

## Comments on Preliminary Report of European Commission's Pharmaceutical Sector Enquiry

### **Intellectual Property Lawyers' Association Comments on Pharmaceutical Sector Enquiry Preliminary Report**

#### **1. Introduction**

- The Intellectual Property Lawyers' Association ("IPLA") is an association of law firms who represent both originators and generics in patent matters (contractual and litigious). The objective of this paper is to assist Commission officials with our observations on how the patent system works in practice, so that they are better informed for their further work on this project. Our objective is not to express partisan views on behalf of originators or generics.
- Although the Preliminary Report is said to be limited to facts rather than opinions, it is clear from public statements made by various Commission officials at and shortly after the launch of the Report that at least initial views have already been formed on the basis of the content of the Report. Some of those opinions appear to be critical of various parts of the industry. IPLA is concerned that some of those views are misconceived, and based at least in part on gaps in the Commission's knowledge of the practical operation of the patent system which our contribution is designed to fill. Hence our attempt to assist in providing practical information.
- IPLA members accept that the way in which pharmaceutical products are developed and sold in Europe is not perfect. We also accept that there may have been isolated examples of patent-related defects in the operation of the system. However: (i) such defects are by no means limited to the pharmaceutical industry, and arguably cannot be avoided entirely by legislation; (ii) they are in large part the result of the legal structure of the patent system in Europe (eg absence of a single patent enforcement system), not the way in which the industry uses that system; and (iii) they are minor in comparison to the impact of the marketing authorisation and pricing systems with which the pharmaceutical industry has to comply when operating in Europe.
- The relationship between originators and generics is symbiotic: the generic model will fail in the medium term if the originators do not continue to develop new products. That is the case whether the research relates to new chemical entities or to improvements in existing products. Patents for "incremental" or "follow-on" innovation can be at least as valuable to Society as those covering NCE's, if not more so. Any action which discourages research leading to such patents would be to everyone's detriment.

#### **2. IPLA**

The Intellectual Property Lawyers' Association ("IPLA") acts as a representative body for law firms in England and Wales with intellectual property practices, who wish to lobby for improvements in IP law. Over 50 firms are members of IPLA, and the vast majority of patent and other litigation and transactional work relating to intellectual property rights in England and Wales is conducted by these member firms. Because of the international nature of patents, member firms are also familiar with how the patent system operates in many other countries, including across Europe and in the United States of America. Members act for a wide range of clients, from major multinational groups of companies to SMEs and

technology start-up companies, as well as universities and private inventors and investors. As a group, IPLA probably has unparalleled experience of how the patent system works in practice in the UK.

The working party which has prepared this submission comprises lawyers who regularly represent originator companies, lawyers who regularly represent generic companies, lawyers who have represented both originator and generic companies, as well as lawyers who have acted for patentees and accused infringers in other industry sectors. The working party has taken care to ensure that the views expressed in this submission are shared by all members of the working party, and of IPLA generally, and do not favour one part of the pharmaceutical industry at the expense of the other.

### **3. The Purpose of the Patent System**

The patent system has an important function in the European Community. As stated in the communication from the Commission to the European Parliament and the Council of 3 April 2007 on "Enhancing the Patent System in Europe", "... intellectual property rights, and patents in particular, are linked to innovation, which in turn is an important contributor to competitiveness." The Commission is actively promoting reform of the system for enforcing patents (in the form of a new supra-national European Patent Court), but the basic patent law as set out in the European Patent Convention is fully accepted by the European Union.

There are suggestions in the Preliminary Report that originators are to be criticised in some circumstances for engaging in research and obtaining patents. IPLA submits, however, that the Enquiry should start from the position that patent law under the European Patent Convention is in accordance with the policies of the European Union and accordingly, innovators who carry out research and make inventions which satisfy the requirements set out in the European Patent Convention are entitled to a patent monopoly for 20 years from the date when the patent application was filed, and are entitled to engage in research with the intention of securing such protection for their investment. The Commission will also appreciate that the patent system as a whole is regulated by international agreements, notably TRIPS (the Agreement on Trade-Related Aspects of Intellectual Property Rights, Annex 1C of the Marrakesh Agreement Establishing the World Trade Organization).

