

# Simmons & Simmons

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## EC Pharmaceutical Sector Enquiry

**Preliminary Report dated 28 November 2008**

### 1. Who We Are

Simmons & Simmons is a substantial law firm based in London, with offices in seven other EU Member States and six countries outside Europe. The European intellectual property practice has 52 fee-earners, including 16 partners, and works closely with our EU and competition law practice, which has 29 fee-earners, including 7 partners.

The firm's London office is a founder member of the English Patent Solicitors' Association (now called the Intellectual Property Lawyers' Association ("IPLA")). The partners in the 28-fee-earner London IP group include: Kevin Mooney, past President of the European Patent Lawyers' Association (EPLAW), one of only two UK representatives on the expert legal group advising the European Commission on the creation of the proposed European and Community Patents Court, and also a member of the UK IPO advisory group on the same proposals; Rowan Freeland, Secretary of IPLA and a faculty member on the Oxford University Diploma in Intellectual Property Law; and Richard Binns, a member of the IP Committee of the City of London Law Society. The group has extensive experience of patent litigation in England and across Europe and in co-ordinating patent litigation in several jurisdictions. Our patent litigation clients come from many different business sectors, including pharmaceuticals, medical devices, electronics, telecommunications and chemicals.

The EU, Competition and Regulatory group works closely with our Intellectual Property Group on all aspects of the interface between intellectual property and competition law, and includes Tony Woodgate, a past Chairman of the Solicitors' European Group and current member of the Joint Working Party of the Bars and Law Societies of the United Kingdom, Marco Slotboom, who has particular experience of litigation in the Court of First Instance and European Court of Justice, and Oliver Heinisch who has substantial competition and regulatory experience.

### 2. Public Interest

The Preliminary Report focuses on the public interest in breaking the originator's monopoly in relation to a particular pharmaceutical as soon as the first patent granted to the originator expires, or on expiry of regulatory data exclusivity, so as to achieve as early as possible the fall in drug

prices that accompanies generic entry<sup>1</sup>: and anything which prolongs the originator's monopoly beyond these dates is presented as undesirable.

Clearly, there is a public interest in early generic entry and the resulting fall in prices. However, this public interest conflicts with other important public interests, such as the proper working of the patent system, the potential health benefits of follow-on innovation, access to justice etc., as we will discuss.

### 3. **Public Perception Created – Proper Application of EC Competition Law**

The Preliminary Report makes it clear that it is dealing only with facts found in the investigation to date, and not with legal analysis or conclusions as to whether any agreement or conduct infringes EC competition law. We are concerned, however, that the Commission's statements, amplified by the media, have encouraged a public belief that anticompetitive agreements and conduct have delayed generic entry, and that enforcement action by the Competition Directorate will deliver the €3 billion savings to national pricing reimbursement schemes referred to.

We do not anticipate that agreements or practices in breach of EC competition law are a major cause of the apparent delay in generic entry reported upon, and we note that the Commission has not in the Report said that they are. Clearly, other factors including the operation of patent law, the patent litigation systems of the Member States, the procedures of national marketing authorisation and pricing and reimbursement authorities, decisions and actions of generic companies, and decisions and actions of market players including pharmacies, prescribers and others are involved.

The Report is inevitably perceived to criticise the employment by pharmaceutical companies of the "tools in the tool box" referred to (although not as concrete breaches of competition law). This will tend to raise concerns about Commission action, and will certainly serve to chill pro-competitive conduct, such as, for example, litigation against competing products (an essential element of our free market system based on the property rights of undertakings, presumptively (except in the most extreme circumstances) not an infringement of the competition rules (*ITT v Promedia* (case no. T111/96))).

We believe the Commission should not be responsible for such a chilling effect, and not leave uncertainty hovering over the agreements and practices it reports upon. Uncertainty is liable to be especially damaging in this industry when compared with other sectors the Commission has considered in similar procedures. Firstly, dynamic competition through innovation, protected by intellectual property rights, is critical, and secondly the period until the innovator makes a

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<sup>1</sup> Although the Commission's figures suggest that the fall in prices – 20% in the first year, and 25% after two years (paragraph 180) is very much less than one would expect from a generic sector which does not have significant research and development or marketing costs, which together amount to 40% of the originators' costs

commercial return is very long (as recognised uniquely for this industry in the enactment of the Supplementary Protection Certificate Regulation to extend patent-like protection in view of the necessary regulatory delays to product commercialisation). Innovation is a fragile flower and any increased uncertainty as to the ability to recoup typically very expensive investment in highly risky innovation, given the long lead time to commercialisation, is liable to lead to sub-optimal levels of investment.

