deduction can be claimed. This impact is likely to become more pronounced as the UK accounting standards converge with International Accounting Standards which require more intangibles to be capitalised and at an earlier point in time. Tax relief could therefore be delayed for several years where relief was previously obtained in the year of the expense. For AstraZeneca, the post tax cost of purchasing intellectual property in the UK has actually increased as a result of the new regime.

In a number of other countries, tax relief is available from the date expenditure is incurred whereas in the UK it becomes available when the IP is amortised in the accounts. Typically, within our industry this is when a product is launched and therefore there can often be a long period of several years before any relief can be claimed.

We comment further in section 3 (i) below.

3 (f) : Are there specific barriers to licensing IP in your sector?

We have no particular comment on this.

3 (g) : Does your organisation use methods to facilitate exchange of IP – such as cross-licensing or pooling IP rights with other firms or organisations?

We are members of various Research Consortia and, as such, we share our IP in agreements with other research companies. These Research Consortia typically focus on pre-competitive research.

3 (h) : Are there specific barriers to licensing IP rights for small businesses or individuals – for example barriers to entry to patent pools?

We are not in a position to comment.

3 (i) : Are there barriers to trade and exchange of IP internationally?

Taxation : Tax legislation introduced in 2005 potentially restricts double tax relief in the UK for foreign tax suffered on overseas royalty receipts (withholding tax).

Under the new rules, where a company suffers overseas tax on royalty income, the trading profit associated with the arrangements must be examined to determine whether relief can be obtained in the UK for the foreign tax. For example, a company that has in-licensed IP in return for a royalty payment and subsequently sub-licenses some of these rights, would be required to calculate the net trading income arising from the arrangement, i.e. after allocating overheads and financing costs, to determine if relief is available, as illustrated below:

	£m
Royalty income	100
Royalty expense	(50)
Other expenses – admin	(30)
Operating margin	20
Tax @ 30% on operating margin and so level of withholding tax recoverable	6
Actual withholding tax suffered (100 x 10%)	(10)
Loss of withholding tax and so cost to company	4

We believe that these rules can penalise genuine commercial transactions and in the case of a multi-national company, may act as a disincentive to acquiring IP in the UK when there are more attractive locations elsewhere within the group.

3 (j) : Does your organisation consider renewing patents using “Licence of Right” provisions in patent law (which entitle any person to a licence under your patent and reduce your renewal fees by half)??

We do not use this provision. As alluded to in 2 (j) above, most companies review their patent portfolio on a regular basis and abandon patents of low interest.

In addition, AstraZeneca does receive enquiries for licences under our patents which we carefully consider; and we also identify patents for possible out-licensing.

3 (k) : What could be done to improve “Licence of Right” provisions and business awareness of them?

No particular comment.

3 (l) : Do you have any experience of the compulsory licence provisions within current patent law? Are they effective? How could they be improved?

There is provision in the UK law for compulsory licences to be issued in a range of situations as a remedy for abuse of monopoly rights. There is a similar provision providing the Government with powers (‘Crown Use’). The use of these provisions is exceedingly rare and should remain exceptional.

4. How IP is challenged and enforced?

4 (a) : Are there specific problems with enforcing the main different forms of IP: patents, copyright, trade marks, and designs?

We mentioned above that quality is paramount – quality of obtaining IP rights and quality of the enforcement process.

UK patent litigation is expensive, often because of the need to consider complex technology and associated fact finding, and is generally good. Recent efforts have been made to simplify and accelerate procedures. We support these and other efforts provided that quality is not adversely affected.

4 (b) : Are there barriers to challenging infringement and enforcing your IP rights on grounds of cost? What drives these costs?

Whilst we welcome any reduction in costs associated with litigation, this must not be at the expense of any reduction in quality and rigour.

4 (c) : To what extent does your organisation make use of other methods than litigation to resolve IP infringement cases, for example the Patent Office opinion service, mediation services, alternative Dispute Resolution, or the Copyright Tribunal?

We have Alternative Dispute Resolution and/or mediation services in certain of our agreements but we do not consider that the use of such methods is useful for resolving typical IP infringement disputes.

