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**European Commission  
Directorate General for Competition  
Anti-trust Registry  
1049 Bruxelles  
Belgique**

**EU Pharmaceutical Sector Inquiry**

**Response to the Commission's Preliminary Report**

**by the  
Association of the British Pharmaceutical Industry**

**29 January 2009**

## **Executive Summary**

The British Pharmaceutical Industry concurs with Sir Robin Jacob's speech on 28<sup>th</sup> November 2008 at the launch of the Preliminary Report in which he said "The big truth is that if you damage the income stream of research companies, you are going to imperil future research at the expense of European – indeed World – citizens. Yes, you will save money now, but at the cost of less future medicines". It also endorses the EFPIA response and its reservations about the way in which conclusions are drawn by the Preliminary Report.

ABPI welcomes the Commission's words in the Preliminary Report endorsing the importance of IP to reward innovation and support investment in R&D in the pharmaceutical industry.

The Association of the British Pharmaceutical Industry (ABPI) will seek to show the Commission in this response that the EU average of 7 months to competitors' market entry post patent expiry can be reduced significantly by following some of the government, patent court & pharmaceutical industry practices used in the UK.

ABPI say that

- primary factors at work for the perceived failure in innovation by the industry do not relate to a failure of competition
- patents are necessary to the general advancement of science and technology
- there is no fundamental difference between the pharmaceutical industry and other hi-tech industries in the use of patents to protect incremental innovation
- patent oppositions are not the only route in the UK to "clear the path" to market entry for competitors
- the UK Patent Court procedure can be used as a possible role model for patent litigation in the European pharmaceutical market and we suggest that it can be incorporated into the proposed Single European Patent litigation system

and we explain difficulties in application of European Regulatory legislation concerning abridged applications and data protection for results of originator's pre-clinical and clinical research.

ABPI supports the Commission's work on the future of funding in European medicines research through the Innovative Medicines Initiative and the EU Presidency's work in creating a single European Patent Litigation system and Community patent.

**ABPI respectfully submit that there are areas where UK practices in promotion of innovation and competition could be addressed in more detail by the Inquiry before publication of the Commission's final findings.**

## Introduction

1. The Association of the British Pharmaceutical Industry (ABPI) represents companies in Britain producing prescription medicines and organisations involved in pharmaceutical research & development. Our members manufacture and supply about 80% of the medicines prescribed through the UK National Health Service (NHS) and are major exporters to countries all over the world.
2. During 2006 UK Pharmaceutical companies undertook 35% of the UK private sector R&D activities<sup>1</sup> over all fields of industry, an increase of 10% since 2004<sup>2</sup>. The Gowers Review of the UK Intellectual Property system commissioned by the UK Government in 2006 specifically mentions this significant contribution of the pharmaceutical industry to the UK economy, as an illustration of the conclusion that the IP system provides an essential framework both to promote and protect the innovation and creativity of industry.
3. The ABPI is a member of the European Federation of Pharmaceutical Industry Associations (EFPIA) and the International Federation of Pharmaceutical Manufacturing Associations (IFPMA). We endorse and concur with the detailed submissions and responses made by EFPIA to the Commission during this Sector Inquiry.
4. ABPI further supports the speech made by the UK's leading Intellectual Property Judge, the Right Honourable Sir Robin Jacob, at the launch event of the Preliminary Report on the 28<sup>th</sup> November 2008.
5. ABPI welcomes the opportunity to comment on the Commission's Preliminary Report and will endeavour to respond to any queries which the Commission might have in relation to the issues raised.
6. **In this response ABPI questions a number of the assertions made in the Preliminary Report and suggests that on the basis of UK experience the pharmaceutical market is a competitive one which delivers investment in innovation, access to market, competition and value for money, with the aim to get the "Right Medicine to the Right Patient at the Right Time" in accordance with the ABPI Manifesto.**

## The EU average of 7 months to generic entry post patent expiry

7. The UK has the highest levels of generic prescribing in Europe. According to data published by IMS Health, in 2007, 82.6% of all prescriptions – i.e. over eight in ten - were written out for generic medicines in the UK. That is a significant increase from the reported 60.3% in 1997, since when it has been growing year on year.

In the UK, generics companies usually enter the market as soon as a branded medicine goes off-patent. Within the first year, generics will usually have taken nearly half of the market for that medicine. As the Commission already knows from statistics collected by IMS Health and quoted in the EFPIA submission to the Inquiry, it frequently takes less than 3 months<sup>3</sup> for a

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<sup>1</sup> BERR 2007 R&D Scorecard for top 850 UK and 1250 global companies by R&D investment [www.dius.gov.uk](http://www.dius.gov.uk)

<sup>2</sup> Gowers Review of Intellectual Property in the UK Dec 2006 [www.hm-treasury.gov.uk](http://www.hm-treasury.gov.uk)

<sup>3</sup> IMS Health statistics & CRA analysis reported at Figure 25 of the EFPIA submission to the Sector Inquiry

competitor product to arrive on the market – although it should not be assumed that generic companies will always necessarily wish to enter or compete on every market that opens up following loss of patent protection. Further there is little evidence to show that any delays are generally due to IP reasons - factors affecting this decision by a competitor post loss of exclusivity may include: low profit margin, or difficulty in manufacturing products. These are explained in more detail within the EFPIA response at Sections 2 and 4.

