

GlaxoSmithKline (“GSK”) Response to Gowers Review on IP

I - Introduction

GSK welcomes this Review and the opportunity to contribute to it.

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Our response is based on our experiences, as a significant and sophisticated user of the IP system, in obtaining and enforcing IP. It is therefore necessarily a view of the IP system as it applies to the pharmaceutical industry and is primarily focused on patents.

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In addition to answering specific questions, where relevant, we have also provided some background on the pharmaceutical industry and some general comments on the patent system. The response provided below does not therefore completely track the format of the questionnaire but does address all relevant issues.

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In general, we take the view that the IP system in the UK and EU is suitably balanced and serves its principal purpose of promoting innovation. We believe that any costs created by the system are in general outweighed by its benefits. However, it is not a perfect system and we welcome evidence-based attempts to identify specific problems, to quantify their effects and to identify solutions. However, altering a system which seeks to balance various societal interests risks upsetting that balance. It is important that potential solutions to identified problems are carefully analysed so as to avoid any unintended consequences and to ensure that they do not create more problems than they solve.

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Starting from the proposition that the system works well in general, we take the view that it is for the advocates of change to show that change is needed and to show that the changes proposed will clearly be beneficial.

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II - GSK in figures¹

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GSK is the UK’s largest healthcare company by market capitalisation. Its businesses encompass both prescription pharmaceuticals and consumer healthcare products.

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The pharmaceuticals business encompasses the fields of respiratory, central nervous system, anti-viral, anti-bacterial and malarial, metabolic, oncology and cardiovascular medicine. In addition, GSK has a large and highly innovative vaccines business.

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The consumer healthcare section of the business ranges from oral healthcare (e.g. AQUAFRESH® and SENSODYNE®) through OTC medicines (e.g. PANADOL® and TUMS®) through smoking control (NIQUITIN®) and nutritional products (e.g. RIBENA®, LUCOZADE® and HORLICKS®).

¹ All figures in this section are taken from GSK’s 2005 Annual Report available at <http://www.gsk.com/reportsandpublications.htm>

For y/e 31 December 2005, GSK had a turnover of £21,660 million (pharmaceuticals - £ 18,661 million; consumer healthcare – £2,999 million).

5 Research and development expenditure for the period was £3,136 million (pharmaceuticals - £ 3,030 million; consumer healthcare – £106 million).

Of the approximately 100,000 employees worldwide, approximately 15,000 are employed in R&D.

10 Pharmaceutical sales on an invoiced basis were apportioned as follows – USA - 49%; Europe - 30%; Rest of World - 21%). Approximately 4% of sales were in the UK.

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III - The R & D process for pharmaceuticals and its cost

The development process for pharmaceuticals is long, costly and risky. This is due both to the nature of the process and the high degree of regulation aimed at ensuring both that the development process (clinical trials) and the final product are as safe as can be achieved within the grounds of practicality. The key objective is to produce a product which is safe and efficacious.

20 It is not appropriate in this document to describe in detail the R&D process. We refer the Review Team to a submission made by the Biomedical Industry Advisory Group (BIAG) in May 2005 to the WHO Commission on Intellectual Property Rights, Innovation and Public Health². This contains papers on various issues (including costs) relating to the development process and an interactive guide to that process.

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Some salient features of the research and development process are the following:

- Safety and efficacy requirements mean that it generally takes between 8 and 12 years (and sometimes more) to bring a product to market, and the vast majority of this time passes while the 20 year patent term is running. Returns on the investment therefore usually only begin relatively late in the patent term, thus reducing the effective period of patent protection in which adequate returns can be obtained³.
- For every 10,000 compounds that are tested for pharmaceutical activity, only 3 reach the market.

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² Available at <http://www.biag.org> A hard copy (including the Guide on CD-ROM) accompanies this submission.

³ It is by virtue of the fact that pharmaceutical products have an “effective patent life” (the term remaining after the product can first be marketed) far shorter than the 20 year term that some industrialised countries (including the US, the EU, Australia, Japan and Korea) have granted an extended term of patent rights for pharmaceutical products.

- Estimates of the costs of bringing a drug to market vary from about \$200 million to \$1.7 billion⁴
- Only 3 of every 10 drugs which reach the market is profitable.
- The cost and risk of copying (i.e. producing a generic version of) a product is low. Industry estimates vary, but it is unlikely to exceed \$2 million and the figure may be very much lower⁵. And the risk is low as the demand for the drug is known after the market for it has been created by the innovator.

Thus, the cost and risk of developing a new drug are very significant. As noted above, GSK spends £300,000 per hour on developing new medicines. This would simply not be feasible were it not for the limited period of exclusivity conferred by the IP system, in particular patents and data protection. A robust IP system is a key feature of the business model of the pharmaceutical industry. As Europe is GSK's second largest market, the importance of its IP system is self-evident.

Limited market exclusivity for pharmaceuticals is provided primarily by patents (and patent term extension) and regulatory data protection.

Trade mark protection is also of great importance generally. Copyright and design protection can be of importance for, for example, drug delivery devices.

All these types of protection (other than regulatory data protection) are also of great importance to GSK's consumer healthcare business.

It should also be noted that IP rights (in particular trade marks, copyright and design protection) are of great importance both generally and in preventing or limiting counterfeiting. Counterfeiting of consumable products, particularly pharmaceuticals, gives rise to potentially significant public health dangers. Thus, in our business, IP rights are also a means of protecting against public health dangers.

Given this background, it is not surprising that GSK is a significant user of and takes great interest in the IP system.

GSK therefore welcomes this Review. Before addressing the individual questions raised by the Review, we wish to make some preliminary but important general remarks. Many of these refer specifically to patents but are to a large degree applicable more generally.

⁴ This significant variation in estimates is dependent on many factors including the basis of the calculation. Further analysis can be found at Article 3 of the BIAG submission; see <http://www.biag.org/BIAG/images/articles/art3b.pdf>

⁵ On 5 September 2003, the secretary general of the Indian Pharmaceutical Alliance, an association of generic manufacturers, was quoted in the Business Standard (an Indian publication) as saying "it will take the Indian company at least 2 years to reverse engineer the product and will cost anywhere between \$100,000 and \$200,000 to come out with a bioequivalent drug".

IV - The IP system - identifying problems and solutions

5 The principal purposes of the IP system are to promote innovation/creativity and the dissemination of knowledge. Not only do innovation and knowledge dissemination have the capacity to bring social benefits in and of themselves, but they also facilitate and promote competition.

10 To the extent that the IP system creates social costs (chiefly the grant of limited and slightly different forms of exclusivity) careful analysis of the balance between the costs and benefits – principally by reference to the objectives of the IP system - is necessary.

15 The Call for Evidence refers to there being a “highly complex IP system” which has become “increasingly opaque”. Whereas there are clearly some complexities (which the Call for Evidence accepts is inevitable), it is important to distinguish between complexity in the sense of there being several and perhaps overlapping, complex (and sometimes unclear) legal instruments providing protection of an apparently similar nature (structural complexity) and complexity in applying laws to particular fact situations.