Further, the purpose of the patent system is to promote research so as to lead to innovation: as Charlie McCreevy, Internal Market and Services Commissioner, said on 3 April 2007: "Patents are a driving force for promoting innovation, growth and competitiveness ...". The data in the Preliminary Report indicate that there is substantial research in the pharmaceutical industry and consequent patenting activity: this is precisely what the patent system is intended to encourage.

Patenting activity is particularly important in the context of research in the pharmaceutical industry for the following reason. The patent system requires publication of the invention so that, when the patent expires, the fruits of the patentee's research are available to others so that they do not have to duplicate the work. Because of the lengthy life cycle of pharmaceutical products, the pharmaceutical industry is one of the few industries where the technology disclosed in published patent specifications is still of interest and benefit to competitors following patent expiry (in most other sectors, the patented technology is superseded long before patent expiry).

Research activity is not confined to the originator or the original inventor of a drug: as noted in paragraph 364 of the Preliminary Report, there is significant competition in research and development on important products and generic companies as well as originators carry out research on established products, especially in relation to synthetic procedures and formulations. For example, for one well known medicine, third parties, mostly generic companies, hold 234 related patent families, compared with the innovator's mere 40 patent families<sup>1</sup>. Given that originators appear to face substantial patenting activities in relation to their own product by competitors (other originators and generic companies), it would be inappropriate to suggest that competition law should restrict the originator company from competing in this area of activity.

What this information demonstrates is that originators and their competitors are doing what the patent system is designed to encourage, namely, continuing research and innovation. All of the patents which are granted cover inventions in respect of which the European Patent Office (or national patent office) examiners are satisfied that they meet the criteria for patentability laid down in the European Patent Convention.

Furthermore, one objective of all patent-related activity – research, patent prosecution and infringement litigation – is to enable the patentee to prevent its competitors from using the patented technology. This is what the patent system is for, and this is why innovators obtain patents (see also section 7 below). The references to the use of patents to keep generic companies off the market, which are cited in Section 2.1 of the Preliminary Report, are not evidence of anti-competitive behaviour: they are evidence that the patenting companies are proposing to use patents for the purpose for which they are granted.

#### **4. How the patent system works in practice**

IPLA endorses much of what Lord Justice Jacob said in his speech on 28 November 2008. Lord Justice Jacob is a highly regarded patent specialist. He is currently a member of the expert group advising the European Commission on the creation of the proposed European Patent Court, and IPLA would accordingly expect the Commission to pay due respect to his views. As a barrister, he had an extensive practice acting for patentees and accused infringers in many sectors including pharmaceuticals. His time as a first instance judge was a time when the English courts were regarded as being generally unfavourable to patentees and he certainly found against patentees, in the pharmaceutical sector as in all other sectors, in a substantial majority of his judgments (for example, in 8 out of his first 10 patent infringement and validity cases). His experience puts him in an extremely strong position to speak on the matters which he covered.

In particular, IPLA endorses Lord Justice Jacob's observation that the European Patent Office, and national patent offices, cannot practicably do a better job than they currently do in "weeding out" weak patents. Once it is accepted that the granting patent office can at best be only a "coarse filter", patentees will necessarily end up having patents which are less than fully robust. This is a fact of the system, and applies in all sectors of industry. Accordingly, the fact that companies have in their portfolios patents which they themselves may acknowledge as "inevitably less solid and robust" is unsurprising, and should not be the subject of adverse comment. It cannot be assumed that because a patent is regarded as "less solid and robust", it is necessarily invalid: a significant proportion of patents which are regarded as weak are upheld by the courts.