We would respectfully suggest that the responsible course is to clarify, no later than in the final Report, the approach the Competition Directorate intends to take to competition law enforcement in the pharmaceutical industry, and to detail the other steps it proposes should be taken arising out of the Report other than competition law enforcement (which appear to include recommending harmonisation or amendment of national laws, amendment of regulatory Directives or Regulations, Commission action for Member State failure to implement properly certain Directives, etc).

We now set out some comments focussing on the patent law and patent law litigation issues raised by the Preliminary Report.

We think it is of limited utility to seek to comment on the competition law position, as the Commission has not sought itself to include any competition law analysis in the Report. We would simply note that the Commission should in our view give appropriate weight in applying the competition rules to: the importance of competition through innovation, rather than copying, and the importance of the protection of the fruits of innovation by intellectual property rights; the intellectual property laws; the litigation systems of the Member States, which are at present the only appropriate mechanism to resolve issues of patent validity and infringement; the important public policy interests in the settlement of litigation; and the absolute right for all economic actors to have recourse to the courts (as stated in *ITT v Promedia*, access to the Court is a fundamental right and a general principle ensuring the rule of law).

Any discussion about the proper functioning of the patent system, such as “patent clusters”, defensive patenting, the maintenance and enforcement of patents which are “less solid and robust” etc, is a matter which does not only concern the pharmaceutical industry, it equally concerns the electronics industry and indeed many other sectors as Lord Justice Jacob has indicated. In order to obtain a full picture of the issues, the Commission is encouraged to broaden the dialogue and bring in stakeholders in other industries. The publicity generated by the publication of the Preliminary Report has focussed on issues which are specific to the pharmaceutical industry, and we apprehend that the Commission will not have the assistance of input from bodies representing other sectors of industry unless it proactively approaches them. Pharmaceutical companies are only one particular group using the patent system and the patent litigation system and should not alone carry the burden (and any blame) of the consultation.

There is no justification for any departure, for a single sector, from the internationally agreed rules on what may be patented as set out in the European Patent Convention or in TRIPs (Article 27(1) of TRIPs provides that: "... patents shall be available and patent rights enjoyable without discrimination as to the place of invention, *the field of technology* and whether products are imported or locally produced." (*emphasis added*))

Before commenting in detail, we must refer to Lord Justice Jacob's speech at the public presentation of the Preliminary Report on 28 November 2008. Lord Justice Jacob is a highly respected Judge who has extensive experience of how the patent system operates in practice. He is not a partisan of the originator companies or of patents generally: indeed, as a Judge, he has probably revoked more patents (including patents owned by pharmaceutical originator companies) than he has upheld. His comments reflect the views of all the patent practitioners with whom we have spoken (these include many who represent generic companies as well as those who represent originators), and we urge the Commission to give the views of Lord Justice Jacob the highest respect.

#### 4. **The Nature of Competition in the Pharmaceutical Sector**

In summary: in most sectors, competition is between entities who operate in the same way and, where the industry is regulated, the regulations apply equally to all players, so there is a level playing field. In the pharmaceutical sector, originator companies face competition from generic companies who operate in a different regulatory environment (after the data exclusivity period, they can rely on data generated by, and at the cost of, the originator companies rather than generating their own data), and who rely on demand for their products generated by the activities of the originator companies who educate doctors into the advantages of their products so that doctors specify them in their prescriptions. Generic companies therefore operate at a very significant competitive advantage.

Thus, in most industries, competition is between organisations who allocate their resources on the same activities – research and development, manufacturing, marketing etc – in an effort to produce goods which meet consumer demand as to quality and price in a better way than their competitors.