20 We are aware of criticisms having been raised to the effect that there are structural complexities in the field of copyright and related rights.⁶

25 However, we do not believe that these structural complexities are significant in the fields of patents or trade marks. These fields of law have grown largely organically (i.e. with relatively limited legislative intervention⁷) over the last few decades. The complexities in these fields tend to be associated more with the difficulties in applying the law to the facts. This is particularly the case in the field of patents where technology is inherently extremely complex and has

30 changed rapidly in the past few decades. It is most unlikely that changes to the system will reduce this type of complexity to any significant degree, at least without reducing the quality of grant and enforcement procedures (see below).

35 These differences should, we believe, be borne in mind in considering whether there are problems in the system and how to solve them.

40 It must also be borne in mind that the creative process involves a wide range of participants⁸ in a wide range of industries who produce a wide range of types of innovations. These participants are funded in different ways and often perform their research functions in collaborations and across international boundaries. The IP system needs to accommodate all these players who generate and use IP in different ways for different purposes.

⁶ We deal with these to some extent in our answers on the Specific Issues raised in the Call for Evidence.

⁷ There has of course been EU legislation of some significance in trade marks. From a UK perspective at least, this has been most significant in terms of providing new fora in which to apply for trade marks. Although this legislation has made some changes to the substantive protection afforded under UK law, the substantive changes have been much less than in the field of copyright and related rights.

⁸ E.g. large and small companies, academic institutions, government research bodies

5 Against this background, we believe that the IP system in Europe as a whole (and the UK where the system is similar for obvious reasons), and the patent system in particular, work well in achieving their objectives of promoting innovation and disseminating knowledge. Although not perfect, the system has proved relatively – indeed perhaps surprisingly - adept at adapting to and coping with changing market conditions and technologies.

10 However, we recognise that the system is not – and probably cannot be – perfect. Changes which will genuinely improve the system without upsetting the delicate balance it seeks to achieve should be encouraged.

15 Starting from the proposition that the system works well in general, we take the view that it is for the advocates of change to show that change is needed and to show that the changes proposed will clearly be beneficial. And this must be shown by evidence, not rhetoric, ideological claims or soundbites.

20 We believe that the following steps need to be followed in identifying any needs for change and any changes themselves:

1. The nature of the alleged problem should be identified with precision.
2. The extent of the problem should be determined. Identification of a limited number of examples of a problem may be representative of a wider systemic problem, but they may not be. Care must be taken not to generalise from the particular unless this is justified.
- 25 3. The impact of the problem – on innovation and society -needs to be assessed. A fairly widespread problem may have minimal impact.
4. Potential solutions to the problem need to be identified. The best solutions to problems may well be outside the IP system itself.
- 30 5. The consequences of the potential solutions must be assessed. In a balanced system, changing one part of the balance may impact other parts. It is necessary to take care to avoid potential solutions having unintended consequences.

35 GSK hopes the Review will follow this analytical process and will welcome real solutions to real problems.

40 **V - Some comments about the quality and cost of IP grant and enforcement**

45 Some of the questions in the Call for Evidence address directly and indirectly concerns about the cost and quality of IP granting and enforcement processes in the UK. We wish to make a few general comments on these issues⁹.

⁹ Again, our comments will focus on patents but apply more generally

Va - Patents

Quality of grant involves ensuring, as far as is practicable, that granted patents meet the requirements of patentability. Quality of enforcement involves ensuring, again as far as is practicable, that patents that meet these requirements are enforced in respect of products and processes that infringe, and are not enforced if not valid or if not infringed.

Maximising quality is important because it maximises business certainty:

1. quality promotes the likelihood that the market protection which provides the incentive for investment in innovation will in fact be available;
2. quality enables 3rd parties to assess with confidence what they can and cannot do without the risk of infringement.

Poor quality of grant and enforcement undermines these objectives. Reducing quality of grant can lead to valid patents being refused (reducing the chance of innovation) or poor quality patents being granted (causing problems for those wishing to compete). Poor quality of enforcement can have similar effects; good patents may not be enforced (reducing confidence in the incentive to innovate which patents provide) and bad patents may be enforced which should not be (unjustifiably limiting competition). Reduction in quality may, in fact, increase the risk of litigation.¹⁰

Quality, and confidence in quality, is important to both large and small companies. Indeed, it may be more important to smaller companies as each investment in innovation may well represent a larger proportion of available resources than is the case for larger companies.

Quality is promoted by high standards of search (determining what is relevant prior art) and examination (assessing whether there is a patentable invention) at patent offices. Reduction of costs in the grant stage will – unless very carefully implemented – reduce quality standards which will lead to patents wrongly being granted or refused.¹¹ Thus, in the patent field in particular, it is inevitable that maximising quality at grant will involve costs which are, at least at first sight, significant particularly for smaller enterprises.

The Call for Evidence refers to the cost (£75,000) of obtaining and maintaining patent protection in several European countries and the USA for 7 years. Whilst this sum is not insignificant, particularly for SMEs whose cash-flow in the early years of business can be extremely limited, it should be seen in context. This sum represents an investment of approximately £11,000 per year to establish a potential exclusive market position for 7 years in the two largest and wealthiest markets in the world. If the quality of grant is good,

¹⁰ High quality grant procedures lead to a presumption of validity being applied by both business and courts. If there are significant doubts as to the quality of the grant and enforcement process, this presumption is reduced and businesses may well be more willing to risk litigation than would otherwise be the case.

¹¹ It is a widely held view that the standard of examination in the US Patent Office in the late 1970s and early 1980s was the highest in the world. However, cost-cutting measures since that time have, it seems, led to a fall in quality.

this may represent very good investment. The problem, we would submit, is not one of the excessive cost of the patent system, but the more general one of how to secure adequate funding of SMEs.

5 It should also be noted that the cost of patent grant in Europe could be reduced, perhaps significantly and with no impact on quality, by adoption of the London Agreement on translations. Adoption of this agreement would reduce the need to translate the whole of the specification of a patent granted by the European Patent Office into the national languages of the countries for
10 which the patent is designated. The failure to adopt this Agreement – and the consequent failure to reduce costs for innovative industry generally (and the significance of those costs for SME's in particular) - is driven by political considerations wholly extraneous to patent (or indeed other industrial or economic) policy.

15 GSK takes the view (which we believe is widely shared) that the quality of grant of the European Patent Office is generally very high. The post-grant opposition process increases the likelihood that a patent granted by the EPO is a valid one.¹²

20 It is sometimes argued that the fact that some patents granted by the EPO are subsequently held in judicial proceedings to be invalid shows that the quality of the EPO process is too low.

25 We believe that this argument is misconceived. Although we have no data on this, we believe that it is likely that in most cases where this happens it is due to facts of which the EPO Examination and Opposition Divisions were not and could not have been aware.¹³

30 We recognise that there is always a balance to be sought between cost and quality. Where there is doubt as to where the balance should lie, we take the view that quality interests should prevail. Cost considerations, especially for SMEs, should be dealt with by means – perhaps alternative funding means - which do not impact quality.

35 Quality of enforcement is equally important. In significant numbers of cases, by the time a patent is enforced, the investment in developing the product and, often, in developing a new market for it, will be sunk. The patent or other IP right which is being enforced may be the only means of protecting that
40 investment and securing the funds needed for future investment. It is therefore just as necessary (perhaps more necessary) to ensure high quality enforcement mechanisms as it is to ensure high quality grant mechanisms.

