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IMPLICATIONS OF THE EU PHARMACEUTICAL ENQUIRY

by
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The Commission's final report on the Pharmaceutical Enquiry

The final Report made a number of statements that are relevant to this paper, which concentrates on the implications of the Report, rather than the Report itself.

1. The main aims of the enquiry were to examine the reasons for the delays in the entry of generic medicines into the market, and the apparent decline in innovation as measured by the number of new medicines.

2. As this was a sector enquiry under competition law, the main focus was on company behaviour delaying generic competition and development of competing originator products. This meant looking at the competitive relationships between originators and generics, and between originators.

3. The enquiry looked "*in broad terms*" at aspects of regulation, especially legislation on patents, marketing authorisations, and pricing and reimbursement. The report did not consider what factors, other than company behaviour, might contribute to the reduced number of new medicines, and made no effort to measure their relative importance.

4. The report did not look at parallel imports between EU Member States. (Now before the European Court of Justice under Article 81 in case C-501/06P, GlaxoSmithKline, see Advocate General's opinion dated June 29, 2009).

5. The report does not provide any guidance on the compatibility of the practices described with competition rules.

6. There is broad consensus on the need to establish a Community patent and a unified specialised patent litigation system (pages 7, 20).

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7. The Commission identifies several unilateral practices against generics, without suggesting that they are, or may sometimes be, illegal:

   - filing numerous patent applications for the same medicine ("*clusters*" or "*thickets*")
   - divisional patent applications
   - patent litigation
   - opposing secondary patents
   - opposing marketing authorisations

The Commission accepts that the use of several instruments, in themselves legitimate, does not make their combination illegal.

(See Technical Annexes to the Final Report for examples, and page 19).

8. The Commission described settlement agreements between originators and generics (page 12):

   - restricting the generic's ability to market its medicines
   - involving a "*value-transfer*" from the originator to the generic
   - other agreements, many involving exclusivity

9. The Commission identifies several practices of originators against other originators:

   - "*defensive*" patents without pursuing innovative efforts
   - exchanges of patents and patent litigation, often involving exclusivity
   - opposing others' patents

10. The Commission comments (pages 20, 27) "*Settlement agreements that limit generic entry and include a value transfer from an originator company to one or more generic companies are an example of such potentially anticompetitive agreements, in particular where the motive for the agreement is the sharing of profits via payments from originator to generic companies to the detriment of patients and public health budgets*".

11. The Commission listed several pharmaceutical cases involving findings of breach of Article 82 (page 19):

   - *Napp Pharmaceuticals (U.K.)*, selling to hospitals at very low prices and through pharmacists to patients at high prices, since doctors prescribe brands used in hospitals
   - *Arrow Génériques (France)*, systematic criticism of a generic product even after market authorisation was given for it.
   - *GSK* case *(Italy)*, refusal by an originator not having exclusive rights to licence production of an active ingredient needed for national markets
   - *AstraZenica (EC Commission,* 2005, on appeal in Case T-321/05) misleading statements in regulatory procedures

Comments on the Final Report

Patent validity

The Report does not discuss the possible reasons why some patents are invalid, or whether it would be useful to try to clarify the law on patentability, or even whether conflicting national court judgments on the validity of patents are due to different findings of fact or to different legal approaches and traditions. The focus is only on the pharmaceutical industry.

Since the validity of the patents is usually crucial to all cases of the kinds that the Commission considered, it is curious that the Commission does not mention the possibility of national social welfare authorities intervening in litigation involving the validity of patents. This would not need any European measures. This suggestion had been made to the Commission before the final Report was adopted. It is disappointing, and an indication of how limited the focus of the Report is, that the Report does not mention it or discuss it.

Presumably it was assumed that national authorities would not be likely to have the expertise needed. But they would not need to initiate challenges to the patents, but only to intervene in support of the company contesting the validity (in most cases, presumably, the generic), if the sums involved and the likelihood of success made that seem worth while.

Natural court procedures could be altered, if necessary, to facilitate such interventions.

Article 82 - Dominance

It is important to remember that ownership of patents does not automatically confer dominance, in particular when the patents in question will soon expire. So in all cases in which it might be suggested that any practice described in the Report was contrary to Article 82, dominance would need to be specifically proved.

Mere ownership of a large number of patents for a given medicine or a group of medicines can of course contribute to market power. But in all cases competition from other medicines for the same medical conditions must be looked at. An originator is not dominant merely because some generics companies use or wish to use the same therapeutic approach or the same active ingredient. Trademarks as well as patents must be taken into account to assess dominance. Single patents for the whole of Europe would of course mean fewer patent validity cases.