**There are factors other than competition at work for the perceived failure in innovation by the industry**

8. ABPI notes that the Preliminary Report contains little direct evidence in support of assertions that patents get in the way of new products reaching market or that the downturn in new medicines reaching market is due to suspected unlawful restraint by patentees<sup>4</sup>.

**A Increasing difficulty of science & regulation of patient safety**

9. ABPI believes that a significant contributing factor to any perceived decline in new medicines is the increased cost of research and development, caused by a significant increase over the last 20 years in the complexity of scientific investigation required to tackle difficult disease areas previously understood to be “incurable”, such as Alzheimer’s or some cancers. A second difficulty is caused by ever-increasing regulatory hurdles for new medicines and new indications regarding the need for patient safety.
10. Pfizer UK Scientists<sup>5</sup> writing in 2005 in the journal “Drug Discovery Today” note that –

*The myth of the innovation deficit is exactly that – a myth. Scientists today have to walk a tightrope of forces that work against innovation and make R&D much more expensive. Never before did scientists have to consider the market, safety and commercial aspects so early in R&D as they must today, in addition to finding ever more-effective drugs for increasingly well-served, but still needy, markets.*

*In refocusing on high medical need areas and bringing priority agents to patients, the drug industry is experiencing the financial impact of attrition and niche markets. The increase in costs through higher attrition and increased regulatory demands, as well as the phasing out of the blockbuster business model, but certainly not a decline in pharmaceutical innovation, are the true reasons for the current woes of the industry.*

In the paper they demonstrate that over a longer time frame, the number of NCE approvals by FDA per year has risen steadily.

11. ABPI will address in more detail some of the difficulties in interpreting current European Regulatory legislation later in this response (*see paragraphs 69 to 95*)

**B Markets for Generic Medicines can be made more efficient**

12. ABPI submits that there is considerable scope for national health systems to save money by making their markets for generic medicines more competitive and efficient.

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<sup>4</sup> EFPIA Observations on the Preliminary Report – sections 1.3, 2, 3 and 4

<sup>5</sup> Esther F.Schmid and Dennis A.Smith, DDT • Volume 10, Number 15 • August 2005 pages 1031 - 1039

13. ABPI notes that the Preliminary Report presently fails to look into competition in the generic to generic market as a means to reduce prices post loss of exclusivity. We endorse the analysis provided by EFPIA and Sir Robin Jacob<sup>6</sup> in asserting that, in the main, generic companies go to market without incurring any of the costs associated with further R&D, and are often able (in other European countries) to join markets at prices starting from as little as 10% less than the on-patent product price.
14. We refer the Commission to the EFPIA response for a more detailed discussion on potential savings to be made by improving competition in the generic sector post expiry profits.

### **C No separate pricing/reimbursement decision in UK**

15. We also note that the Preliminary Report does not presently address the influence of national governments in price setting or promotion of generic entry rate through prescription practices. Originator companies would enjoy a longer period over which to recover their investments if product launch were not delayed by the additional time-consuming hurdle of securing a pricing or reimbursement decision from the relevant national authority.
16. New products can be launched sooner in the UK than in some other countries simply because there is no need for a separate pricing or reimbursement decision from the relevant authority.
17. That generics are marketed effectively and in a cost-efficient manner is borne out by the UK Office of Fair Trading's 2007 report on the operation of the PPRS at paragraphs 2.92-2.94 which reads as follows<sup>7</sup>

' Around 90 per cent of generic medicines (by value) are listed under Category M of the Drug Tariff. Prices for drug in Category M are set by the Department of Health and are based on a calculation that incorporates the volume-weighted average\* prices charged by generics manufacturers in the UK. [\*footnote to the report: The average is a volume-weighted average factory-gate price charged by generic manufacturers, which are obtained from quarterly surveys. A stochastic element is added to the calculations each quarter, to avoid gaming.]

The use of average prices among manufacturers aligns the reimbursement of generic drug with the market conditions in which they are sold. This process maintains the incentives for individual pharmacies to procure generic drugs efficiently, as reimbursement is based on average prices and pharmacies can negotiate with suppliers to secure a better than average price. Rules governing this system are set out in an agreement known as Scheme M.

Scheme M has led to strong competitive pressure on generics prices, with UK prices held to be among the lowest in Europe. The system is considered to be a well managed and efficient form of pricing generics, which has worked well to ensure that competition between generic manufacturers delivers savings for the NHS. There was, initially at least, some concern about the volatility of generics prices, although these have now largely been addressed.'

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<sup>6</sup> page 5 paragraphs 9 -11 of Sir Robin Jacob's speech as published on IPKAT website <http://ipkitten.blogspot.com/2008/11/end-of-pharma-patents-as-we-know-them.html> ("Sir Robin Jacob")

<sup>7</sup> OFT 2007 Report at para 2.92 - 2.94 [http://www.of.gov.uk/shared\\_of/reports/comp\\_policy/of885.pdf](http://www.of.gov.uk/shared_of/reports/comp_policy/of885.pdf)