¹² There is, of course, a need for further improvement, particularly in the speed of the grant and opposition processes (see 1(i) below)

¹³ For example, prior art of which the EPO was not aware is often raised in litigation. This may surface because the parties to litigation are often more knowledgeable about the precise field of the invention than the EPO, because they have access to information sources not accessible to the patent offices (e.g. notes made at verbal conference or poster presentations) or because of the very intensive searches of prior art made by the parties before and during litigation. It should also be pointed out that these issues also arise in other jurisdictions and are not specific to the EPO.

Patents can provide exclusive rights in often very valuable markets and protect often very significant investments. It is not surprising – indeed it is rational - that companies are often (if able to do so) willing to spend large amounts of money to enforce their patents to protect their investments and revenue stream or to resist enforcement to gain access to a revenue stream. And given the complexity of the technology which is often involved, it is not surprising that patent litigation in particular is expensive.

The potential for conflict between cost and quality is therefore as apparent in enforcement as it is in grant and must be managed to the degree possible. As in the grant process, the cost of enforcement may well be more significant for SMEs than for larger firms. And the risk of a patent wrongly not being enforced may be more significant for an SME, as the business deriving from the patent may represent a higher proportion of overall turnover and profit for the SME than for larger firms.

So as with grant, we take the view that where there is doubt as to where the balance should lie, quality interests should prevail. Cost concerns, especially those of SMEs, should be dealt with by means which do not impact quality of enforcement.

That is not to say that there should be no changes to enforcement systems to improve their cost-efficiency without undermining quality. Recent discussions around proposals for the Community Patent and a European Patent Litigation Agreement have as among their key objectives the achievement of improvements in cost-efficiency without undermining quality. Both aim in particular to deal with problems which are perceived to arise from the fact that, in theory at least, European Patents granted by the European Patent Office (which are in effect a bundle of national patents) may have to be litigated in actions in the Courts across Europe rather than in a single action. Concerns have been expressed that this leads to lack of uniformity of outcomes and unnecessary costs.

Unfortunately, as far as the Community Patent is concerned, political considerations led to a Common Political Approach being adopted in May 2003 which made the proposal entirely unacceptable from a cost (and, to a degree, quality) perspective.

As far as the EPLA is concerned, the proposal envisages the creation of a centralised Court which will hear proceedings for infringement and revocation of European Patents for all countries which sign up. Although the procedures to be followed by that Court have not yet been finalised, it appears to envisage a hybrid between the UK system (where expert evidence, limited document disclosure and cross-examination are permitted) and the systems in continental Europe which, although not uniform, are generally less receptive to such features of litigation.

We would clearly support a high quality, more efficient patent litigation system in Europe and there is much in the draft EPLA we can support. However,

while welcoming the work done and progress made on the EPLA, GSK has two significant concerns about the proposal.¹⁴

5 First, there is little – if any – evidence of the scale and impact of any problems associated with the cost of lack of uniformity of outcomes of litigation in multiple jurisdictions. Although multi-jurisdictional enforcement does bring with it the risk of increased cost and inconsistent decisions, we are aware of no analysis of how much such litigation there is in comparison to enforcement in a single jurisdiction. We believe – based on our contacts with other
10 industries and general knowledge – that in many industries patents are enforced in one European country only and that the amount of multi-jurisdictional litigation in most industries is rare. The single market means that a decision in one court will, in practice in a very large number of cases, have *de facto* pan-European effect.

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If this is the case, then the number of cases in which the EPLA system will in fact reduce the amount of multi-jurisdictional litigation may not be significant and the adverse impact of such litigation may be very small.

20 And if this is the case, recent evidence suggests that the EPLA proposal, particularly if it requires European Patents to be litigated in the central Court, will not be cost effective for most users. A February 2006 EPO “Assessment of the impact of the EPLA on litigation of European Patents”¹⁵ suggests that the cost of litigation in the centralised Court will be approximately twice the
25 cost of litigation in each of Germany and France and substantially more than in the Netherlands. If this estimate is accurate, and if it is true that most patents are not litigated in more than one jurisdiction, it seems that to make it mandatory to litigate in the centralised Court will be to increase the costs in the majority of cases without any discernable advantage.

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Second, however attractive the EPLA proposal might seem on paper, it carries with it a significant practical commercial risk that a new Court using untried procedures may not *in fact* consistently deliver decisions of the highest quality. It is currently assumed that after a relatively short period the EPLA
35 system will become mandatory for patent owners. In our view, there should be no presumption that use of the system will become mandatory; this should not happen until the Court has proven to deliver consistently high quality decisions that command the respect of all users of the system over a considerable period of time. Patents are an essential business asset. In the
40 research-based pharmaceutical industry, they represent one of the most important means of protecting, and thus incentivising, enormous amounts of high risk investment. It is not acceptable for owners to be forced to put those assets at risk in an untested enforcement system. This is even more the case for existing patents and applications which were applied for on the basis
45 that they would not be capable of central revocation (otherwise than in EPO opposition) but which would become subject to central revocation in the EPLA Court under the current proposal.

¹⁴ These have been and/or will be communicated in the appropriate fora.

¹⁵ http://www.european-patent-office.org/epo/epla/pdf/impact_assessment_2006_02_v1.pdf

Thus, for reasons relating to both cost and quality, the EPLA system should be an optional system, as was always the proposal for the Community Patent.

5 Finally, all patents granted by the EPO are subject to the translation requirement but the vast majority are never litigated. Thus the costs of translations, but not litigation, apply to all patents. In aggregate terms, it is likely that adoption of the London Agreement would lead to far greater cost savings (and no commercial risk) than adoption of the EPLA.

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Vb - Trade Marks

15 In the context of trade marks, the quality of grant and enforcement is equally important in allowing users of the system to assess with certainty what rights these trade mark registrations are actually embodying. In order for the system to be clear and accessible to its users, there needs to be consistency in the application of the relevant trade mark laws in the UK and across Europe.

20 The UK Patent Office is currently undertaking a consultation on the issues surrounding the way the UK Trade Marks Registry examines new trade mark applications on the basis of their potential conflict with earlier trade mark applications or registrations¹⁶. With its history of examination on relative grounds – a higher standard than that currently conducted for the Community Trade Mark by OHIM – a UK trade mark registration is viewed as a "strong" right with a high presumption of validity. A "secure" right encourages businesses to file in the first place and acts as a deterrent to later filers. It is also seen as a sound basis for a Madrid application due to the thorough search undertaken.

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If the Patent Office moves to a weaker standard of examination along the lines currently operated by OHIM, there would be little incentive for larger companies to use the UK Registry and there would be particular disadvantages to SME's who arguably obtain the greatest benefits from the current system of relative examination as it reduces expense and reduces the need for monitoring of marks. Without the current advantages offered by the UK registration system, larger companies such as GSK would be even more inclined to bypass the UK Registry and seek CTM registration only.

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¹⁶ <http://www.ukpats.org.uk/about/consultations/relativegrounds/index.htm>

VI - Responses to General Questions

5 In general, GSK seeks IP rights on a global basis and this is reflected in the answers below. As indicated in the introduction, our responses are primarily framed in relation to patents.

Question 1 - How is IP awarded?