Article 82 – Abuse

The four examples of Article 82 cases (page 19, and point 11, above) do not look like typical examples of pharmaceutical company practices, and they do not fall into the categories of unilateral practices described in the Report.

It would be difficult if not impossible to adopt a consistent approach to the unilateral practices described in the Report without having a comprehensive definition or concept of exclusionary abuse. At present the Commission has no such definition. The Commission's Guidance paper on Article 82 fails even to attempt a comprehensive definition of exclusionary abuse, apart from its weaknesses in other respects.

All of the unilateral practices described in the Report are legitimate, usually and in principle. They would be illegal, if they were illegal at all, only if there was some exceptional anticompetitive feature in a particular case.

Article 82 - competition from originators

On competition between originators, "*defensive patenting strategies that mainly focus on excluding competitors without pursuing innovative efforts and/or the refusal to grant a licence on unused patents will remain under scrutiny in particular in situations where innovation was effectively blocked*" (para. 1571).

The Commission would be unwise to give too much attention to the motives for obtaining patents. A patent may legitimately be obtained for several purposes and it would be impossible to weigh or measure their importance in the minds of the individuals involved. The effects on competition should be assessed objectively. It is not illegal to apply for a patent even if it is not subsequently exploited. There may be many legitimate reasons for not exploiting it, including *e.g.,* the changing opportunity cost of doing so, compared with other possibilities for innovation. So the more important question is whether another company asks for a licence, and whether it is granted[2].

Compulsory licences from originators

In this context the key question would usually be whether the refusal of a licence would harm consumers by preventing the development and marketing of a new kind of product for which there is a clear and unsatisfied demand. If that was substantially true, one would expect the owner of the patent either to develop the new product itself, or to licence the patent. If a problem arose, it would probably be because the new kind of product would compete directly with one of the existing products of the patent owner in question. (In the *Microsoft* judgment the Court said that there might be infringements of Article 82(b) that do not involve new kinds of products, but it is not easy to see what relevance this might have to pharmaceuticals, unless the licence was needed for a new line of "*pure*" research that might not directly lead to a new kind of product, or in connection with compound medicines).

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[2] Temple Lang, European Commission Law and Compulsory Licensing of Intellectual Property Rights – A Comprehensive Principle, 4 Europarättslij Tidskrift (2004) 558-588.
The Commission's Guidance paper on refusals to contract is unsatisfactory because it fails to state or stress some important limiting principles:
- any duty to contract is, and must be, exceptional
- there can be a duty to contract only if refusal is illegal for some clear identifiable reason.
There cannot be a duty to contract merely because that would add one more competitor in the downstream market.
- there must be scope for added-value competition in the downstream market. There is no duty to supply merely to allow the complainant to distribute, if it does not add value in some way. There cannot be a duty to supply the dominant company's final product to competitors.
- The refusal to contract might have no effect on competition, if there were enough competitors already or if there was a justification (capacity fully utilised, or the party contracting may have helped to finance the investment).
- the Guidance fails to discuss the terms on which compulsory access would be given
- a duty to contract must not take away from the dominant company its principal or only competitive advantage

A company seeking a compulsory licence for an essential patent may need to disclose the new kind of product, for which there an unsatisfied demand, that it intends to produce. It presumably would be a defence if the patent owner could show that it already had developed a business plan to produce the new product in question. The court would have to impose safeguards to ensure that the patent owner did not take and use the new idea itself, if there was no blocking patent that would prevent this.

Article 81: "*focused monitoring*" on agreements between originators and generics

The Commission seems most likely to pursue cases involving agreements between originators and generics under which (i) generic entry is restricted and (ii) there is a "*value transfer*" to the generic, rather than cases under Article 82.

Again, under Article 81 the Commission would be unwise to concentrate competition law scrutiny on the "*motive*" for such agreements. (The EPO made the same comment from a patent viewpoint). Objective analysis is needed.

The essence of the Commission's objection to such agreements is reasonably clear, whether or not the facts justify it in any given case.

Suppose that the originator's primary patent is expiring and its secondary patents appear weak. If the generic could have them declared invalid, it could enter the market. The originator sues the generic. If the generic has only a chance of invalidating all the originator's patents, it might agree to pay the originator for a licence. But if the originator pays the generic, and the generic's entry into the market is postponed or restricted, the suspicion is that the companies have agreed to share profits based on patents of doubtful validity.