4 (d) : To what extent do you use IP litigation insurance? How effective is it?

We do not consider IP litigation insurance to be particularly effective for our industry sector.

4 (e) : Are there barriers to using such methods to settle IP disputes without recourse to litigation? How might they be removed?

We refer to our answer to 4(c) above.

4 (f) : Are there specific barriers to challenging and enforcement of IP rights for small businesses or individuals?

We surmise that the cost of IP litigation is a significant barrier for SMEs and may well be a significant disincentive to pursue certain business activities.

4 (g) : To what extent is the risk of litigation a factor in your organisation's investment in innovation?

Risk is ever present in our industry; there is a low chance of success in getting a compound from test tube to market. There is an increasing trend for generic companies to challenge the patents covering our products. However the risk of IP litigation does not influence our decisions on our investments.

4 (h) : What are the principal barriers to efficient and successful challenge and enforcement internationally?

We are a global business operating in all major countries. We seek return on our investment and therefore depend on good quality patent protection for our innovations and good quality enforcement procedures.

SPECIFIC ISSUES

Current term of protection on sound recordings and performers' rights

We have no particular comment on this.

Copyright

- **Copyright exceptions – fair use/fair dealing**
- **Copyright – digital rights management**
- **Copyright – orphan works**
- **Copyright – licensing of public performances**

We refer to the submission of the Association of British Pharmaceutical Industries (ABPI) to which we have contributed. We have no separate comment on these issues.

Patents – Utility Models

- (a) Do you have a view on some sort of second tier patent system?**
(b) Has your organisation encountered problems in protecting its IP internationally where such systems exist?

Several countries in the EU have Utility Model systems. We do not believe that these systems offer significant benefits for industry, including our own sector. On the contrary, we are concerned that the proliferation of inexpensive, unexamined rights will lead to increased complexity and uncertainty for rights holders and for competitors.

Pharmaceutical Supplementary Protection Certificates (SPCs)

- (a) Does your organisation use SPCs?**
(b) How fair and effective are they in delivering an incentive for investment?
(c) How could they be improved?
(d) Should the term of SPCs be more flexible – perhaps relating straightforwardly to the period between patent award and regulatory approval?

All of our products require long periods of R&D as mentioned above. Therefore, we are eligible for SPCs on most of our innovations and therefore we use SPCs.

The extension of patent term due to regulatory delay is a fair mechanism for delivering the necessary incentive for continued investment into new medicines.

We propose some improvements which we would be prepared to discuss in greater detail:

- Patentees aim to obtain marketing approval in a safe and effective manner as soon as possible; this can take for example 8 -12 or more years depending on circumstances and challenges. The SPC regulation provides that the SPC should expire a maximum of 15 years from the date of first marketing approval in the EEA. This was the balance that the law makers perceived as reasonable in 1993 when the Regulation was first enacted. Development times are lengthening and increasingly innovators are not getting to the market within 10 years of filing the patent application. Thus there is less than 10 years patent life remaining at the time of first marketing authorisation. In such cases the maximum 5 year period for the SPC means that the innovator receives less than 15 years protection, in some cases considerably less. The 5 year maximum cap on SPCs could be removed, whilst maintaining an overall maximum period for protection.
- We have performed some modelling with respect to the importance of the SPC period on return on investment. We assumed that a new medicinal product is launched 10 years into the 20 year patent term, i.e. 10 years of normal patent term remaining. We also assumed that peak year sales are reached after 5 years (i.e. 15 years into the normal patent term) and thereafter remained constant. For simplicity, we ignored pre-launch spend (R&D) and we used undiscounted figures (i.e. not NPV based). Our modelling showed that if cumulative profit at the end of the 20 year term is 100%, the cumulative profit after 1, 2, 3, 4 and 5 years of the SPC would be 114%, 127%, 141%, 155% and 168% respectively. This can be visualised in the following graph.