In the pharmaceutical industry, the amount of resources allocated to discovering new drugs and doing the work which the law requires to demonstrate the quality, safety and efficacy of such drugs to the regulatory authorities, is very substantial – the Preliminary Report indicates that it is 17% of originators' turnover – probably higher than in any other sector. Marketing activities are in substance the process of educating doctors about new drug products (unlike the situation in other sectors, any departures from the purely educational function are strictly regulated). Since the

bulk of marketing activities take the form of personal visits to individual doctors (“detailing”), this process is extremely expensive.

The generic competitors of the originator companies do not compete at all in the efficient allocation of resources in these areas. Their business model is quite different: in order to be able to supply cheap drugs, they avoid incurring expense in research and development, and in marketing. Thus, generic companies only make drugs which they already know, from the success of the originators, are efficacious and successful, and so are able to avoid all “discovery” research costs and much if not most development costs, while the abridged procedure for approval of generic drugs allows generic companies to avoid the very substantial costs of clinical trials.

Further, the generic companies spend little or nothing on marketing, relying instead on the fact that demand for their products depends on the number of prescriptions against which their products may be dispensed<sup>2</sup>. The number of such prescriptions depends on the efforts, before generic entry, of originator companies in educating doctors to prescribe their products. Indeed, the generic companies decide what products to produce by reference to the success which originator companies have had in their marketing.

Thus, in the pharmaceutical sector, competition works in a significantly different way, as originator companies are obliged to permit the benefits of their substantial expenditure on research and development and on marketing to be used to the benefit of the generic companies. Most of the behaviours identified in the Preliminary Report are, in sectors where there is a “level playing field”, ways in which companies compete effectively with each other. It is only in the pharmaceutical sector that the playing field between originators and generic companies is distorted, partly by State regulation and partly by the business model adopted by the generic companies who choose not to compete with the originators in research and development or in marketing. The question then is whether the way in which originators compete with their competitors should be restricted by reference to what their competitors do (or decide not to do).

In some cases, the originator companies may stop marketing a product (when they introduce an improved version). The generic companies object, and describe this process as “evergreening”. But, in a free market, an originator should never be obliged to continue to market a product solely for the benefit of its competitors: rather, the decision as to what products to offer is a matter for the person who pays for the development of those products, and the way for competitors to compete is to carry out their own, better, marketing activities.

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<sup>2</sup> The degree of encouragement or incentive for generic prescribing, and the rules governing generic substitution, vary from country to country. These differences go some way towards explaining the national variations in generic penetration.

## 5. Quality of Patents

There is no necessary connection between the amount of money spent on research and the quality of patents on the results of that research. An example of a “speculative” patent can be found in the case of *Conor v Angiotech* [2006] RPC 28 (paragraph 28) where the judge pointed out that “at the priority date the Patentees had neither made nor tested [the patented device].” The patent was held to be valid by the House of Lords (the UK’s highest appellate court) (the case report is at [2008] RPC 28)).

By contrast, for example, is, the case of *Teva Pharmaceutical Industries Ltd v Istituto Gentili SpA* [2003] FSR 29, concerning the patents relating to alendronate, an important drug for treating osteoporosis. It was acknowledged by the trial judge at paragraph 95 that “They [the patentee] must surely have had to make a very considerable investment and incurred considerable risk in bringing [alendronate] to market. And mankind is better off as a result”, but the patents were nevertheless held invalid.

The problem is that the strength of a patent depends not on the quality of the research leading to the invention but the nature of the prior art and whether other companies are researching in the same area. This is a fact of any system of research and the patent system deals with it by the law on priority. Since research is necessarily carried out in secret, overlaps are inevitable.

When looking at whether a patent is strong or weak, the ultimate fact is that there are simply patents which are upheld by a court, and patents which are revoked by a court. Even here, the issue is not a binary one: there are numerous cases where a first instance decision one way or the other is reversed on appeal – and where the Appeal Court decision is in itself reversed by a third instance appeal (in England, about one third of judgments are reversed on appeal, and this proportion of reversals is found in patent cases as in all others).

Furthermore, there are cases (11% in the examples examined by the Commission) where different decisions are reached by different courts across Europe. There is debate among patent lawyers as to the reasons for such different decisions – differences in judicial approach or interpretation of the law, and differences in procedure, provide some explanation. But there is general consensus that in all of the cases where courts have diverged, the decision was difficult – reasonable judges could reasonably differ as to the correct application of the law to the facts of such cases.