So the key element is the probable validity of all of the originator's secondary patents (and the probable validity of the generic's patents). To enter the market, the generic might need to prove that all of the originator's secondary patents were invalid in all the EU Member States where patents had been obtained. Proving that, even if it were ultimately possible, would be slow, expensive, and uncertain. A competition authority would not normally be able to make a useful assessment of the validity of a series of patents, including patents in other Member States.

So the first conclusion is that improvements in patent law and practice to reduce the number of patents of doubtful validity would significantly reduce the number of settlements requiring competition law scrutiny, and reduce costs for the industry as a whole.

Some principles concerning agreements between originators and generics under Article 81:[3]

1. In general, agreements to settle patent or trademark litigation, if made in good faith, should be accepted, even if they involve some restrictions on the freedom of one or both parties to market their products. (Patents inherently involve restrictions, after all).

[3] Temple Lang, Current European Competition Law Questions for Pharmaceutical Companies, St. Gallen International Competition Law Forum (2009), to be published shortly. That paper also analysed Article 82 issues that are not discussed in detail here.

2. If there was uncertainty about which party would succeed, in relation to each of a number of patents, a payment to the generic and a delay on entry might be a reasonable part of an overall settlement to end the litigation, made to facilitate planning and to avoid the confusion, inconvenience and uncertainty to both parties of prolonged litigation, in particular if the generic would win on some but not all of the patents. Companies in the pharmaceutical industry cannot afford long delays and uncertainty, and are entitled to pay to avoid it.

3. If the settlement involves a licence of any of the generic's patents to the originator, a payment by the originator would be natural and should cause no concern.

4. If the originator granted a licence to the generic, enabling it to produce a more advanced product, the effect might be that the generic might postpone or cancel introduction of its less advanced product. (The originator might pay the generic to produce medicines that the originator would sell as branded products).

5. A settlement might involve the purchase of the patent from the generic by the originator, and in such a case a payment to the generic would be natural. (This would be open to scrutiny only if the originator bought the patent without having any intention of using it. However, it is not illegal to buy a patent and later to decide not to use it, after considering *e.g.*, the opportunity costs of doing so, compared with available alternatives).

6. In the case of an interim injunction against the generic, a payment might be made to the generic on the basis that it would be accepted as full compensation for any loss shown to be unjustified if the generic ultimately succeeded in the litigation.

7. If there were blocking patents, or if patents were definitely valid in some Member States and invalid in others, the only way to allow either party's products to be sold throughout the EU might be a settlement that could involve a payment to the generic.

However:

8. If the agreement is broader in scope or longer in duration than the patents being litigated, that might be a cause for competition concern. It would also be cause for concern if the settlement restricted competition in any other way in which it would not have been restricted if either patent owner had been completely successful with its patent claims.

9. Competition law does not allow intellectual property rights to be used to achieve indirectly results that could not have been achieved directly by agreement. (*Consten and Grundig* case, 1966). This principle applies to restrictions on parallel imports, but also to field of use licences dividing the market between licensees or cross-licensees.

10. An agreement under which the generic agreed to delay its new medicine and the originator agreed to delay its follow-on generic would invite scrutiny.

In some cases, trademarks and brand names associated with the originators patents would also need to be taken into account also. It follows from all this that even what might appear

to be a “pay for delay” case must be thoroughly investigated, and not made the subject of the superficial and limited economic analysis proposed in the Commission’s Guidance paper for supposedly simple cases.

Complications in Article 81 cases due to national patents

While the Commission's concern in a simple "*pay for delay*" case is clear, it will be seen that in practice there are a number of more complicated circumstances in which the concern would not be justified.

More generally, because patents in Europe are national patents, it would be very much more difficult in Europe than in the USA to show that a settlement was illegal because the generic would be likely to have succeeded in showing that every one of the originator's patents was invalid in every EU Member State where it had patents. (Originators are more likely than generics to have patents in all or most Member States). Because patent litigation in Europe is national, it would be much more difficult in Europe than in the USA to show that a settlement covering, perhaps, all 27 Member States plus the three European Economic Area countries was not a reasonable result of both parties' assessments of their chances of doing better in litigation.