### **Patents are necessary to the general advancement of science and technology**

18. ABPI welcomes the Commission's words in the Preliminary Report endorsing the importance of IP to reward innovation and support investment in R&D in the Pharmaceutical Industry.
19. ABPI also supports the view expressed by Sir Robin when he said that<sup>8</sup>  
*"The key thing to note is that the income produced by the sales of today's patented medicines pays for the ongoing R&D which may lead to new and better medicines.... Current income pays for current research and all other things a company does.... It is the patents system which has made the advances in medicines possible... without a reliable patent monopoly there is simply no incentive to invest... it (is) the pharmaceutical industry which has undertaken the risk of the considerable costs of development"*
20. ABPI seeks to rectify any misperceptions that might be gained from reading the Preliminary Report about the conduct of the pharmaceutical industry in relation to enforcement of patents by respectfully reminding the Commission of the basic nature of patent protection.
21. Society has granted this monopoly right in the public interest in exchange for disclosure to the world of scientific breakthrough and innovation. This is done by publishing patents to promote scientific & technological advances in the world. The use of the science disclosed actually helps others to innovate and build on those advances to increase knowledge, as opposed to getting in the way of innovation. The patent right is an intangible right of property with no inherent value and useless by itself unless it can be enforced through the courts by bringing infringement proceedings or by sale of licences to others to exploit the invention.
22. Each patent is granted separately for its own new and inventive increment to the state of the art, and cannot by definition extend the life of another granted patent. Each application is examined by expert examiners precisely to ensure that it is novel and inventive over other disclosures forming the state of the prior art anywhere in the world before it is granted.
23. Patents are granted as national rights with no jurisdiction outside each territory – so that a patent granted by the EPO may become a bundle of up to 27 identical national patents (with the bundle being a so called "patent family"). ABPI endorses the EFPIA response in asserting that the statistics used by the Commission in respect of the number of patents on medicines are incorrectly calculated, and supports Sir Robin's caution to the Commission that "*in any event one needs to divide by 27 for the membership of the EU*"<sup>9</sup>. ABPI agrees with EFPIA that the numbers to be quoted in the Commission's Preliminary and Final reports should refer to patent families and not individual patents.

### **There is no fundamental difference between the pharmaceutical industry and other hi-tech industries in the use of patents to protect incremental innovation**

24. ABPI agrees with Sir Robin<sup>10</sup> that the Commission's assessment of activity by companies enforcing patent monopolies would be improved by comparing the behaviour in the

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<sup>8</sup> Sir Robin Jacob, Ibid page 3

<sup>9</sup> Sir Robin Jacob, Ibid page 7 at para 2

<sup>10</sup> Sir Robin Jacob, Ibid page 2

pharmaceutical industry with other hi-tech industries, rather than by just looking between innovator & generic companies. No evidence has yet been provided in the Preliminary Report that pharmaceutical companies are behaving beyond the parameters of normal competition, or in an abusive fashion. To attack the strategies of patentees in the pharmaceutical industry in this way undermines the entire basis of patent protection in all industries where patents are granted to reward innovation.

25. Equally the Preliminary Report does not make any considered analysis of the full ambit of Article 82 of the Treaty of Rome - which includes rules against the inhibition of technology development. The Commission's final Report should carefully consider and avoid any such inhibition which would actually achieve just such a result by seriously undermining the primary key incentive to innovate.
26. **The ABPI respectfully submits to the Commission that further work is required to look into the nature of general enforcement of patent rights on the wider European market before publication of the final report.**

**Pharmaceutical patents are not a monopoly on a particular disease or treatment and innovation in healthcare is not just about the discovery of new chemical entities**

27. The only key difference between the pharma industry and other high tech industries (in markets such as cars, mobile phones or mp3 players) is that in a mobile phone or a car there are thousands of different patents on components which contribute to the essential working of the designed product – compared with a single chemical entity (usually protected by the patent covering the original discovery) in a pharmaceutical product, whose basic ingredient patent once lost through challenge or expiry, may open up an entire market to copies of the therapeutic product.
28. Unlike the situation in most other industries, patent protection on the basic invention contained in the discovery of any new chemical entity is generally applied for early in the medicine discovery and development process - long before specific candidates are shown to be suitable for use in man, and frequently years before any product is available to reach market.
29. It may take investigation in the region of 10,000 molecules before a single candidate has passed successfully through clinical trials in man and other regulatory checks to reach market authorisation as a product safe and fit for human use. It is further discoveries along this journey to market from the point of the first patent application to marketed product that results in the additional applications filed post initial discovery.
30. Companies are always free to compete to find alternative therapeutic solutions provided they don't directly utilise the disclosed advancement of science in the patents filed by other innovators. It remains true that patents can be legitimately either worked around to create an alternative solution to the therapeutic problem, or the invention licensed for use in competitors' medications, so that alternative products can co-exist on the market even during a particular patent's lifetime.
31. The development of new formulations for dispensing medicines takes considerable investment. New delivery mechanisms and improvements to reduce side effects are

continually under development, for patient benefit. Many of the best selling medicines on the UK market are actually the 5<sup>th</sup> or 10<sup>th</sup> to market in their field<sup>11</sup> and are certainly not necessarily the first patented formulation or the first marketed method of treatment.