10 Question 1 (a) and (b)

As noted in the Introduction there are inherent complexities in the IP system, which to some extent are inevitable. For major users familiar with the system these complexities do not generally represent a barrier to obtaining IP. The perceived complexity of the IP system may be more of a barrier to SME's and private inventors. However the real barrier for such users may be lack of access to professional advice.

Patents

20 In relation to patents, UK applicants generally file a UK 'priority application' which serves as a basis for filing corresponding applications outside the UK, within 12 months of the original UK filing date. Applicants have the choice of filing such applications via:

- 25 • national patent offices
- a regional patent office such as the European Patent Office (a European patent application now covers up to 31 states, plus several 'extension states') or
- 30 • an International application, which may designate over 100 states, including the EPO. Within a further 18 months the International application must be converted into national applications in those designated countries where the applicant chooses to proceed and from that point the application is dealt with by the national or regional (e.g. European) patent offices.

35 The variety of routes may appear complex but in general the 'national route' is taken only by those applicants who require protection only in the UK or a small number of other territories. The national route may also be useful to obtain grant quickly (which can be useful for inventions made in fast-moving areas such as the consumer healthcare field, but which is not usually an issue for the pharmaceutical industry).

45 In practice the majority of applications¹⁷ are filed using the International/European route, which is now a well-worked and generally efficient system. One advantage of filing an International application is that it gives applicants the option of seeking protection in a wide range of countries, whilst keeping initial costs relatively low, thus allowing time for further

¹⁷ In 2004 around 28,000 applications were filed in the UK patent office; in contrast 123,000 applications were filed at the European Patent Office, of which 121,000 (98.5%) designated the UK. Some of these will have been 'parallel applications' filed in both the UK patent office and the EPO, but we have no figures for the extent of this duplication.

assessment of the invention. It is also useful for SMEs wishing to seek partners and funding before committing to the costs of filing national patent applications.

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Design Rights

10 Generally, design rights (DRs) are obtained at a national level and consequently the process of obtaining global rights is a complex and time-consuming exercise. Understanding and appreciating how the system varies from country to country can be unclear.

15 Obtaining UK design rights (DRs) is not difficult because clear information is provided on the Patent Office website (POW), part of which is solely dedicated to DRs. One criticism that can be made is that insufficient exposure is given to the importance of obtaining DRs on an international basis. This can be levied at both the POW and the literature in general.

Trade Marks

20 In relation to trade marks, we believe the system is not unduly complex and the information and assistance provided by the UK Patent Office is helpful in facilitating access to trade mark registrations for SMEs and larger
25 organisations alike.

Questions 1 (c) and (d)

30 The cost of obtaining IP rights in the UK is likely to be of most concern to private inventors or very small firms. For the majority of applicants the more relevant issue is the cost of obtaining IP rights in the wider European community and we believe these costs to be commensurate with the size of the market. As noted above, we acknowledge that this can cause problems
35 for some SMEs, but do not believe that cutting cost – and therefore in all likelihood quality, is the solution.

Question 1 (e)

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We have no comments on this issue.

Question 1 (f)

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In our view, trust in the system for all forms of intellectual property is based on
(i) quality of grant and
(ii) quality of enforcement, as discussed in the Introduction.

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Patents

5 A good quality examination for both novelty and inventive step – which itself depends on the quality the search carried out by the patent office– should result in granted rights in which there is a workable level of confidence. We believe that in general the standard of search and examination, while clearly capable of being improved, is in general fairly high in both the UK Patent Office and the EPO.

10 It must be stressed here that quality of examination is different from the question of the criteria for patentability. These two issues are independent and should not be conflated. Thus, the criteria for patentability, particularly that the invention must be ‘non-obvious’ introduce some degree of inherent uncertainty in the validity of a granted right. In our view this must be accepted. If the criteria for patentability are set too high there is a danger that real inventions may not be capable of protection and thus there may be no incentive to invest in them.

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Design Rights

In relation to design rights there are some particular areas that make that system perhaps more tenuous than for other forms of IP. Firstly, because there is no formal system in the UK for substantively examining an application for a registered design, one cannot look to the Patent Office for any level of endorsement of validity. Secondly searching, whether it be a product infringement clearance or prior art searching, can only ever be of a general nature because (in many jurisdictions) the design right awarded is not limited by indication of a product or classification. Because design searches are inherently subjective it will rarely be possible to give an absolute judgment without involving specialists in the field which can be very costly.

Trade Marks

We refer to our comments in the Introduction (Section Vb) concerning the proposed removal of relative examination for UK trade mark applications.

40 In launching new and innovative products in the UK, we rely strongly on registered IP rights to protect our innovations and ideas including the visual appearance of the product. In particular, in our consumer business, new products which do not benefit from patent protection can be readily copied by our competitors and be placed on the market within months of the product being made public. As discussed below under “Coherence between IP Policy and Competition Policy”(Section VII) when a product has only been on the market for a short period of time, we are unable to rely on the laws of passing off to bring a claim against competitors who copy our product and we would be supportive of moves to introduce a tort of unfair competition to provide appropriate legal redress where our products are copied by our competitors.

Questions 1(g) and (h)

We have no comments on these issues

5 Question 1(i)

Patents

10 On the whole we perceive the European and International (PCT) systems and to the extent we use it, the UK Patent Office, to work well. In some areas however, it appears that the increasing workload of European examiners can have a detrimental effect on the quality of examination. We appreciate that the EPO is making efforts to streamline the examination and grant procedure in response to past criticisms and an increasing backlog of unexamined
15 applications. Nevertheless, quality of examination remains an important factor both to applicants and third parties and must not be sacrificed in the name of speed. Ultimately poor quality examination at the EPO would lead to an increased number of Appeals (in the case of rejected applications) and Oppositions (in the case of patents wrongly granted). We urge the EPO to
20 maintain high standards and avoid the reduction in quality seen with the US Patent and Trademark Office. (see footnote 11). Of course, as we noted in the Introduction (Section Va), the fact that a European patent may be opposed does not in itself suggest that the grant procedure is flawed, and indeed, post-grant opposition increases the likelihood that a patent granted by
25 the EPO is a valid one.

However, some criticism can be made regarding the speed of the Opposition procedure and any subsequent Appeal. In some cases both the Opposition
30 and Appeal can each last around 4-5 years (sometimes more), leading to a considerable period of uncertainty for both the patentee and third parties.

Trade Marks

35 We believe that the UK Trade Mark Registry is effective overall and provides a good level of service to its customers. The European Trade Mark Registry at OHIM is no longer in its infancy and appears to be operating more effectively than in its early years when people were unsure how the system would operate in tandem with national rights, although there is still a degree of
40 inconsistency in its approach to registrability of more unusual marks and the assessment of likelihood of confusion in opposition cases which leads to doubts as to the strength and value of the rights obtained.

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Question 2 - How is IP used?