It is possible to put patents into three categories (although of course there is in fact a continuum):

- Patents which are regarded as sufficiently likely to be upheld that they will not be challenged;

- Patents which are worth challenging, and which are worth defending;
- Patents where the chances of a successful defence by the patentee are too low to warrant litigation.

Within the middle category, every patent law practitioner will have stories of cases thought to be weak where the patent was upheld, and cases thought to be strong where the patent was revoked. We are aware of two instances in our own practice where we advised a patentee that the patent was in the third category, but the counterpart patents were later upheld by courts in Canada and Holland.

As indicated above, the strength of a patent does not depend on the patent itself – it depends on what “prior art” there is. Finding relevant prior art is not easy, even when searching in the patent literature (where there is a sophisticated indexing system). Searches by different people will identify different prior disclosures. Indeed, a large proportion of patents which are invalidated by courts are held invalid over prior art which was not known to the patentee or to the Patent Office. In addition, it is our experience that, where a patent is invalidated by prior art, the invalidating fact in many cases is not expressly stated, but is found only on repetition of an experiment described in the earlier document – something which no prior art search or Patent Office examiner can discover. Further, all patent lawyers have had cases where a patent which was thought to be strong becomes weak or hopeless when a new piece of prior art is identified.

We refer again to *ITT v Promedia*: there is nothing wrong (save in “wholly exceptional cases”) with seeking to enforce a patent which is perceived to be “less solid and robust”, and, indeed, it is inherent in the nature of the patent system that most patents which are litigated fall into this category. Nor can it be wrong to apply for or to own such patents.

We would also draw attention here to the related proposition that what type of innovation can properly be the subject of a patent is a matter for patent law and the Courts charged with the correct interpretation of patent law. The Preliminary Report uses extensively the term “innovative product”: this term is not defined in the Glossary, but there are statements from which we infer that the Commission has in mind only new chemical entities (for example, the first page of the Executive Summary (p. 5) refers to the “decline in *innovation* measured by the number of *novel medicines* reaching the market ... [and] the decline of *new chemical entities* reaching the market” (*emphasis added*). If our inference is correct, then we apprehend that the Commission is taking an unduly narrow view of “innovation” which is not consistent with the type of innovation which is protectable under the European Patent Convention and the International Conventions with which it complies. There is accordingly a danger that the Commission’s conclusions may be based on an incorrect view of what is properly protectable by patents.

## 6. Defensive Patenting

Because of the pressure imposed by the “first to file” system, most patents are filed long before any assessment is made as to whether the invention will be exploited. This is common-place in all industries of which we have experience, although lead times are particularly long, of course, in the pharmaceutical industry.

Further, it is common that a patent covering an invention will not necessarily cover products which will compete directly as “me too” products on the market. If the patentee is to recover his investment in bringing his invention to market, he must be able to use patents arising from the research which he has carried out to block products which on the market would be perceived as interchangeable, indeed effectively identical, and would deprive his product of a fair return.

Defensive patenting at later stages in the life of a product is also critical. If a company does not keep on researching in relation to its products, other companies will do it instead and the originator company will find that its development of its own product will be blocked.

Defensive patenting is routine in all industries, both as a result of research directed to improving a patented product, and as a result of research into ways in which a competitor might circumvent the existing patents and produce a product which would prevent the patentee fully exploiting its patented product. The Commission should be aware that this has been established practice in all industrial sectors, not only pharmaceuticals, for many years. The general view is that companies are perfectly entitled to compete in their research activities as well as in selling their products, and that the system is policed by the ability of the courts to rule on the validity of patents. The Commission should therefore be aware that a conclusion that such defensive patenting practices are undesirable will have significant ramifications in all sectors of industry.

## 7. “Evergreening”

Once a product has been launched, no subsequently-obtained patent can prevent a generic company from copying the product that was originally launched, as soon as regulatory data exclusivity and the patents and applications pending at the time of launch have expired. No amount of research or patenting activity following the launch of a product can prevent generic versions of the product as launched. Accordingly, continuing research and development by originator companies following the launch of a product cannot delay or prevent generic market entry<sup>3</sup>.