32. All patents must fulfil the criteria for patentability - there is no distinction in law between primary and secondary patents. Indeed there are examples where a compound could not be marketed without a new formulation having to be invented. For example the decapeptide goserelin treatment for prostate cancer developed by AstraZeneca. This required a formulation that delivered the medicine in a very slow release form in a controlled way over 3 months, rather like an implantable rice pellet of polymers. Years of research by AstraZeneca scientists eventually arrived at a novel and inventive way of making a solid implant degradable polymer formulation that can be injected into the body.
33. Patents are key to recouping the significant investments in such continued research following the discovery of the initial therapeutic intervention and recognise innovative developments in manufacturing process as well as the initial discovery of the chemical entity which might go on to form a marketable medicine.
34. Patent “clusters” or “thickets” therefore have no basis or meaning in international patent law and do not restrict innovation – in fact the opposite, they represent continuing innovation in matters involved for the public benefit – in the instance of the pharmaceutical industry this would directly affect the numbers of therapies available to patients. Indeed, a way of solving a technical problem for one product (and published in a patent application) may well stimulate another company to solve their own technical problems.
35. As Sir Robin indicated,<sup>12</sup> it is unlikely that a new medicine will ever benefit from more than 10 or 11 years of the term of any granted patent (even with an additional term granted by a supplementary protection certificate). Certainly, it is infrequent that a new drug will ever benefit from the full 15 years of protection envisaged by the Commission at the foundation of the SPC regulation. Indeed never more so than in the current financial climate are Sir Robin's words true that *“it is in the nature of investors – human that they are – that the higher the risk the more reward is needed to persuade them to put their money up”*. ABPI endorses his personal view that *“this is not enough time to encourage the risk and expense involved in seeking further medicines”*.
36. **ABPI encourages the Commission to look into how the patent system can be used effectively to reward, protect and promote investment in R&D, through its own work on the Innovative Medicines Initiative.**
37. **We fully endorse the conclusions of EFPIA<sup>13</sup> that creating an effective climate for innovation and a competitive pharmaceutical sector in Europe will require:**
  - (i) **Strong intellectual property and other exclusive rights and the concomitant right vigorously to defend those rights;**
  - (ii) **A fair reward for innovation, including incremental innovation;**
  - (iii) **Early and equal patient access to innovative medicines;**

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<sup>11</sup> ABPI refers the Commission to look at IMS data on the statin market for cholesterol-lowering medicines

<sup>12</sup> Sir Robin Jacob, Ibid page 4 para 7

<sup>13</sup> EFPIA Response to the EC Sector Inquiry Preliminary Report

- (iv) **Transparent, objective, fair, swift and predictable pricing and reimbursement processes that are as close to a free market as possible, in line with the overall goals of the EU;**
- (v) **A territorial limit to the impact of State controls (implementing G10 Recommendation 6);**
- (vi) **A holistic (versus silo-budget) approach to national healthcare budgets, with the focus shifted from the cost of new medicines to their overall value;**
- (vii) **An efficient generics market that allows savings to be reinvested in innovative medicines;**
- (viii) **A reasonable risk-benefit balance in regulatory processes; and**
- (ix) **Removal of R&D bottlenecks and reduction of the costs of development through public-private partnerships exemplified by the Commission’s “Innovative Medicines Initiative” work.**

### **Expert and efficient Patent Officers examine applications before grant**

38. In an ever increasing rise in applications in all fields of technology, and access to information published in previously inaccessible countries (such as China) the European Patent Office is working alone, and with colleagues in other Patent Offices, to ensure that examination of prior art is undertaken to the best possible standard and efficiently. The EPO is a benchmark of quality and they seek to maintain and improve quality. Competitors have the opportunity to file observations during the examination procedure, the opportunity to oppose the grant of any patent and, if disappointed by the decision on opposition, they have the further opportunity to appeal. As Sir Robin points out it will never be possible to expect the grant of a patent by a patent office to act as a certificate of 100% validity, even if undertaken to a best possible standard. The job of such an examination is to challenge the scope of the patent in front of opposition proceedings held before the Patent Offices and on appeal to the specialist patent courts, not for the Commission or Competition authorities to dictate.
39. It is not realistic to request applicants to disclose “all” information on prior art known to it – Sir Robin<sup>14</sup> is correct in saying that *“it would be impossible to see how this can work satisfactorily or at a reasonable cost... could involve complicated question of what the patentee knew when he knew and what he **should have** known”*.
40. In the US examination of such questions adds significantly to the costs of patent litigation – a factor which the EU Presidency’s work on the proposed single pan-European patent litigation system is anxious to avoid. As Sir Robin reminds us<sup>15</sup> it remains the case in UK litigation that *“if there is material which is a clear knock-out it will normally emerge in the course of a proper and ordinary search”*.

### **The notion of a “tool box”**

41. ABPI believes that fundamentally it should not be an abuse of a dominant position to enforce a patent as a society-granted monopoly created to promote the advancement of science. The granted patent “right” is of no value unless it is capable of being enforced in a court of law. It would be antithetical for patent law (*as a granted monopoly*) to form part of competition law

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<sup>14</sup> Sir Robin Jacob, Ibid page 8 at 3a

<sup>15</sup> Sir Robin Jacob, Ibid page 8 at 3a

(*working against the monopoly culture*) as such would usurp the specialist role of the patent offices in examining the novelty of inventions within each scientific field. The fact that the validity of a patent must be examined before it is granted supports the legitimacy of the right owner in initiating actions to protect his property.