## 5. Strength of Patents

Patent validity is recognised as a very difficult area of the law. Specialist judges to deal with patent validity issues are required in many legal systems (eg there are specialist judges in the Federal Patents Court in Germany, the Patents Court in England, and in the Court of Appeal for the Federal Circuit in the United States). It is not surprising that reasonable people may differ on the correct result of a patent validity case. The Preliminary Report notes that in 11% of cases there are divergent decisions in different countries in the EU. This comes as no surprise to patent litigation lawyers: it simply reflects the difficulty of the decision as well as differences in the application of law and differences in the procedures of those jurisdictions.

In circumstances where judges (and patent examiners) frequently differ as to the validity of a given patent, it is not surprising that only a small number of patents can be regarded as "robust": in most cases, the patentee cannot be fully confident that the patent will be upheld. Furthermore, the strength of a patent depends on the nature of the prior art identified, and the arguments developed, by the other side. There is accordingly a limit to the extent to which a patentee can know what prior art exists around the whole world, can anticipate what the arguments attacking validity might be and accordingly how it can assess the strength of its own case. This lack of certainty is not a failing of the system, it is inherent in the system and, whether in the pharmaceutical sector or otherwise, companies should not be criticised for pursuing claims which are ultimately unsuccessful.

The Preliminary Report gives an overall success rate for patentees of 38%. It must be remembered that cases which go to court involve only a tiny minority of the total number of patents granted, and the decision as to whether to fight a patent case depends on the parties' perceptions of the strength of the case and its commercial importance – strong patents tend not to be litigated, and less strong patents are more likely to be litigated where the commercial importance is high (as in the pharmaceutical sector). Further, the "down side" for a patentee who loses (ie exposure to payment of the other side's legal costs) is much less than the "down side" for an infringer (ie an injunction and payment of damages as well as costs). Accordingly, patentees have less incentive to try to settle more difficult cases, and as a result more patentees lose cases than accused infringers.

In addition, the party which starts the litigation tends to choose to litigate where it thinks its case is good, and it is not surprising that patentees have a better success rate in cases which they initiated than where the litigation was initiated by the generic company.

IPLA is not therefore surprised at the success rates reported in the Preliminary Report – they are not out of line with the experience of IPLA member firms of patent litigation in all sectors. There are no official statistics for success rates in Europe, but according to an informal survey<sup>2</sup>, the "win rate" for patentees in the main European jurisdictions, across all industries, has been reported as:

Germany – 45.5%, 32%, 31% (three different estimates)<sup>3</sup>

France – 55%

Italy – 40%

GB – 26%<sup>4</sup>

Netherlands – 27%

According to more detailed statistics for the United States<sup>5</sup>, the "success rates" for patentees

(in all sectors) were on average 37% in 1995-2000 and 40% in 2001-2007. The figures in the Preliminary Report relating to the Pharmaceutical sector are in line with these statistics.

IPLA submits that, if a patent is valid, a patentee cannot be criticised for enforcing it. It must be appreciated, however, that although parties may form views as to the strength or weakness of the case regarding a particular patent, they can only know whether or not a patent is valid in a case when final judgment has been given. Given the complexity and difficulty of patent law, it is not practicable for competition authorities who are not patent specialists to judge the accuracy of a patentee's assessment of its prospects in advance of final judgment.

There is a further question, whether a patentee which is unsuccessful in litigation should be criticised for having brought proceedings in the first place. We consider that the best arbiter of this is the court which heard the case: and it is illuminating that, at the meeting on 28 November 2008, Lord Justice Jacob, who has very extensive experience and who very frequently found against patentees, could think of only one case where the patentee was open to criticism for having brought the proceedings.

In the final paragraph of section C2.1 in the Executive Summary, it is stated that "enforcing patent rights in court is *generally* legitimate ..." (*emphasis added*). This implies that the Commission contemplates a number of circumstances in which enforcing patent rights in court is not legitimate. This is, however, a matter which has already been considered by the Court of First Instance in *ITT v Promedia* (case no. T111/96) where the court said:

"The ability to assert one's rights through the courts and the judicial control which that entails, constitute the expression of a general principle of law which underlies the constitutional traditions common to the Member States and which is also laid down in Articles 6 and 13 of the European Convention for the Protection of Human Rights and Fundamental Freedoms of 4 November 1950 ... As access to the Court is a fundamental right and a general principle ensuring the rule of law, it is only in *wholly exceptional circumstances that the fact that legal proceedings* are brought is capable of constituting an abuse of a dominant position within the meaning of Article 86 of the Treaty." (*emphasis added*)

The Preliminary Report goes on to state: "Litigation can be an efficient means of creating obstacles in particular for smaller general companies." Litigation can create an obstacle in two ways: if the court grants an order enforcing the patent, or if the accused infringer decides that the cost of defending the litigation is too much. The investment necessary to develop and bring to market a generic product is substantial and the marginal additional cost of patent litigation is small by comparison. We are not aware of any cases where a small generic company has backed away from launching a generic product in the face of a threat of litigation: but in such a case, such a decision by a small generic company would be based on an analysis of the expected profits to be made from launching the generic product and its prospects of winning any litigation, as well as the cost of fighting such litigation: it would not be because it lacked the resources to fight the litigation if it chose to do so.

Patents are monopolies, and the exploitation of patents can give rise to competition law issues. Accordingly, patent lawyers with experience of commercial dealings with patents as well as patent litigation need to have expertise in competition law. Thus, patent practitioners are fully aware of the possibility of complaints to the competition authorities or private claims under Article 82 and corresponding national laws where it appears that a patentee is

abusing a dominant position. It is notable that IPLA is collectively aware of only one current patent infringement case (and that is outside the UK) where breach of competition rules is being alleged<sup>6</sup>. This suggests that it is generally recognised that the complexity of patent law and the difficulty of forecasting the result in a patent case, mean that the obtaining of a patent which is thought to be weak, and its assertion, are not generally seen as being capable of being breaches of Article 82.

## **6. Expertise and the use of the patent system**

We understand that the Competition Directorate has not previously had occasion to examine in detail how the patent system is used in any particular industry sector. We further understand that the Sector Inquiry team has been advised on patent law by the European Patent Office, by other directorates within the European Commission, and in meetings with EFPIA and the European Generics Association. With the exception of the two industry associations, about whose submissions the Commission may have been sceptical, the organisations consulted are knowledgeable about substantive patent law and the granting procedure, but are not necessarily in a position to advise on how the patent system works in practice, that is, on how companies in any industry make decisions to carry out research and to apply for patents, and to licence or enforce those patents.

IPLA is accordingly concerned that the Commission may not be aware that many of the practices which cause it concern are inherent in the patent system. For example, the filing of divisional applications is a necessary part of the patent prosecution procedure, and companies in all sectors use the procedure in essentially the same way. The Commission should be aware that the procedure in the US Patent and Trademark Office (USPTO) allows for a very much more extensive use of divisional applications (and also continuations and continuations in part) and that an attempt by the USPTO to restrict this procedure was recently overruled by the US Federal Court (an appeal is pending).

A further example lies in the Commission's analysis of the outcomes of EPO Oppositions. In paragraph 599 of the Preliminary Report and Figure 88, patents which are amended in oppositions are recorded as successes for the generic company. In practice, maintaining amended claims is usually a victory for the patentee, since the amendments will have been drafted by the patentee to avoid the attack on validity while still providing effective coverage for the invention: patentees have little reason to propose amended claims which can readily be "designed around". This is not of course true in all cases, but it is generally more accurate to record upholding a patent with amended claims as a victory for the patentee than for the generic opponent (although the only properly accurate analysis would assess every case on its own merits).

IPLA is also concerned that the Commission has focussed on delay in generic entry after "loss of exclusivity" without any consideration of other public policy considerations such as the promotion of research and the improvement of healthcare and the patent system (see section 3 above).

Again, we return to the comments of Lord Justice Jacob, who has extensive experience of the way the patent system works. We view with concern public statements by representatives of the Commission (for example at the meeting of EPLAW in Brussels on Friday 5 December 2008) that they "did not agree" with what Lord Justice Jacob said: IPLA submits that proper respect should be paid to the views of experienced, highly respected and independent patent

experts like Lord Justice Jacob, especially where they are already consulted as experts by other Directorates within the Commission.