SPC Impact.ppt

- Innovation takes various forms. We believe that SPCs should be available for all innovations, for example for innovative formulations and uses. Thus we support the extension/clarification of case law sought in the referrals to the ECJ of the MIT and YISSUM applications.
- We also believe that the regulation should be amended to allow multiple patents to be extended by same legal owner - generally this will not give extra term but additional layers of protection within the term of overall exclusivity and would be consistent with rewarding innovation in various forms as mentioned above.
- We believe that there is legal uncertainty of the meaning of the term "protect" within the meaning of the product having to be protected by a basic patent (arising from Takeda case law). We believe that a simpler test, ie an infringement test would be suitable.

Trade Marks – international issues

(a) To what extent does your organisation register its trade marks at the European rather than national level?

(b) Could the UK trade mark system be improved to work better alongside the European system?

We use the Community Trade Mark system and/or with the Madrid Agreement/Protocol international registration system almost entirely.

Designs – registered designs and unregistered design rights

(a) To what extent does your organisation rely on registered designs? And on unregistered design rights?

(b) To what extent does your organisation register its design at the European rather than national level?

(c) To what extent does your organisation rely on the European unregistered design right rather than the national UK unregistered design right?

(d) Could the UK registered design be improved to work better alongside the European system?

(e) Could the UK unregistered design right be simplified to work better alongside the European unregistered design right?

(f) Do you see a useful role for the UK unregistered design right alongside the European design right?

We use Registered Designs and unregistered Design rights when appropriate for the delivery devices for our medicines.

We have used the Community Registered Design system since its introduction.

We have no further comments on these questions.

Legal sanctions on IP Infringement

(a) Are you aware of any inconsistencies or inadequacies in the way the law applies legal sanctions to infringement of different forms of IP or to different circumstances?

(b) For example, should criminal sanctions on online infringement be the same as those relating to physical infringement?

(a) We believe that the recent EU Directive on the Enforcement of Intellectual Property Rights is a welcome move to ensure that minimum standards are applied throughout the EU.

We welcome the additional efforts made to combat counterfeiting and piracy which include criminal sanctions for such offenders. However, we are concerned that the present definitions of intentional IP infringement cover patent infringement. We believe that criminal sanctions for patent infringement are inappropriate and we propose that patent infringement is excluded from the present proposals.

Coherence between competition policy and IP policy

(a) Has your organisation experienced any activity linked to IP rights that you regarded as unfair competition?

(b) How did you deal with this problem?

(c) Was competition law effective at controlling this behaviour?

(d) Should competition law have a greater role to play in regulating IP?

(e) How would you see the system working?

We believe that competition law and policy should respect IP rights. As noted earlier, robust IP rights, reflecting innovation and allowing a period of exclusivity in their use, are fundamental to the pharmaceutical industry to enable the recouping of R&D costs and to fund further innovation. We believe that competition law should have minimal impact on properly granted IP rights.

In an separate aspect, we support any general proposal to introduce a statutory basis for unfair competition into UK law.

Parallel imports/International Exhaustion

(a) Has your company been affected by parallel trade?

(b) What would the impact on your organization of a change in the current rules?

(c) What evidence is there of the costs and benefits, both for consumer and firms of the current rules?

(a) AstraZeneca has been affected adversely by parallel trade. In the EU, current losses to the research based pharmaceutical industry from parallel trade are estimated at over €4.5bn per annum . We enclose details of a study by Kanavos et al (2003).



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In the EU parallel trade is generally consistent with the principle of the single market. However, as member states of the EU operate their own controls on national healthcare expenditure, price lists and reimbursements, there are variation in prices. This patchwork variation leads to parallel trade and distortion of the market.

(b) Changes in the current rules would benefit society overall. The London School of Economics study (Kanavos et al) shows that EU governments do not normally receive much of the benefit from parallel traded medicine . Most of the financial benefit is captured within the supply chain and does not benefit the patient or government.

Additionally, there are risks of supply chain disruption, and consequential inefficiencies and costs for manufacturers, when medicines are diverted from the lower fixed price markets by parallel importers.

We would add that outside of the EU, parallel trade and reimportation often consists of illegally diverted product and, as the supply chain is also not regulated, there is a risk of introduction of counterfeit and reduced quality product resulting from poor handling. This creates new risks and uncertainties in the supply chain, and reduces reliability of supply for patients in both the exporting and importing countries.