42. This response already mentions that patents in the pharmaceutical industry are usually applied for long before the existence of a suitable candidate for use by doctors in the clinic with patients is confirmed by the patentee – and as Sir Robin mentioned, opposition processes are required to be undertaken within 1 year of application acceptance. At that time, it will not be known whether the new discovery will work in humans, and companies who may later seek to compete will have no market value to assess whether it is worth entering that market with a competing product.
43. ABPI asserts that the Commission's objections to the use of the toolbox of protective remedies cannot be resolved in any meaningful way without destroying the very basis upon which innovation occurs, is brought to the market and rewarded. The Commission should note that there is a real danger that the law of "unintended consequences" will set in and any remedy would result in a worse situation than is currently the case, and be the cause of even fewer new products/ innovations coming to market.
44. **Before attempting to change the current limited patent protection for medicines further, the ABPI believes that it is imperative that the Commission conducts an empirical analysis of the likely impact of doing so on future innovation in medicines development.**

#### **In the UK Oppositions are not the only route to "clear the path" to market entry**

45. The "Bolar" exemption to patent infringement recently enacted as an amendment to European patent laws now allows competing companies to perform preparatory acts in medicine development in order to be ready to launch as quickly as possible post-patent expiry. This enables competing companies to perform clinical trials and apply for regulatory marketing authorisation long before loss of exclusivity, without infringing the relevant patent(s).
46. In relation to European Patent applications a competitor already has 3 opportunities to oppose the grant of a patent before it is made (i.e. 3<sup>rd</sup> party observations during the examination phase of the application; a formal opposition; and, on appeal from the decision of the opposition). In addition to this, under UK patent law the competitor has further opportunities to clear the path of barriers to entry, by applying to the UK Patents Court for a declaration of non-infringement or of invalidity of the relevant patent(s).
47. As Sir Robin points out in his speech,<sup>16</sup> there can be no interim injunction if such a path clearing exercise is undertaken, and a generic company may launch without the risk of patent infringement proceedings being initiated:

"Where litigation is bound to ensue if the defendant introduces his product, he can avoid all the problems of an interlocutory injunction if he clears the way first. That is what the procedures for revocation are for." Jacob J, in *Smithkline Beecham v Apotex Europe Ltd*

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<sup>16</sup> Sir Robin Jacob, Ibid page 9 para 4d

[2002] EWCA 2556 (pat); [2003] F.S.R. 30, para. 68, upheld on appeal in Smithkline Beecham v Apotex Europe Ltd [2002] EWCA Civ 137; [2003] F.S.R. 31.

48. By contrast the patentee has only one real opportunity to step in to prevent its competitors' products and enforce its IP rights. That is the moment just before launch when patent infringement is imminently threatened. This is so even if regulatory authorities have notified the patentee that they have granted marketing authorisation to a competitor's product using the patentee's own clinical trial data on product safety. At this stage the patentee is powerless to do any more than write to request the competitor not to launch until the patent expires.
49. Accordingly, where a generic company chooses not to clear the path of potential patent barriers, the court may restrain its sales by an interim injunction until the trial of the issues of infringement and validity of the originator's patent.
50. While both sides face the risk of un-compensatable loss if they do not win - the originator being unable to re-establish its market position and the generic being unable to calculate what its losses are - the UK courts have in recent years seen the failure to clear the way as a reason for granting an injunction. Novartis v Dexcel [2008] EWHC 11266 (Pat), 10 June 2008 and Leo Pharma v Sandoz [2008] EWCA Civ 850, 25 June 2008 are recent illustrations where the courts have granted interim injunctions in such cases.
51. **ABPI agrees with Sir Robin's suggestion<sup>17</sup> that the fact that in the UK such an opportunity to clear a path exists means that it is not necessary to attempt to introduce a new additional costly stage of pre-grant opposition in the patent application process. As well as being unnecessary, we also believe any new additional hurdles to be both disproportionate and potentially counter-productive.**
52. **ABPI explains to the Commission that this is one reason why there are so many cases initiated by generics in the UK patent courts.**

#### **UK Patent Court procedure as a role model for patent litigation in the pharmaceutical market**

53. ABPI notes that the UK is a sophisticated and well developed jurisdiction for resolving pharmaceutical patent disputes well in advance of generic entry.

#### **A Swift conclusions to cases by specialist judges bring business certainty**

54. Court procedures are flexible and can be adopted to reduce the time to trial, which now usually takes place less than a year from the start of a case. There are specialist patent judges in the Patents Court, Court of Appeal, and the House of Lords and the UK appeal courts have ruled on a broad range of complex patent issues over the last decade. All courts give detailed written decisions. The court usually hears oral evidence from independent experts and can appoint its own technical advisers if appropriate. Witnesses are usually cross-examined. The availability of expert patent attorneys and lawyers facilitates the dispute process.

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<sup>17</sup> Sir Robin Jacob, *Ibid* page 8 para 3b

## **B Interim protection pending trial**

55. ABPI notes that the grant of interim injunctions by the court are not without risk for the patentee. If an originator company is successful in obtaining an interim injunction to prevent generic sales before trial it must give a cross-undertaking in damages to compensate the generic company for any loss caused by the interim injunction if it transpires that it should not have been granted. This safeguards the generic company.
56. In Les Laboratoires Servier v Apotex Inc. [2008] EWHC (Ch) 2347, 9 October 2008 the UK Patents Court has set out an approach to the assessment of damages payable to a generic company which otherwise would have been the first competitor on the market but for the wrongful injunction. The Patents Court held that the generic company has to (i) establish on the balance of probabilities that the chance of making a profit was real and not fanciful and (ii) evaluate that substantial chance.