## **7. Patenting policies, defensive patenting and "evergreening"**

When a company applies for a patent, it does not necessarily know the full scope of the prior art which will be revealed by the Patent Office's searches, so it does not know whether the patent will be granted and how strong it will be<sup>7</sup>. Further, at the time of applying for the patent, the originator company does not know whether the invention will in fact be incorporated in a product which will be marketed or whether the patent will be only of defensive benefit. Even with research carried out later in the life of a product, it is rarely possible to distinguish between, on the one hand, research directed at improving or finding better versions of the product, from, on the other hand, research directed at keeping competitors away from a product: the nature of the patent system (see section 3 above) which provides a monopoly as the incentive for successful research means that all research which is incentivised by the patent system will have as one of its objectives the securing of the monopoly. In this way, many patents are applied for which are not in fact exploited by the patentee. This practice is not in any way improper – it is simply the result of the uncertainties which accompany the processes of research and patenting.

It should be noted that the European Patent Convention has recently been revised to make it clear that continued research into pharmaceutical products is to be encouraged. Article 54(4) and (5), added by "EPC 2000"<sup>8</sup>, make express provision for patents for inventions consisting of "second medical uses"<sup>9</sup>, which by definition can only be the result of continuing research into a product. 24% of all "secondary" patents relate to second medical uses, according to Table 17 in the Preliminary Report.

Furthermore, the scope of the claims of a patent are a matter of patent law and do not necessarily bear any relation to competition in the market. Thus a product can fall outside the scope of the patent but can still deprive the patentee of a significant proportion of its sales: this will prevent the patentee from recovering its investment in just as damaging a way as a product falling within the claims of the patent. It is this concern which underlies most defensive patenting, although, as indicated above, it is rare for research to be carried out for the single purpose of achieving a defensive position.

Nevertheless, in the experience of IPLA member firms, companies in all industry sectors apply for, or acquire from third parties, patents which they do not themselves exploit. As pointed out by Lord Justice Jacob, this happens most extensively in the electronics and telecommunications sectors: a mobile telephone or a silicon chip can be the subject of thousands of patent families (ie tens of thousands of patents within the EU).

If a patent is not exploited, third parties may apply for compulsory licences. Compulsory licences are governed by TRIPs and are available throughout the European Union. This provides an adequate mechanism for ensuring that originators cannot control unexploited patents which constrain the activities of their competitors, while nevertheless providing the patentee with a suitable reward for the making of the invention.

Experience suggests that, in fact, very few companies apply for compulsory licences. This means that originator competitors prefer to "design around" any blocking patents, or to take a licence by agreement. The licence royalty is not an extra cost which would not be incurred if

the defensive patent had not existed - it is simply the result of a decision by the licensee to pay a royalty to the patentee rather than pay for its own research to avoid the patent. Generic companies rarely apply for compulsory licences, but this is because their business model is to avoid as much expenditure as possible so as to be able to compete on price: they therefore avoid products in respect of which they may have to pay a royalty.

In addition, in the pharmaceutical sector, once a product is launched, no later-filed patent can legitimately prevent a generic version of that product from being launched<sup>10</sup>, and the patent system does not provide any mechanism (apart from supplementary protection certificates) through which an originator can extend the protection for a product which has been launched, beyond the date of expiry of the patents applied for at the time of launch.

The Preliminary Report refers to "patent clusters" consisting of as many as 1,300 patents and applications. Although the Preliminary Report mentions this figure frequently, Figure 45 shows that there are only 9 INNs which are the subject of more than 400 granted patents. In respect of the INN where there are 1,300 reported patents and applications, there are in fact only about 800 patents, and this figure is based on counting separately the designation of the European patent in each of the designated states across the EU (the EU patent "family" for a single invention). After adjustment, then, the real figure would be much lower. For example, if the 800 patents designated all 27 Member States, the 800 patents would represent only around 30 patent families (ie 30 separate inventions). Since the product is an important one, it is likely that all Member States of the EU are designated. Even if only the average number of countries designated per EPO patent (14.8 countries) were designated, this would give only about 54 families. This represents fewer than 3 inventions per year over the life of the patent. The 500 applications are likely to designate all EPC countries (this is the usual practice, since new countries cannot be designated subsequent to the filing of the application) so may represent only around 18 patent families (ie 18 separate inventions). And for all but 9 of the top INNs, there are (by the same calculation, of 14.8 countries designated per patent) fewer than 27 patent families – in most cases, much fewer.