The Commission has rightly stressed the likelihood of conflicting national court judgments (paras. 284-291). 11% of national court judgments were conflicting (para.1308). This is both a strong argument for a single European patent court, and a reason for saying that it would be difficult to show that settlements between originators and generics were restrictive, rather than being based on an assessment of the chances of one party winning in every Member State in question. If one party is likely to win in one large Member State and the other party to win in another, a settlement is clearly desirable. This is so in particular because national court practices and procedures differ so much in the 27 member States.

This is important because it seems unlikely that the Commission would have launched the enquiry if the Federal Trade Commission had not brought such cases in the USA. In Europe, the industry never looked like a fruitful field for a sector enquiry, since it was always clear that the main problems were not competition law problems.

In other words, one would expect the Commission to bring fewer successful "*pay for delay*" cases than the FTC in the USA.

Patent Law - three major improvements needed

The report gives reasons to improve European patent law and practice. The following ideas are mentioned, but not developed in the report, since the enquiry was concentrated on potential competition law issues, and so gathered few new facts about patent practice:

- a single Community Patent. Even European patent designating only 13 out of 27 Member States is about nine times more expensive than a US patent that applies throughout the USA (paras 1298-99).
- a unified and specialised patent litigation system which would be "*swift, high quality and cost effective*" and which would avoid the costs of multiple filings, avoid parallel court cases in different Member States, and avoid conflicting rulings. Multiple litigation is much more difficult financially for generics than

for originators (paras 1300-1310). When non-uniform results of litigation are likely, settlements are sure to be considered favourably.

- EPO patents should meet a "*high quality standard*". EPO procedures should be speeded up. The recent limit on the time within which voluntary divisional patent applications can be filed is welcomed (paras. 1311-1340).

Because there are differences between national legal systems on *e.g.,* duration of court proceedings, conditions for obtaining interim injunctions, and important procedural issues, until there is one European patent court it would be difficult to introduce Community-level mechanisms to "*clear the way*" by solving all patent issues before market entry (paras. 1352-1359). In the absence of such mechanisms, settlements are desirable.

It would have been useful for the Commission to say that improving the quality of EPO patents and the efficiency of its procedures is primarily a matter of giving it additional resources.

Unless the quality of EPO patents is improved, it would be difficult to insist on *e.g.,* presumptions of validity, or obligatory adjournments while EPO opposition procedures continue. National courts have no duty to defer to findings by the EPO, except perhaps when the EPO revokes a patent (although in Germany invalidity proceedings cannot begin while an opposition procedure is continuing in the EPO).

The Commission would be wise to concentrate its efforts on improving the patent system in these three fundamental respects. Providing extra resources for the EPO would not require significant new European legislation. The Commission will not significantly reduce the cost of medicines in Europe using only competition law. Better quality EPO patents would reduce the volume of litigation in whatever courts were dealing with it.

However, the Enquiry may prove to be useful in calling attention to the enormous costs resulting from the failure to carry out these three reforms.

It would have been useful if the Report had suggested procedural improvements and clarifications, based on "*best practice*" or the need to correct obvious defects, that could be adopted at national level even without a new directive or regulation, but the Commission did not try to do this. The inefficiency and delays of some national courts is notorious, and is regrettable that the Commission did not point this out more clearly. The difficulty of getting procedural harmonization measures adopted at European level in 27 Member States is not a reason for failing to call attention to the urgent need for improvements.

Commission Interventions in National Court Cases

Under Article 15 of Reg. 1/2003, the Commission may intervene on its own initiative in national courts where competition law issues arise. Although the Commission had done this even before Reg. 1/2003, (in *Hasselblad v. Orbison*, 1984, English Court of Appeal, and in the USA), the Commission has been remarkably reluctant to use this possibility even when it has been asked to do so. The Dutch tax court judgment of the ECJ (Case C-429/07, June 11, 2009), which confirmed that the Commission may make written submissions, on its own initiative, to national courts on issues related to competition law even if the issues could not be decided by the Commission itself, may encourage such interventions. The usefulness of such interventions may be limited in the pharmaceutical industry, but they can be on both

procedural and substantive issues of EC law. If Commission observations were sufficiently well-informed and convincing, they might be accepted by the national court as an alternative to a reference under Article 234, and much time would be saved.

However, Commission's observations on the basis of Article 82 will suffer from the Commission's incomplete and unsatisfactory understanding of that Article. On Article 81 issues, the Commission could hardly make useful written observations unless it had first enquired carefully into the facts of each case.

Commission "*guidance*" for pharmaceutical companies?

The Commission has been criticised for not telling pharmaceutical companies what they can and cannot do under competition law.