## **C Clearing the path to market**

57. As discussed already the UK court has an inherent power to grant declarations (even if no other remedy is claimed). Further, any person doing, or proposing to do, an act can seek a declaration of non-infringement from the court irrespective of whether the patentee has made any assertion that that act is, or would be, an infringement - Patents Act 1977, section 71(1).
58. Under the Act, the applicant must first have applied "*in writing to the proprietor for a written acknowledgment to the effect of the declaration or declarator claimed, and...furnished him with full particulars in writing of the act in question*". If the patentee has refused or failed to give a written acknowledgment that the relevant acts do not infringe, then a declaration may be sought. The burden of proof that the generic product does not infringe lies on the applicant. The application may consider a hypothetical product - Minnesota Mining and Manufacturing's Patent [1999] R.P.C. 135 at 152.
59. The UK courts will also grant negative declarations beyond non-infringement. In Nokia Corporation v InterDigital Technology [2006]EWCA Civ 1618 Civ 618; [2007] FSR 23, Nokia sought a declaration that specified Interdigital patents were not essential for compliance with 3G telecommunications industry standards. The Court of Appeal held that Nokia's interest in making telephones that must comply with industry standards was sufficient to show that the declaratory relief sought would serve a useful purpose.
60. In Arrow Generics Limited and another v Merck & Co. Inc. [2007] EWHC 1900 (Pat), 31 July 2007 the court held that it had a discretionary power to grant a declaration that Arrow's generic pharmaceutical was obvious at the priority date of divisional patent applications owned by Merck.

## **D UK courts recognise EPO decisions on patent law**

61. The UK courts are keen to follow the settled EPO view of European patent law (see Actavis v Merck [2008] EWCA Civ 444, 21 May 2008).

62. The UK courts are alive to the commercial needs of the parties and may allow a UK validity case to proceed to trial where there is an ongoing EPO opposition. The risk of duplication of proceedings is outweighed by the need for commercial certainty.
63. A European patent can be revoked by opposition proceedings at the EPO or by an application for revocation in the national courts of each designated European Patent Convention state. EPO opposition proceedings currently usually take about four years to complete (and often longer) while UK national proceedings to revoke the UK designation of a European patent come to trial in about 12 months, with any appeal proceedings taking a further 12-18 months.
64. In *Glaxo Group Limited v Genentech Inc.* [2008] EWCA Civ 23, 31 January 2008 the Court of Appeal provided guidance on the correct approach to granting stays in such cases that takes account of delay and commercial certainty for the parties. A key factor in deciding whether to stay UK patent proceedings is the length of time that it will take for the respective proceedings in the national court and the EPO to achieve some certainty on validity. The longer the EPO opposition proceedings are expected to take compared to the national proceedings, the readier the national court should be to refuse a stay. This is so that "business knows where it stands".
65. Evidence that at least some commercial certainty would be achieved at a considerably earlier date in the national proceedings than in the EPO will entitle the UK judge to resist an application for a stay of UK proceedings.

#### **The proposed Single European Patent litigation system**

66. ABPI has contributed directly to the UK Government's input on the EU Presidency proposals for a Centralised European patent court system. ABPI advocates to the Commission that in order to be workable the procedure for the proposed Central Court will need to contain sufficient mechanisms to replicate some of the best practices of the UK Patents Court in particular the ability to
- grant of interim injunctions
  - "clearing the path" by declarations of non-infringement
  - challenge validity before the same court dealing with questions of infringement
  - challenge by cross examination of expert evidence
67. ABPI echoes Sir Robin's comments on the shortcomings of the present proposals for "bi-furcation" – or the splitting of issues of validity and infringement between two different courts. These will serve only to increase the length of time that patent cases take to be resolved and the commercial uncertainty that this entails for both parties in the meantime.
68. **ABPI urges the Commission to concentrate work on the future of competition in the patent system by ensuring the pragmatic workability of the proposed European Patent Litigation System for both patentee and potential competitor.**

#### **Difficulties in application of European Regulatory legislation concerning abridged applications and data protection for results of originator's pre-clinical and clinical research**

69. The Preliminary Report creates the impression that, for the period of review (2000 - 2007) many originator companies made unmeritorious interventions with competent authorities

and/or in the Courts concerning application of the abridged procedures for grant of copy authorisations and issues of data protection (sometimes also called or referred to as “data exclusivity”). The Report states that litigation concerning data protection had been brought by 25% of the originator companies responding to the Sector Inquiry (see paragraph 730). The suggestion is made that the main intention behind these interventions was to create legal uncertainty and thereby delay authorisation of generic copies of originator products, rather than because originators had a reasonable case that their legal rights were being undermined.

**70. ABPI suggests that this proposition is not a fair reflection of the state of the law and the bona fide attempts to clarify it during the period 2000-07.**

71. Taking steps to delay entry of a generic product that one believes is being approved in breach of the proper application of the abridged procedures is a perfectly legitimate exercise, and it should not surprise the Commission that interventions are pursued with particular vigour where they concern a major product. We make no comments here on issues of linkage of regulatory approval to patent status; as that raises individual national legislation and issues not directly relevant in the UK.

72. However ABPI suggests that the true reason for legal uncertainty in this period and the delays in approval to which that uncertainty may have contributed, was the lack of clarity in the relevant pharmaceutical EU law, coupled with the legal framework in which regulatory data protection rights of originators were determined and the substantial delays inherent in determining the correct interpretation of the law through references to the European Court of Justice (“ECJ”).

**A The substantive law was unclear**

73. The Report suggests at paragraph 703 that the framework was easy to apply. ABPI submits that this was not so<sup>18</sup>. The substantive provisions were difficult to interpret and lacked the legal certainty that the legislative process should have ensured existed on such important matters. The abridged procedures were established by Directive 87/21/EEC which represented an attempt to balance the protection of public health, (including incentivizing innovation that could contribute to improved public health), with the need to clarify the circumstances in which copy medicinal products could be authorised without the repetition of studies in animals and in humans, the results of which were already known to the authorities through the research of the originator companies.