The practice of "evergreening" is criticised in the Preliminary Report (by "evergreening", we refer to the practice where an originator company stops selling a product and sells instead an improved version of that product, as described in paragraph 830 of the Preliminary Report). This practice can make it difficult for generic companies to sell generic versions of the original product. However, this is because generic companies adopt a business model which avoids incurring the costs of marketing: effective marketing of the generic version of the originator's abandoned product would enable substantial sales to be made. Thus, the strategy succeeds only because the originators' competitors choose not to compete.

This raises an important question under competition law: if a competitor adopts a business model whereby it chooses not to compete in certain ways, for example by not engaging in marketing activities, but relies instead upon the marketing activities of the originator companies, does this require the originator company itself to limit its activities so as not to take advantage of the shortcomings of its competitors' business models?

The complaint by generic companies is that the improved products introduced by originator companies frequently have no therapeutic benefit, but simply keep prices high and make it difficult for generic companies to enter the market. There are, however, mechanisms for preventing this from happening, in the form of reimbursement decisions by the relevant national authorities, and the actions of doctors in prescribing products. If it is the case that



originator companies engage in product switching, they are permitted to do so because the relevant national authorities decide that the new product should be reimbursed at its full price, and because doctors decide to prescribe the new rather than the old product. IPLA takes the view that the relevant national authorities, and doctors, are in a better position than generic competitors (or competition authorities) to assess the medical benefits of a product switch.

## **8. Pricing issues**

IPLA has anecdotal evidence that, in the UK market, when generic products enter, the reimbursement authorities continue to reimburse pharmacies at the full list price of the originator product for around 4-6 months. Furthermore, in many cases, when the reimbursement price is reduced, it tends to follow the highest available generic list price, and does not take account of the high level of discounting which can take place when generic products are first launched<sup>11</sup>. Thus there is a significant difference between the prices actually charged by generic suppliers and the reimbursement prices paid by national health authorities, which appears to have a very significant impact on the failure of generic entry to lead to significant reductions in drug prices paid by the health authorities.

## **9. Settlement Agreements**

There is a public policy in favour of litigation being settled rather than fought: indeed, in English litigation, parties are encouraged to settle litigation and can be penalised by the court in some circumstances if they fail to seek a settlement by mediation. The question then arises, in the context of a patent settlement, whether the strength of a patent should be taken into account when assessing a settlement agreement. IPLA considers that, in general, the agreed settlement terms should reflect the negotiating skills of the parties and the balance of their views on the strength of the patent and the importance of the particular product, and it is inappropriate for a third party such as a competition authority to try to second guess the outcome. This view appears to have been endorsed by the United States Court of Appeals for the Federal Circuit in the Ciprofloxacin Hydrochloride anti-trust litigation, where the Court held that what was important was whether the agreement was in accord with the monopoly inherent in the patent and that an analysis of patent validity is inappropriate in the absence of fraud or sham litigation.

Furthermore, settlement agreements frequently involve some form of licence. The thrust of the Preliminary Report is to express concern where settlements delay generic entry. However, this is not a matter which is addressed in Commission Regulation (EC) No 772/2004 of April 27, 2004 on the application of Article 81(3) of the Treaty to categories of technology transfer agreements (2004/L 123/11) and its accompanying guidelines entitled "Commission Notice: Guidelines on the application of Article 81 of the Treaty to technology transfer agreements (2004/C 101/02)", to which parties are directed when assessing the effect of licence agreements falling outside the block exemption.