Question 2 (a)

5 The pharmaceutical industry makes use of all types of IP (patents, trademarks, registered and unregistered designs and copyright) in order to protect the huge levels of investment required to research and develop new drugs (as noted in the Introduction)

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Question 2 (b)

15 We frequently seek different forms of IP protection in relation to the same product, as each type of IP right performs a different function. Thus, a single pharmaceutical product may require protection via:

- a patent directed to the new chemical entity (NCE)
- a patent directed to a specific formulation
- a trademark to protect the name and other aspects of the appearance of the product and packaging
- 20 • a design right e.g. shape of tablet or aspects of delivery device or appearance of the whole or part of the product
- copyright – in drug delivery devices, packaging, patient information leaflets

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Question 2 (c)

30 Decisions on what forms of IP to seek are generally informed by the nature of the product and we would seek to protect all relevant aspects as indicated in our response to Question 2(a).

Question 2 (d)

35 We have no comment on this issue.

Question 2 (e)

40 In view of the costs and risks of developing a pharmaceutical product, as discussed in the Introduction, the IP position is often crucial to investment decisions. The duration of protection available is a part of the overall equation – this is why Supplementary Protection Certificates are so important for pharmaceutical products (see further below). The decision as to how to

45 allocate finite R&D resources between different assets or different research paths may be influenced or determined by the strength and duration of protection available.

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Question 2 (f)

5 A robust IP system should facilitate innovation. It is a necessary pre-condition to development of an innovative economy in Europe and achieving the goals of the Lisbon Agenda.

10 As noted above, we believe that the IP system in Europe as a whole (and the UK where the system is similar for obvious reasons), and the patent system in particular, works well in achieving its objectives of promoting innovation and disseminating knowledge.

However, the system is not – and cannot be – a sufficient condition for innovation.

15 The problems in promoting innovation which Europe faces are far more fundamental than any problems with the IP system. They are deep-seated political and cultural problems the nature of which have been highlighted, for example, in debates of the European Constitution.

20 As the Aho Report on R&D and Innovation “Creating an Innovative Europe” states:

25 “At the core of our recommendations is the need for Europe to provide an innovation-friendly market for its businesses, the lack of which is the main barrier to investment in research and innovation...

30 Europe must break out of the structures and expectations established in the post WW2 era which leave it today living a moderately comfortable life on slowly declining capital. This society, averse to risk and reluctant to change, is in itself alarming but it also unsustainable in the face of rising competition from other parts of the world.

35 There is a large gap between the rhetoric of a political system that preached the knowledge society and the reality of budgetary and other priorities that have shown little shift in preparing to engage with it.”

40 Changes to the IP system may have some impact on innovation but any positive impacts are likely to be second order impacts¹⁸. Far more needs to be done.

Question 2 (g)

45 GSK uses a range of Government funding schemes to partner with the UK academic base. Examples include:

- Knowledge Transfer Partnerships (<http://www.ktponline.org.uk>)
- Faraday Partnerships e.g. Crystal Faraday, Intersect Faraday and Insight Faraday

¹⁸ Negative impacts from change are likely to have far more significance than positive impacts.

- Engineering & Physical Sciences Research Council (EPSRC)- GSK call for work on Array chemistry
- DTI Technology Programme

5 Innovation can come not only from schemes, such as those above, specifically designed to enhance innovation but also other industry-University partnerships such as Research Council CASE awards and the Dorothy Hodgkin Postgraduate Awards.

10

Question 2 (h)

Such data can be used as indicators of the level of innovation, but no more, and when used should be interpreted with care.

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Question 2 (i)

We have no comments on this issue.

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Question 2 (j)

Patents

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In our experience, it is rare to find patents being used simply to prevent exploitation by others, i.e. where the patentee is not themselves exploiting (or considering exploiting) the IP or willing to offer licences to others. Indeed, the UK Patents Act contains provisions to enable compulsory licensing in such circumstances, as do the patent laws of many other countries.

30

In the pharmaceutical industry patent applications are generally filed at an early stage of a research programme. At this point there are frequently a number of potential drug candidates, which often results in a portfolio of patent applications in a particular research area. Over a number of years these potential candidates may be whittled down to a key candidate and a few 'back-up compounds'. In view of the uncertainties inherent in drug development it is essential to maintain patents arising from the research programme as a whole – and not only the lead compound – for a number of years. It is legitimate and necessary to protect not only the specific asset being developed at any given time, but related compounds which may themselves be potential assets to be used as and when development of individual compounds in the programme must be halted.

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40

Trade Marks

Defensive trade marks are no longer permitted under the 1994 Trade Marks Act and we have not encountered a problem with these marks being filed or used by third parties. We believe there are sufficient provisions in the current

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Act to prevent defensive trade marks being obtained and used given the requirements for UK applications to be filed with a *bona fide* intention to use and marks that are not used become vulnerable to cancellation 5 years after registration. Provided the system is sufficiently robust and the quality of grant and enforcement is maintained there should be no need to register defensive marks as the actual marks desired to be protected should be given sufficient protection to prevent the adoption of confusingly similar marks by competitors.

10 **Question 3 – How is IP licensed and exchanged?**

Question 3(a)

15 It is generally no easier (nor more difficult) to negotiate transactions relating to IP than any other form of commercial contract negotiation.

Problems that can arise include the following:

- 20 • some smaller entities sometimes have unrealistic expectations of the value of their contribution and undervalue the contributions of others (in terms of IP or otherwise) to a given partnership, which can make negotiations difficult. For example, it is not realistic to expect high downstream payments on a product which has yet to be invented, based on an agreement which gives access to one of the tools intended for use in research which may give rise to a potential product.
- 25 • sometimes smaller entities have an insufficient understanding of the core business interests of potential partners and the ways that different types of transactions can impact those interests. This can lead to unnecessary difficulties in identifying shared objectives.
- 30 • there is sometimes an apparent lack of IP sophistication amongst SMEs in terms of protecting their assets – a potential product will be a less attractive licensing opportunity if it has been patented in few territories or if patent applications have not been filed in respect of all the key aspects of the asset. Sometimes the failure to protect adequately can be a cost issue, in which case (as discussed elsewhere – see Section Va) it will be best addressed as a question of how to
- 35 secure adequate funding for SMEs. However, it is sometimes a result of lack of IP awareness/education, rather than funding.

40 We should also mention that recently, application by academic institutions in the UK of principles relating to recovery of full economic costs have caused difficulty. While not objecting to this in principle, we are finding that there is increasingly a tendency to ignore or undervalue the non-financial contributions industry brings to collaborations of different types and a failure to distinguish between collaborative research arrangements and simpler contract research

45 arrangements in applying full economic costing principles. This leads to the danger that UK academic institutions, which compete globally with other institutions in being potential collaborators for industry partners, will price themselves out of the market.

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Question 3(b)

It is not appropriate to comment on this.

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Question 3(c)

10 Although the case law on the “research exemption” to infringement is limited, we are able to assess individual situations on their specific facts in order to provide reasonable business certainty as to whether or not an activity falls within or outside the exemption. It is rare that we are in disagreement with a third party over whether a given activity would be “research exempt” or not.

15 We are aware that there have been calls for the exemption to be clarified; however we believe that in its current form it provides the flexibility needed for the Courts or other bodies to arrive at an equitable result in a variety of different technologies and a variety of different cases. We would not encourage legislative intervention to “clarify” the provisions, as it is hard to see how the provision could be clarified without narrowing it whilst any
20 amendment designed specifically to broaden the scope of the exemption would risk cutting a swathe through the value of intellectual property relating, for example, to research tools.