However:

- the legal rules under Article 81, as summarised here, are broadly known to well-informed lawyers (although it is true that many competition lawyers know little patent law, and many patent lawyers know little competition law);
- the Commission now seems much less likely to say that any infringements of Article 82 have been committed. The call for guidance was primarily due to the impression that the Commission believed that many widespread practices might be contrary to Article 82. If the Commission does not now believe that, the need for special guidance for pharmaceutical companies is less;
- under Article 82, many of the relevant principles are clear, and they do not suggest that the practices investigated by the Commission are likely to be illegal, except perhaps in unusual circumstances;[4]
- the Commission is usually wise to adopt interpretative Notices only after it has adopted some decisions, and the decisions have been considered by the Court of First Instance; and
- the Commission's Guidance on Exclusionary Abuses under Article 82, which deals only with much better known and more traditional kinds of abuse, is not satisfactory,[5] and the Commission would be unwise to try to state additional rules in very much more difficult areas without more experience.

The concept of exclusionary abuse could be comprehensively clarified, as I believe it ultimately must be, by being based on the wording of Article 82(b). That provision has been interpreted by the Court of Justice to prohibit limiting production, marketing or technical

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4 Temple Lang, Current European Competition Law Questions for Pharmaceutical Companies, St. Gallen International Competition Law Forum (2009), to be published shortly.

5 Temple Lang, Article 82 – The Problems and the Solution, Working Paper, Fondazione Eni Enrico Mattei (2009); Temple Lang, The Requirements for a Commission Notice on the Concept of Abuse under Article 82 EC, Centre for European Policy Studies (CEPS) Special Report (2008).

It seems likely that some national competition authorities will bring cases on the basis that the Guidance paper correctly states the law. When this happens the companies will have to defend themselves by pointing out mistakes and omissions from the Guidance paper. This will put the Commission in a difficult position, until a revised Guidance document is published.

development of competitors of the dominant company to the prejudice of consumers.[6] This means "*limiting*" the possibilities open to competitors by methods other than legitimate competition. A dominant company could not be prohibited from competing legitimately, and obtaining new patents and exercising patent rights is legitimate competition. Therefore the principal effect of adopting a comprehensive definition of exclusionary abuse would be to confirm that most if not all of the practices described in the Report are legal even when adopted by dominant companies.

Marketing authorisations and pricing and reimbursement

These could both be improved by national measures, and do not need to be the result of European measures. The Report made no specific suggestions about this. The big differences between national arrangements show clearly that the efficiency of some Member States could be greatly improved without any need for measures at Community level. Again, the Commission could have been more frankly critical.

The apparent decline in innovation

The report says very little about the apparent decline in the appearance of new medicines on the market. Some companies said that this was due to (i) the R & D process becoming more complex; (ii) factors in the regulatory framework; (iii) lack of reward for incremental innovations; and (iv) price regulation (para.1513). It seems that the Commission found no

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6 The case law has made it clear that Art. 82(b) applies to limiting the production, marketing or technical development of competitors, and not merely to limiting the dominant company's own activities. Joined Cases 40/73 and others, *Sugar Cartel – SZV*, [1975] ECR 1663, paras. 399, 482-83, 523-527 ("*the system complained of was likely to limit markets to the prejudice of consumers within the measure of Article [82](b) because it gave other producers … no chance or restricted their opportunities of competing with sugar sold by SZV*": para. 526); Case 41/83 *Italy v. Commission* (*British Telecommunications*), [1985] ECR 873; Case 311/84, *Telemarketing CBEM*, [1985] ECR 3261, para. 26; Case 53/87, *CICR v. Renault*, [1988] ECR 6039; Case 238/87, *Volvo v. Veng*, [1988] 6211; Joined Cases C-241/91P, *RTE* and *ITP* ("*Magill*"), [1995] ECR I-743 at para. 54 ("*The applicants' refusal to provide basic information by relying on national copyright provisions thus prevented the appearance of a new product, a comprehensive weekly guide to television programmes, which the applicants did not offer and for which there was a potential consumer demand. Such refusal constitutes an abuse under heading (b) of the second paragraph of Article [82] of the Treaty.*"); Case C-41/90, *Höfner and Elsner*, [1991] ECR I-1979 at 2017-2018 ("*Pursuant to Article [82](b), such an abuse may in particular consist in limiting the provision of a service, to the prejudice of those seeking to avail of it*": para. 30; Case C-55/96, *Job Centre*, [1997] ECR I-7119 at 7149-7150; Case C-258/98 *Carra*, [2000] ECR I-4217; Case T-201/04, *Microsoft*, [2007] ECR I-3601 para. 643-648 ("*The circumstance relating to the appearance of a new product, as envisaged in Magill and IMS Health … cannot be the only parameter which determines whether a refusal to licence an intellectual property right is capable of causing prejudice to consumers within the meaning of Article 82(b) EC. As that provision states, such prejudice may also arise where there is a limitation not only of production or markets, but also of technical development*": para. 647). Bellamy & Child, European Community Law of Competition (6th ed., 2008) pp. 1025-1026; Commission Decision, *P&I Clubs*, OJ No. L-125/12, May 19, 1999, paras. 128-133.