## **10. Causation**

IPLA members have provided anecdotal evidence that, even where there are no patent, regulatory or pricing obstacles to generic entry, generic companies do not necessarily launch generic drugs at the earliest possible opportunity but often choose to delay launch for their own commercial reasons. IPLA therefore questions whether delays in generic entry are

necessarily caused by so-called defensive strategies developed and practised by originator companies. We note, for example, from the executive summary of the Preliminary Report that "the average time to enter after loss of exclusivity was about 7 months on a weighted average basis, whereas also for the most valuable medicines it took about 4 months".

This is corroborated by a comparison between: figure 14 (on page 68) of the Preliminary Report, which shows the average time for entry for generics following "loss of exclusivity", country by country; figure 64 (page 179) which shows the number of patent litigations per country; and figure 97 on page 220, which shows the number of patent settlements per country. There is a degree of correlation between figures 64 and 97, as would be expected: the countries where there is most patent litigation are the countries where there are most patent settlements. If the patent litigation and patent settlements succeeded in delaying generic entry, one would expect to see a correlation between these two figures and figure 14. However, there is no correlation at all: figure 64, for example, suggests that the UK and Spain have about the same amount of patent litigation, but in Spain the time before generic entry is almost five times greater than in the UK. Similarly the Netherlands has a large number of "disputes and contacts" (see figure 54 - page 168), yet is comparatively quick so far as time to entry is concerned. Of the ten countries with the greatest amount of litigation, all but two - Spain (over 14 months) and France (just over 8 months) – have a time to generic entry less than the seven month average.

The Preliminary Report also suggests that the extent of defensive strategies by originator companies increases for the most valuable medicines. If the activities of originator companies were the cause of delays in generic entry, one would therefore expect that there would be longer delays in the case of the most valuable products, which is not the case. It is therefore important, in any particular case, that the reasons for the timing of generic entry are clearly established. It is probable that the speed with which generic products are brought to market depends in fact on the efficiency with which pricing, reimbursement and substitutability are handled in each country, and the profitability of the generic market in the country, than on the activities of the originators.

**Intellectual Property Lawyers' Association  
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<sup>1</sup> See Commentary, *Scrip* magazine, 19 December 2008, page 41

<sup>2</sup> 'Global Patent Litigation - Win Rates and Strategies' by Michael Elmer - presentation to FICPI conference, May 31, 2007

<sup>3</sup> A German correspondent of an IPLA member firm has looked at the 58 nullity cases that were decided by the German Federal Patents Court from January to late November 2008. In 45% of the cases the patent was declared completely invalid, while the patent was declared invalid in part in 34% of the cases. Hence, the patent was entirely upheld in 21% of the cases.

<sup>4</sup> We have checked the results of all patent appeals in England since the beginning of 2006: during this period, appellate courts have overturned the decisions of lower courts in approximately one-third of all patent infringement or validity cases which went to appeal.

<sup>5</sup> '2008 Patent Litigation Survey: Damages awards, success rates and time-to-trial' published by PriceWaterhouseCoopers.

<sup>6</sup> The Commission will have a better idea than IPLA of the proportion of cases where generic companies have made complaints to the competition authorities on the basis that the obtaining or enforcement of patents was a breach of Article 82.

<sup>7</sup> Although pharmaceutical companies have sophisticated information systems and are probably better informed about what patents have been published in their areas of research interest, they cannot know about pending but unpublished patent applications, nor are they likely to know about older publications before they entered the relevant research field.

<sup>8</sup> Decision of the Administrative Council of the European Patent Organisation of 28 June 2001 adopting the new text of the European Patent Convention

<sup>9</sup> "Second medical use" patents were already permitted by EPO case law, but EPC 2000 reflected the prevailing view that the case law should be expressly confirmed.

<sup>10</sup> There is an exception where the invention covered by the later patent is used in the product which was launched, but in a way that is not "enabling": such cases are rare.

<sup>11</sup> There is a "claw back" mechanism which takes account of discounting generally, but it does not prevent pharmacies making substantial profits when generic products are first launched.