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<sup>3</sup> This is an important qualification to the passage from T A Blanco White’s book quoted by Lord Justice Jacob, in particular the statement that: “*by the time the original patent expires a would-be imitator should be faced with this situation: that the article described in the original specification is too inferior to contemporary designs to be commercially saleable, while he cannot imitate the newer models without risking an action for infringement*”: in the

Most post-launch research and development is directed to the improvement and development of the product. There is a public interest in originator companies carrying out such research which can produce improved treatments for patients in the form of new indications, better formulations etc. None of this activity prevents the generic launch of a copy of the original product.

This leads onto the issue of “evergreening”, when an originator company may move to a new version of a product and stop marketing the old version (see also section 4 above). There is, of course, nothing to stop a generic company from selling a copy of the old version. Generic companies object to the practice because they claim that they will make no sales if the originator whose product they copy promotes instead an improved product, as they do no marketing to doctors themselves. There are two possible solutions (if the generic companies are to stick to their business model): to prevent originator companies from researching improvements to their products; or to compel originators to continue to promote products in which they have no commercial interest. Both alternatives are absurd.

#### 8. **Delayed Generic Entry – Causation**

The summary at the end of section 2.7 of the Preliminary Report (“cumulative use of practices against generic companies” states that “the combined use of life cycle instruments *may* increase the likelihood of delays to generic entry” (emphasis added)). In our experience, it cannot be assumed that delays in generic entry can necessarily be attributed to the use by originator companies of “life cycle instruments”.

We have been involved in 5 cases in the past 8 years where the launch of the generic product took place 6 months or even more than 1 year after “loss of exclusivity”. In none of these cases did the delay have anything to do with the use by the originator company of any of the “tool-box” of life cycle strategies – indeed, in each case our client was puzzled why the generic companies had not launched at the earliest opportunity<sup>4</sup>.

Our experience is reflected in the statistics in the Preliminary Report. The Executive Summary states (paragraph C.2.7) that: “The sector enquiry shows that more life cycle instruments are used for best-selling medicines” – which comes as no surprise: the more important the market, the harder a company is likely to compete. But it is also stated (section A) that “The average time to enter after loss of exclusivity was about seven months on a weighted average basis, whereas for the most valuable medicines it took about four months.”

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pharmaceutical sector, the “article described in the original specification”, that is, the original drug, remains of paramount commercial importance when the original patent expires.

<sup>4</sup> In one case, the generic company had already successfully invalidated the patents which would have prevented it launching its product after expiry of the main patent, but over a year has elapsed since actual loss of exclusivity, and the generic company still has not launched its product.

If these two statements are correct, it cannot properly be concluded (paragraph C.2.7) that “The combined use of life cycle instruments may increase the likelihood of delays to generic entry.”

## 9. Public Health Cost Savings

The operation of the market for the supply and reimbursement of generic medicines varies from country to country. It is clear from the presentation about the Dutch market on the launch of the Preliminary Report that there are substantial opportunities for profiteering on the part of pharmacists as a result of the failure of the Dutch health insurance bodies to monitor actual pricing in the market and to set reimbursement levels accordingly. A similar situation obtains in the UK: within our limited experience, reimbursement prices can remain unchanged for several months following generic market entry, and then take some time to fall to a level commensurate with the prices actually paid by pharmacists for the reimbursed medicines.

The problem arises, first, because reimbursement prices are normally set by reference to list prices, and take little or no account of discounting by generic suppliers, which in many markets can be by as much as 80%.

Secondly, the reimbursement authorities are frequently very slow to adjust reimbursement prices following generic entry: in the UK, it can be several months following generic launch before the reimbursement price falls below the list price of the originator product.

This is corroborated by the Commission’s figures. Generic companies do not bear the research and development costs or marketing costs that the originator companies do – 40% of their turnover: so in the absence of profiteering, one would expect generic prices to be at least 40% lower than originator prices (our experience is that actual prices paid to generic companies can fall to below 80% of the originator’s list price). But health funders in the European Union, according to the Commission’s figures, see savings of only 20% in the first year and 25% after two years. This discrepancy has nothing to do with the activities of the originator companies, but the cost is significantly greater than the reductions in cost which would be obtained if generic entry were not delayed. And in conclusion we re-iterate that the Preliminary Report does not substantiate the suggestion that this delay occurs as a result of the activities of the originator companies.

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