Questions 3(d) to (f), (h) and (i)

We deal with these questions together as they all relate, to a greater or lesser extent, to barriers to licensing. Our answers to 3(a) are also relevant here.

30 There are a number of complexities in IP transactions which derive from the fact that they often have trans-national elements and impacts. This means that laws in different jurisdictions (within and outside the EU) will often have to be considered and taken into account. So, differences in IP laws in different jurisdictions bring layers of complexity to transactions which, to those not
35 familiar with how IP laws operate in practice, may seem to be simple transactions.

40 For example, there are differences in laws relating to who is the original owner of IP (particularly IP created in an employment relationship or created by a contractor) and the rights of co-owners of IP to exploit that IP in different ways.

Further, particularly in technological fields, the due diligence necessary as a precondition to a transaction can be complex.

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Factors such as these do of course lead to transaction costs (we would not necessarily describe them as barriers) and, on occasion, frustration for some of the parties involved. However, these issues are not significantly different from issues which arise in commercial transactions and collaborations more
50 generally; due diligence and the need to take into account varying national

laws can be significant issues in many different types of commercial transactions. IP transactions are not special in this respect.

5 One particular issue that should perhaps be mentioned is the need to take into account different competition laws in undertaking collaborative research. It can be difficult to determine how these laws will impact proposed transactions and some appear to positively inhibit licensing transactions. An example of this is the EU's Technology Transfer Block Exemption Regulation.

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Question 3(g)

15 GSK does, where appropriate, enter into cross-licensing agreements or into group arrangements such as research consortia in which IP brought to the table by the parties may be licensed to all and/or IP arising under the arrangement is licensed to all members of the group and sometimes outsiders. Such arrangements are more common in relation to early stage research or research technologies than in relation to marketed products or products in late development, where (for reasons discussed at various points in this response) exclusivity is desirable.

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25 Other systems have been set up to facilitate IP exchange or licensing, for example the "Lambert Agreements" introduced in 2005. These are a suite of template agreements which may be used or adapted to suit individual circumstances, the aim being to reduce negotiation complexity and to speed deal-making. GSK supports this approach (we were represented on the body which implemented the system) and uses the Lambert agreements wherever appropriate. More than 35 Lambert agreements have been executed by GSK to date, mainly with academic institutions, including some with overseas universities, but also with ex-university spin-out companies.

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Questions 3(j) and (k)

35 GSK does not use the voluntary "licenses of right" system. Patents are maintained while they are considered to be of commercial interest to the company. Because we file a high number of patent applications, we carry out regular reviews of our entire portfolio. Patent families which are not of interest to GSK and which are unlikely to be of interest to third parties are abandoned. We have internal mechanisms for identifying patent families which might be of interest to third parties and these are made available for out-licensing.

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Question 3(l)

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The UK, like many other countries, has laws which provide for compulsory licensing (and Government powers to use or authorise use of patented inventions for Government purposes) on a fairly wide variety of grounds. However, those powers, which are intended to control what may loosely termed "abuse" of patents are very rarely used; we are aware of no recent

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exercise of the powers indicating that (i) there are few such “abuses and/or (ii) any abuses which might occur are dealt with by other means

5 **Question 4 – How IP is challenged and enforced**

Questions 4(a), (b) and (f)

10 The system in the UK for litigating all intellectual property and patents in particular is often criticised as being overly costly. However, a few points should be made briefly:

- all litigation in the UK, whether personal or commercial litigation, is expensive. “Access to justice” is a problem generally; it is not a problem specific to IP litigation.
- 15 • The amounts at stake (in terms of recovery of sunk costs and access to lucrative revenue streams) can be very significant in IP litigation, particularly patent litigation.
- Patent litigation is often inherently factually complex due to the fact that complex technology is involved.
- 20 • As noted above, quality in the enforcement process is vital to the continued confidence in the patent regime.

The cost of UK litigation generally is driven by a number of procedural factors including:

- 25 • The availability of limited document disclosure
- The ability to call expert evidence in appropriate cases
- The power to cross-examine witnesses.

30 We regard these procedures as being very important to the fact-finding exercise that should be part of any litigation in which the facts are key. The facts are key in patent litigation.

35 It is, of course, desirable to reduce these costs to the extent that reduction does not adversely affect the quality of litigation outcomes. Appropriate procedural rules and case management by the judiciary are key. Significant steps have been taken in the UK judicial system generally (the Woolf Reforms) and the Patents Judges in particular (for example, the introduction of “paper only” trials in appropriate cases) in seeking to accommodate concerns as to costs without reducing quality.

40 We recognise that issues concerning the cost of litigation can be particularly significant for smaller businesses and individuals. However, as noted above, although we would support any proposals that would reduce cost without reducing quality, GSK would be very concerned about any changes that would reduce quality in the interest of cost- saving. Instead of reducing costs at the expense of quality, consideration should be given to how best to fund those who cannot afford litigation.

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Questions 4 (c-e) – ADR and insurance

We make no use of litigation insurance so are unable to comment.

- 5 We rarely use ADR methods to resolve infringement disputes against generic competitors. We do not believe they are generally useful in resolving the types of disputes we are most commonly involved in.

- 10 We have on occasion used such methods in seeking to resolve disputes concerning commercial contracts relating to IP. Our experience in such cases is at best mixed.

Question 4(g) – the risk of litigation as a factor in investment decisions

- 15 The risk of litigation is endemic to our business. That risk, *per se*, does not impact investment decisions.

- 20 However, the attitude and approach that a country takes to framing the substance of IP protection and enforcement of that protection is one factor we take into account in taking strategic decisions as to conduct of R&D. However, it is only one of a variety of factors taken into account in investment decisions

- 25 We have viewed with increasing concern what we regard as negative perceptions of IP generally in the EU and what appears to be a willingness of some policy makers at UK and EU level to allow IP to be a scapegoat for far more systemic social problems in the EU and elsewhere. IP has become a tool used by some policy makers for political gain, instead of a policy tool to promote innovation and economic growth. Policy makers need to take a more robust approach to the defence and promotion of properly balanced IP systems.
- 30

35 Question 4(h) – principal barriers to efficient and successful challenge and enforcement internationally

- The United States is our biggest market. There are a number of problems associated with the cost and quality of enforcement litigation in the US. The cost of litigation in the US is likely to be a particularly acute problem for SMEs.
- 40

- Elsewhere, the problems of enforcement tend to arise from the substance of the protection afforded by IP laws and the quality of enforcement processes. These problems are most often highlighted in the context of counterfeiting.
- 45 The problems also exist in relation to other aspects of IP law.

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VII - Specific Issues

Patents – utility models

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There are a number of utility model systems in the EU. They differ in terms of such things as exclusions from protectable subject-matter, scope of protection and term of protection.

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They are characterised as being, in general, rights that are granted with no or minimal examination (and therefore quicker and cheaper to obtain than patents). In some – but not all – countries they are ultimately sustainable (if challenged) if they display a lesser degree of “innovation” than patents (albeit the distinction between the “inventive step” needed for a patent and the level of innovation needed for a utility model is hard to define in theoretical terms and hard to identify in practice).

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Thus, utility models are cheaply obtained unexamined rights which provide protection for a lower degree of innovation than patents.