See Elhauge, Defining Better Monopolisation Standards, 56 Stanford Law Review (2003) 253; Temple Lang, Anticompetitive Non-Pricing Abuses under European and National Antitrust Law, in Hawk (ed.), 2003 Fordham Corporate Law Institute (2004) 235-340; O'Donoghue & Padilla, The Law and Economics of Article 82 (2006) Ch. 4; O'Donoghue, Verbalizing a general test for exclusionary conduct under Article 82 EC, in Ehlermann & Marquis, European Competition Law Annual 2007: A Reformed Approach to Article 82 (Hart, 2008); Vickers, Abuse of Market Power, Vol. 115 (6) The Economic Journal (2005) 244

real evidence that the decline in innovation is due to any deliberate policies of originators. It may not be the Commission's fault, but in this respect the Report is disappointing.

Compliance programmes for companies

Presumably any company that has not already carried out a compliance programme in the light of the Final Report will be doing one now.

Any company taking over another pharmaceutical company should investigate carefully to see if it has been involved in anything that the Commission might investigate. Investigations can be expensive even when the Commission finally concludes that no infringement has occurred. The legal principles are well enough established for compliance programmes to be developed satisfactorily.

Claims for compensation

If any agreements of the kinds described in the Report were ultimately found to be contrary to Article 81, it seems probable that national social welfare authorities in the Member States affected would claim compensation, in accordance with the principles stated by the Court in the *Crehan* and *Manfredi* judgments. The same result would occur in the less likely event of findings of infringement of Article 82, if loss and causation could be proved.

Conclusions

The Commission's pharmaceutical enquiry will be a success if it leads in due course to the adoption of the European Patent and to a single European patent court, and perhaps to other improvements, primarily in national regulatory systems. If it does not lead to these reforms, it will probably not have been worth the considerable expense involved for the companies.

With hindsight, it is clear that the Commission overestimated the number of infringements in the industry, partly due to misunderstanding patent law and partly through not having a clear concept of exclusionary abuse under Article 82. If the Commission had had a clear understanding of exclusionary abuse, the Commission could have concentrated on agreements between companies, and greatly reduced the scope and the cost of the enquiry. The Commission should be careful to make sure that it does not put the companies in a given industry to the expense of a sector enquiry unless it is clear that there is a substantial competition law problem. The Commission sometimes seriously underestimates the cost to companies of answering the Commission’s questions. It should also make sure that it does not bring weak cases after a sector enquiry report, merely to try to prove that the enquiry was justified. It would not be surprising if the officials who launched the enquiry and wrote the report would prove to be too easily convinced that infringements had occurred, when under the Commission's procedure the same individuals act as both "*prosecutors*" and "*judges*" in individual cases. This defect in the Commission’s competition procedure is not, of course, peculiar to pharmaceutical cases, but it might be particularly important if the officials concerned had formed their opinions initially during a sector enquiry.

Unfortunately, as is well known, there is significant opposition to a European Patent. The ostensible reason is differences of opinion over official languages. As is often the case when

the ostensible reason for a position or policy is unconvincing, this is because the true reasons cannot be given. The real reasons for the opposition to the European Patent are essentially protectionist - national patent offices do not want to lose revenue, some national governments fear that their industries are less inventive than those of other States.

Such reasons should no longer be allowed to prevent badly needed reforms. The additional financial and economic costs imposed on European industry due to patent systems being national are enormous. They seem far greater than the additional costs imposed on European taxpayers by supposedly restrictive agreements between originators and generics. The European Commission needs to change its focus and its priorities, and to concentrate on the most important issues. There may be some competition cases to be brought, but the most important issues are patent issues, not competition law issues.