74. This is understandably a complex exercise, but the drafting of the relevant legislation fell well short of an acceptable standard and ABPI submits that the Commission should accept its fair share of responsibility for this. Had the law been tolerably clear, national courts would not have found it necessary to refer to the ECJ so many questions, covering virtually every element of the legislation. The national courts are required under European law to make references where the provisions of European law are unclear and in none of the key cases during this period was it seriously maintained (by the competent authorities, originator companies or generic companies) that the provisions were clear.

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<sup>18</sup> We also note that this paragraph fails to recognise that bioequivalence is a separate criterion for use of the procedure and is not a conclusion that flows from the existence of the same qualitative and quantitative composition of active substance and same pharmaceutical form.

75. For instance, central to the legislation appeared to be the need to determine when products were “essentially similar” and when they were different and benefited from their own protection period. However, the legislation failed to define the concept of ‘essentially similarity’ or even to explain the criteria relevant to the assessment of the concept.
76. It should be remembered that the interpretation of the Commission itself on the implications of adding new indications to existing products, as set out in the Notice to Applicants for some years, was subsequently set aside by the ECJ in the *Generics UK* case (Case C-368/96). Similar issues arose in relation to other parts of the relevant provisions. In *Generics UK* the ECJ determined the definition of essential similarity and decided that the data developed to register new indications should not gain any separate data protection. However, because the reasoning adopted by the ECJ was relatively narrow it did little to clarify the interpretation of other important aspects of the legal framework for abridged procedures.
77. On a separate reference concerning the concept of when active substances are different, Advocate General Jacobs noted:
- “Plainly, the text of the Directive does not in itself supply a solution to the questions referred. The meaning of essential similarity is not defined. Nor is it entirely clear whether any limits attach to the additional data which may be submitted in the context of an abridged application. ... The Court’s case-law is similarly open to interpretation. The judgment in Generics does not specify in any detail what is meant by “the same qualitative and quantitative composition in terms of active principles”.<sup>19</sup>”*
78. In the *Novartis* case (C-106/02) the ECJ considered several questions including the critical issue of the data protection status of products that were the result of substantial incremental research on the same active substance to develop a new version of benefit to patients (e.g. improved pharmaceutical forms). The application of the definition of essentially similar product provided by the ECJ in the *Generics UK* case implied that such products should be treated as different. The reference by the English Administrative Court on these issues provoked a very detailed analysis of the legislation and took a long time to resolve.
79. The fact that the innovator’s principal challenge in this and in other related cases failed before the ECJ does not diminish the reasonableness of bringing the case in the first place. In this respect it should be noted that some national courts found in favour of Novartis and were not initially persuaded that there was any need for a reference<sup>20</sup>. Nor is it surprising that many national challenges were dropped over this period once decisions of the ECJ that concerned the same or a related issue had been delivered. In many Member States companies are obliged to commence judicial reviews within a certain time from the decision in issue otherwise their right to complain is lost. The statistics presented by the Commission showing a “low” success rate for litigation begun concerning data protection issues should not be interpreted to imply that the litigation was vexatious.
80. The Commission comments at paragraph 731 on the fact that a significant amount of the data protection litigation was commenced in “new” Member States. The Report does not mention the nature of that litigation, but important cases were begun in this period by innovator

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<sup>19</sup> See paragraph 34 and 35 of the Opinion of Advocate General Jacobs of 16 September 2004 in Case C-74/03 (*SmithKline Beecham plc v Laegemiddelstyrelsen*)

<sup>20</sup> See decision of *District Court of Arnhem in Novartis Pharma BV v the Medicines Evaluation Board* of 20 December 2001 and a similar decision of the District Court of Amsterdam in separate litigation on 21 June 2004 in *Merck B.V. v Medicines Evaluation Board*.

companies seeking to defend the 10 year protection period for centrally authorised products in the face of national approvals that pre-dated accession.

81. When those new Member States joined the Community, Regulation 726/2004, which governs centralised assessment by the EMEA, became directly effective. It grants reference products approved centrally 10 years of data protection. Originators understandably argued that it was incompatible with this rule that products approved nationally within the 10 year period should remain on the market. In these cases the Commission appears to have conceded the reasonableness of the originator challenge and, indeed, has taken its own steps to investigate the circumstances that arose post-accession in certain Member States.
82. Similarly, the Commission implies at paragraph 706 that it was vexatious for an innovator to challenge the commencement of assessment of a generic application before the data protection period had expired. However, at the relevant time the Commission's own Notice to Applicants and the Mutual Recognition Facilitation Group guidance<sup>21</sup> suggested that until the originator product's data protection had expired, a condition for a valid generic application was not met and the originator's data was not available for assessment.
83. The fact that this interpretation, in practice, delayed the approval of the copy product until 6-12 months after the protection period has expired was dealt with in the 2004 amendments to the Directive by allowing validation of applications for copy products after 8 years of data protection, but continuing the marketing protection for 2 more years, after which the generic product could immediately be launched.
84. It should be noted that the Commission's own preparatory memorandum for Directive 87/21/EEC<sup>22</sup> emphasised that data protection was a most important protection for the fruits of research that might not otherwise be protected by a patent. Moreover, when the provisions were adopted, the Commission issued a statement saying that the fundamental aim of the provisions was to encourage and protect innovative effort<sup>23</sup>. Against this background, it is hardly surprising that innovators should wish to monitor closely the way in which the legal provisions were being applied.