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Because they are unexamined, they are of uncertain value to the right-holder. The grant of a utility model provides little certainty that any exclusive right can be exercised against “infringers” and, therefore, provides little incentive to invest.

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Conversely, and for the very same reasons, utility models create uncertainties for competitors. Because the right is not examined, competitors have no means of assessing (without incurring the cost and uncertainty associated with undertaking infringement clearance) whether proposed activities will or will not infringe third party rights.

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Therefore, GSK believes that whatever advantages are claimed for utility models will be outweighed by real disadvantages.

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Pharmaceutical Supplementary Protection Certificates (SPCs)¹⁹

Question (a)

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GSK makes use of the SPC system. It is a key part of the incentive system in the EU.

Question (b)

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SPCs are an effective and necessary part of the IP protection for a pharmaceutical product. As explained above, patents facilitate and promote

¹⁹ We note that there are two inaccuracies in the “background” section to this question: the term of an SPC is based on the time which passes between the date of the patent *application* (not grant) and the date of first EEA *regulatory approval* (not first marketing) of the product.

innovation but, because it generally takes 8-12 years to bring a pharmaceutical product to market, return on the investment in innovative pharmaceutical research and development usually only begins relatively late in the patent term. The years in which a product is protected under SPC are generally those in which the product generates the most income. The availability of an SPC can therefore make the difference between a return being made or not.

10 **Questions (c) and (d)**

Several improvements could be made in relation to the calculation of the term of SPCs and the innovations which may benefit from them. For example:

- 15 • Under the current system if first EEA approval for the product is more than 5 years after the patent application was filed then an SPC will be available, up to a maximum SPC term of 5 years. However, the 5 year “cap” means that the full delay caused by the process of seeking regulatory approval for a new product may not always be recouped.
20 Thus if the first EEA approval for the product is more than 10 years after the filing of the patent application, the extra time beyond 10 years is ignored. The introduction of this cap appears to have been driven by political considerations; it is entirely without other justification as there is no logic to incorporating a cut-off to the term of protection, if the aim is to compensate the patentee for the effective patent life lost in the regulatory process.
25

- 30 • In some countries the Regulation is interpreted as limiting the grant of SPCs to one per pharmaceutically active ingredient, whereas other countries appear to use a more flexible interpretation such that an active ingredient might benefit from more than one SPC, for example where different products containing the active, or several aspects of one product (NCE, formulation, use) might have been separately patented. A recent case was referred to the ECJ from Germany because the German Patent Office had decided differently from (amongst others) the UK Patent Office (which granted the SPC). In this case the active compound had previously been protected and an SPC was sought in relation to a new formulation in which the combination of the drug with new excipients enabled a new disease to be treated. In his opinion (which may or may not be followed by the Court in their final decision) the Advocate General of the ECJ spoke of the need to stimulate research into new applications of known substances, saying that protection of innovative products is "essential to the progress of treatment and the competitiveness of the Community pharmaceutical industry". This is clearly the correct approach from a policy perspective. If a new pharmaceutical product containing an already used active ingredient requires regulatory approval and the time to obtain that approval impacts the effective patent protection for that product, then there seems no logical reason to deny SPC protection for the new product, whether or not the previous product utilising that
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active ingredient has been protected. If the ECJ does not follow the Opinion of the Advocate general, the existing law should be changed.

- The ECJ confirmed in 2005 that a Swiss MA is proper basis for calculating the term of SPCs²⁰. This resulted in a harmonised, but illogical, outcome for the SPC system. SPCs are an EU system, governed by EU Regulations. Since the ECJ decision, if a product is approved by the European Medicines Agency, say, 8 years after its patent application was filed, then the product will receive a 3 year SPC throughout the EEA. However, if the Swiss health authorities approve it more quickly, say after 5 years, then no SPC will be available however long the EU authorities take. This makes a nonsense of the system which was set up to compensate patentees in Europe for European regulatory delays and means that the effective term of protection is eroded for that product in all 28 EEA States. The Swiss have amended their local regulations to try to solve this problem, but the “fix” is untested by the Courts and is incomplete (will not apply to pharmaceutical products containing more than one active ingredient). Rationalisation of the SPC system in this respect will increase business certainty for the pharmaceutical industry in Europe.

A current proposal for a **Paediatric Medicines Draft Regulation** should also be noted in relation to SPCs. The aim of the Regulation is to increase the development of medicines for use in children. It requires that for most new medicines, studies must be conducted to determine whether they are suitable for paediatric populations. An incentive of a 6 month extension of an SPC is given for conducting these studies.

We clearly welcome such a proposal in principle. However, several provisions of the draft Regulation appear to run contrary to the stated aim by undermining the incentive

For example, the current proposal is to grant a 6-month paediatric extension **only** where there is an existing SPC. There is no logic to this and it clearly discriminates against products which have been brought to market speedily and are therefore not eligible for an SPC. We believe that the aim of the Regulation would be enhanced by making the incentive a new type of SPC – a paediatric SPC – whose term could be added to that of the basic patent or SPC, as applicable.

Further, the incentive is only available if the product is authorised in all Member States. This contrasts with the existing SPC system, whereby SPCs

²⁰ Although Switzerland is not a member of the EU or the EEA, a Swiss marketing authorisation (MA) also covers the territory of Liechtenstein (an EEA member) under a bilateral agreement between the two countries. Since the duration of an SPC is based in part on the date of the first MA in the EU/EEA, there had been debate in Europe about whether the Swiss MA was proper basis for calculation of SPC term. When products received a Swiss MA earlier than the first MA in any EU or EEA Member State, some countries relied on the Swiss as the “first” MA to calculate the SPC term (resulting in differing SPC terms in different countries).

are granted on a national basis and are not dependent on whether the product is authorised in all Member States.

5 It is regrettable that the UK Government has been unsupportive in seeking to change these two features of the proposal which would have benefited innovation.

10 **Trade Marks – International Issues**

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(a) Where a trade mark is to be used on a global or pan-European product, we make use of the Community trade mark and Madrid systems for registration where appropriate but the national system of trade mark registration also remains relevant for our organisation on a case by case basis.

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(b) We believe that overall the UK system for trade mark registration works well in parallel with the other systems available for registration at a Community and International level. There are inconsistencies in the application of European laws between the UK Courts and Trade Mark Registry and the Community Trade Mark Office, the European Courts and the other legal and administrative bodies across Europe. Greater harmonisation and consistency in the application of these laws should lead to a more transparent system with higher quality rights and greater certainty of the strength of the rights granted which should in turn result in less litigation based on these rights.

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30 **Designs – registered designs and unregistered design rights**

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Design registration is a very useful form of IP protection, particularly for products that derive their market value from their appearance. Registered design protection is used across all business sectors in GSK where the visual appearance of a product is important. As design registration provides protection against reproducing the actual design or a very similar design it is an important right for products that can be easily copied.

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Unregistered design rights, although an automatic right, are difficult to enforce because it is essential to show actual copying, with intention, of the design.

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GSK has been using the EU Community registered design system since it was first introduced in 2003. It is still necessary to use the national registration systems in countries where protection is sought outside of the EU.

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There are certain aspects of the UK registered design system that are not aligned with the EU Community system e.g. the possibility of requesting multiple registrations (more than one design) in a single application and also the possibility of deferring the publication of the application.

The UK Design Registry is at present conducting a consultation to address some of these issues and can be found at <http://www.patent.gov.uk/about/consultations/regdesignfees/changes.htm>

5 GSK will be making submissions on this consultation through other avenues, e.g. TMPDF or Registry Practice Working Group (RPWG)

10 Although it appears that a UK unregistered design right can run in parallel with an EU Community unregistered design right, the term of protection of each is different. It would therefore appear that harmonisation of this unregistered right is required to avoid irregularities.

15 **Legal Sanctions on IP Infringement**

We believe that the civil sanctions available where intellectual property rights are found to be infringed in Europe are generally acceptable and proportionate although the enforcement of sanctions can sometimes be an issue. The recent Directive on the Enforcement of Intellectual Property Rights should eliminate many of the remaining anomalies in Europe.

20 When considering criminal sanctions for IP infringement, care is needed to ensure that ordinary commercial activities, which may lead to *bona fide* disputes as to whether IP rights are infringed, are not criminalised. Some form of distinction (which may be difficult to draw) is needed between what may loosely be defined as counterfeiting or piracy (for which criminal sanctions may be appropriate) and other infringements (for which they may not be). Recent proposals in the EU to criminalise IP infringements which were “intentional” and “on a commercial scale” were neither clear nor satisfactory. Although the proposals have been withdrawn for the present, it is likely that similar proposals will be introduced. If they are, they should be subject to careful consideration.

35 We believe that it would be entirely inappropriate for the EU to require the introduction of criminal sanctions for any type of patent infringement. This would serve no useful purpose and the fear of criminal sanctions could stifle innovation.

40 **Coherence between competition policy and IP Policy**

It is not clear whether this section of the Call for Evidence relates to laws controlling what might be referred to as unfair commercial trading practices or to use of competition law to control exercise of IP rights

45 If it relates to the former, as with many other companies producing branded consumer goods in the UK, we have experienced problems with copycat packaging produced by own label manufacturers and retailers. A product’s packaging acts a signpost for a brand’s reputation and allows consumers to quickly and easily select the goods they are looking for. Where similar

packaging is adopted by competitors it misleads consumers into thinking there is a connection with the known brand where there isn't one either leading the consumer to buy the copycat by mistake or in the belief that due to the similarities of the packaging it is made by the same manufacturer.

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Whilst copycat packaging is a problem throughout Europe, the UK provides less protection against this (and other forms) of unfair competition than most other European markets because the remedies available are not effective at addressing this problem. Typically, the copycat packaging borrows elements of several aspects of an original product without reproducing any of the elements completely. This means that the copycat can avoid infringing any single intellectual property right such as a registered design or trade mark while still resembling the look and feel of the branded product in order to mislead consumers. In particular, the UK does not provide unfair competition laws to deal with this form of misleading trade practice which are the basis of protection against this type of copying in most European markets. We refer to and support the full submissions being made by the British Brands Group on this issue.

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If the Call for Evidence relates to the use of competition law to control exercise of IP rights, technology industries such as IT and Pharmaceuticals have always recognised that exploitation of IP, like the exploitation of any other commercial asset, is subject to a number of overarching regulatory controls, e.g. Health & Safety and Competition Law. There is sufficient competition law jurisprudence dealing with the exploitation of IP in commercial transactions.

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Similarly, the exploitation of IP to prevent competitors entering a market or otherwise increasing or maintaining barriers to entry has been the subject of competition law regulation for decades, e.g. the Commission's investigation into IBM's interconnectivity restrictions 25 years ago.

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There is therefore no need for greater regulation of IP.

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The only special pleading on behalf of IP that we would make, would be that while it is logical and appropriate that competition law applies as equally to the exploitation of IP as to any other right or asset, the intervention of competition law in respect of the **creation** of IP, regardless of the original motive of the creator, should be resisted, otherwise one does risk freezing innovation and ideas.

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Parallel Imports and International Exhaustion

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As a leading pharmaceutical company, GSK has been adversely affected by parallel trade in the European Union from the inception of the parallel trade of price controlled prescription medicines in or about the early 80s. Over the years the company has taken steps to mitigate, as opposed to eliminate, the impact of that reduction in revenue. We currently have a number of cases

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before the Court of First Instance and the ECJ as well as domestic courts and competition authorities seeking to clarify the law.

5 IP has been used to seek to deal with the European arbitrage market created by the exclusive right of national government to fix the prices at which pharmaceutical companies may place prescription medicines (which are mainly reimbursed and paid for by governments) on their national markets. This distortion of competition and exploitation by arbitrageurs offers no benefit to consumers and payor governments and reduces the income of the
10 innovative R&D pharmaceutical companies.

Change is needed but this will not be achieved via IP law but by court decision or legislation which distinguishes trade of price controlled medicines from other products which operate in free markets. This is supported by Advocate
15 General Jacobs' opinion in the Syfait case (28 October 2004). Unfortunately, the ECJ will not deliver a view on the case as it concluded it had no jurisdiction to do so.

The recent opinion by new Advocate General Sharpston (6 April 2006) in
20 GSK's litigation against parallel importers Dowelhurst and Swingward has highlighted the potential for uncertainty and unfairness in determining when and how trade mark rights are exhausted. She has concluded that overstickering of imported products does not constitute repackaging. This is directly contrary to previous case law of the ECJ. If followed by the court, it
25 will effectively allow unrestricted parallel trade between EU member states.

We are opposed to any move to switch from the Community exhaustion of trade marks to international exhaustion.

30 In summary:

- Parallel trade results in lost sales revenue for UK based pharmaceutical companies which reduces the economic contribution that the companies can make to the economy and the amount of
35 money available to fund research and development for new products.
- The benefits of parallel trade of pharmaceuticals accrue to the parallel importers and not to the patients or the purchasers of the product such as the NHS.
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- Parallel trade can affect the safety and quality of medicines by increasing the complexity of the supply chains, making product recalls difficult to organise, reducing the effectiveness of quality controls and increasing the likelihood of mishandling of the products.
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- Parallel trade can lead to the increased risk of illegal and counterfeit products entering the legitimate supply chain beyond the control of the manufacturer endangering the health and safety of the patient.

- The repackaging and re-labelling of foreign language packs imported from non-English speaking countries (particularly the necessary replacement of patient information leaflets) increases the risk of human error in the patient information provided.

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- The move to international exhaustion would also jeopardise the supply of lower priced medicines to developing countries.

10 We support the position put forward by the European Federation of
Pharmaceutical Industries and Associations (EFPIA) whose position papers
set out the detailed reasons why international exhaustion for pharmaceutical
products should not be adopted²¹. We also refer to a recent study by the
15 London School of Economics which suggests that although the overall
number of parallel imports is continuing to increase, healthcare stakeholders
are realizing few savings and which demonstrates that profits from parallel
imports accrue mostly to the benefit of the parallel traders that buy and resell
the medicines²².

²¹ see http://www.efpia.org/2_indust/Paralleltrade.pdf,
http://www.efpia.org/4_pos/legal/internexhau.pdf and
http://www.efpia.org/4_pos/legal/protectpatients.pdf

²² <http://www.lse.ac.uk/collections/LSEHealthAndSocialCare/pdf/Workingpapers/Paper.pdf>