## **B The basic framework for determining regulatory data protection rights promotes uncertainty**

85. The basic framework of the legislation has created uncertainty because it does not provide that the entitlement of the innovator's product to data protection should be established at the time the product is authorised. Nor has there been any specific policy that the status of the innovator's data should be clarified at the time of assessment.
86. The status of the originator's product, therefore, only falls to be resolved when (usually many years later) a generic company applies for a copy authorisation and seeks to persuade the authorities that, on a proper interpretation of the legislation, it is entitled to have its product assessed by reference to the data lodged by the originator for one or more of the products already approved.

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<sup>21</sup> See report of meeting of 24 April 2003.

<sup>22</sup> COM (84) 437 Final of 25 September 1984.

<sup>23</sup> Note from the Services of the Commission on the consequences of entry into force of Directive 87/21/EEC.

87. In this abridged regulatory process, the originator is not a participant nor is it automatically consulted - despite the fact that the generic company is seeking to cross-refer to the originator's data for the so-called reference product.
88. Given the uncertainty of the law and the significance of the issues at stake, it is hardly surprising that originators will seek to protect their legitimate interests by pro-active intervention with the authorities to explain their interpretation of the law and, if necessary, bring proceedings to clarify that law. This is no more surprising than that generic companies should challenge competent authorities where they believe the authority has wrongly interpreted the same law (see for instance Synthon case C-452/06).

### **C Delays in resolving issues of interpretation**

89. The time-lines under which questions of interpretation were resolved by the ECJ during this period were exceptionally slow and this compounded the uncertainty throughout the period from which the Commission has derived its statistics.
90. For instance, the issues in the Novartis case were referred to the ECJ in February 2001. However, the Advocate General's Opinion was not delivered until January 2003 and the ECJ's decision was not delivered until April 2004.
91. Anyone involved in this case was acutely aware from the comments of the Court at the oral hearing that the issues were viewed as difficult and, therefore, it is perhaps unsurprising that it took so long to reach a unanimous decision. However, delays of several years in resolving questions of a enormous commercial importance undoubtedly compounded the uncertainty for all stakeholders.
92. In the meantime this unsurprisingly led to other references (see for instance Approved Prescription Services Case C-36/03), and national proceedings, some of which were stayed pending the outcome of the reference to the ECJ.
93. **ABPI submits therefore that it is plainly wrong for the Preliminary Report to suggest either (a) that interventions by originators and generic companies (whether before the competent authorities or the courts) were vexatious rather than reasonable attempts to defend rights and/or clarify the law or (b) that they were the major cause of legal uncertainty and delays in processing generic applications. The root cause of the uncertainty has been the poor quality of the legislation which failed to provide the legal certainty that stakeholders can reasonably expect.**
94. As a result of the gradual clarification of the law by the ECJ and the legislative amendments of 2004, many (but not all) of the issues that have given rise to uncertainty and interventions by originators and generic companies are now resolved
95. **ABPI urges the Commission to initiate further work on adding clarity to the Regulatory legislation to assist the smooth operation of the pharmaceutical market.**

## Conclusion

96. The pharmaceutical market is unique in normal market standards as national government monopsonies control purchasing, price setting and uptake of new medicines through technology assessments.
97. It remains the responsibility of national governments in Europe not just to provide access to medicines for patients through their national health systems, but to ensure product safety through efficient regulation and to provide incentives to pay for the costly research to innovate new therapeutic solutions.
98. The methods of doing this have become increasingly complex, and ABPI welcomes this opportunity to contribute to the Commission's work to promote legislative clarity for companies operating in the European pharmaceutical market.
99. ABPI urges the Commission not to lose sight of patients throughout this inquiry and to consider some of the methods outlined in this response currently in use in the UK as best practice to ensure that access, value and innovation can co-exist in this financial climate of cost cutting in healthcare budgets and health technology assessment decisions on the uptake of innovative medicines.
100. We support the Commission's continued work to incentivise development of new medicines through the Innovative Medicines Initiative, and on protection of Intellectual Property Rights through a proposed centralised European Patent Court and Community Patent system, as a means to contribute to a competitive marketplace across Europe.
101. We fully endorse the conclusions of EFPIA<sup>24</sup> that creating an effective climate for innovation and a competitive pharmaceutical sector in Europe will require:
  - (i) Strong intellectual property and other exclusive rights and the concomitant right vigorously to defend those rights;
  - (ii) A fair reward for innovation, including incremental innovation;
  - (iii) Early and equal patient access to innovative medicines;
  - (iv) Transparent, objective, fair, swift and predictable pricing and reimbursement processes that are as close to a free market as possible, in line with the overall goals of the EU;
  - (v) A territorial limit to the impact of State controls (implementing G10 Recommendation 6);
  - (vi) A holistic (versus silo-budget) approach to national healthcare budgets, with the focus shifted from the cost of new medicines to their overall value;
  - (vii) An efficient generics market that allows savings to be reinvested in innovative medicines;
  - (viii) A reasonable risk-benefit balance in regulatory processes; and
  - (ix) Removal of R&D bottlenecks and reduction of the costs of development through public-private partnerships exemplified by the Commission's "Innovative Medicines Initiative" work.

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<sup>24</sup> EFPIA Response to the Sector Inquiry Preliminary Report