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## The EU pharmaceutical sector inquiry: what next?

The European Commission believes it has enough evidence from its sector inquiry to take action against some pharmaceutical companies, and patent settlements between originator companies and generic firms are likely to be a prime target. But proving that the EU competition rules have been breached will not be an easy task, say Jonathan Radcliffe and Brian Sher.

The European Commission's interim report on the pharmaceutical sector inquiry highlights pharmaceutical industry practices that the Commission considers have cost the taxpayer €3 billion since 2000. Particular criticism is levelled at the range of practices used by originator companies to extend their drug monopolies by keeping out generic competition.

The report draws broad conclusions from practices that are well known in the industry. Significantly, this is the first time that hard evidence has been compiled documenting these practices - and only because the Commission was able to flex its coercive muscles through dawn raids and requests for data.

Among the Commission's conclusions are that in the period 2000 to 2007, originator companies deployed a "tool-box of instruments" - procedural objections that can be used to derail the market entry of generic alternatives. From an intellectual property practitioner's perspective, the practices described in the report are perfectly legitimate.

That said, the Commission's fear is that they are being systematically and endemically deployed in combination by originator companies to the detriment of generics and the general public, something that appears to be supported by the results of the Commission's investigations.

### the main practices

The main practices the Commission identifies are:

- patent filing strategies;
- patent enforcement strategies;
- direct settlement agreements between competitors; and
- interventions against marketing authorisations.

**Patent filing.** Originator companies have adopted patent filing strategies to expand the breadth and duration of the originator's monopoly over a successful medicine. This commonly involves filing a large number of patents to protect the same product, creating a so-called "patent-thicket" to deter anyone from attempting to manufacture products or use processes whose patent protection has expired. The headline figure quoted in the report (and frequently reported in the press) is that in one instance 1,300 patents had been filed to protect the same medicine. This is an extreme case, but as a strategy it is commonplace.

**Patent enforcement strategies.** The Commission reported that there was a four-fold increase in patent litigation between 2000 and 2007. In more than 90% of cases, the litigation was instigated by an originator company. Litigation is a complex and lengthy process. The threat of litigation is enough to deter generic competitors, and we are increasingly seeing it used as such, rather than as a legal process through which patent rights can be enforced.

**Settlements.** This is a key issue for the Commission, and the one area that is likely to see proposals for major reforms once the final report is published, and in the interim is most likely to lead to enforcement action being taken (see below). The preliminary findings suggest that more than 200 settlement agreements were entered into between originator companies and generic companies between 2000 and 2008. The terms of private settlements often impose restrictions on the sale of cheaper generic alternatives to branded products. The Commission's figures suggest that the sale

of 49 of the best selling medicines was affected in the relevant period in the EU, with a potentially damaging impact on the market for alternative products and restricting consumer choice.

**Marketing authorisation intervention.** This is seen as primarily a delaying tactic. Originator companies are alleged to have challenged (via stakeholders) the efficacy and quality of generics to leading branded medicines. Of the 211 cases of marketing authority intervention reported, the originator companies involved claimed that 158 of the generic alternatives were unsafe.

These findings are not wholly surprising. The Commission's intentions are clear. It commissioned the report because of its belief that the pharmaceutical market had become "distorted".

Its main finding is that certain well known practices act as a deterrent to generics companies. Specialists have long suspected that originator companies deploy these tactics to extend their de facto monopolies, and the statistics bear out this suspicion.

A prime example is "evergreening" and the proliferation of weak patents to prolong the monopoly on the breakthrough product. Generic companies with the resource to challenge originators' patents have a 62% success rate in all patent trials, and a 75% success rate in all European patent office oppositions.

Such litigation is only worthwhile if the potential rewards are there, so no matter how much of a social good is served by lower cost generic medicines, in practice the patents on many medicines are never challenged.

However, for generics companies the attractions of a private settlement are clear.

The generic companies can avoid complex and lengthy litigation and acquire certainty, often on commercially advantageous terms.

**where is the report likely to lead?**

First, some clarity on what the report is not. It is not an assessment of the behaviour of originators, generics firms or anyone else in the pharmaceutical industry under EC competition law. The report is confined to an assessment of the factual practices of the companies concerned. And it is an interim report, with the final report due in the spring.

Second, it is nonetheless clear that enforcement action by the Commission under the EC competition rules is a likely next step. This is what happens in EC sector inquiries – the facts are established at an industry-wide level and then, to the extent that the Commission believes it has evidence of anti-competitive behaviour, it opens separate enforcement investigations. Such investigations often begin with unannounced inspections (“dawn raids”) and the Commission in fact raided the premises of a number of originator and generic firms in the week before the preliminary report was issued.

Third, in assessing the kind of enforcement action that is likely, and the challenges ahead for the Commission, it is critical in our view to distinguish between two categories of practices identified in the report which broadly correspond to the two legislative “tools” the Commission

has in its own “tool-box” to deal with these practices under EC competition law.

The two categories are (i) practices which involve an agreement between two or more companies – in this case mainly patent settlements and originator/originator agreements; and (ii) the unilateral practices of originator companies.

The two “competition tools” at the Commission’s disposal are Article 81 of the EC Treaty, which prohibits restrictive agreements, subject to an efficiencies defence; and Article 82 of the Treaty, which prohibits the abuse of a dominant position.

The Commission is likely to look at both categories of practices coming out of this sector inquiry, and in truth both are likely to be challenging because competition enforcement in either case is likely to be perceived in some quarters as an undue interference with (essentially national) patent rights. Nonetheless, it is established law that the exercise (as opposed to the existence) of an intellectual property right can be challenged in certain circumstances under EC competition law, so the controversy will not prevent the Commission pursuing enforcement.

Where the two categories differ is that attacking the unilateral practices is likely to be much more challenging because the practices do not correspond to established categories of “abuse” under Article 82.

All sorts of difficult questions will arise: at what point, for example, does applying

for multiple patents for the same medicine become abusive? How is the line to be drawn? It cannot be based on the number of patents applied for as that would seem artificial; if it is to be based on some notion of how “genuine” the application was, then this starts to stray into judgements about the quality of the intellectual property rights themselves – which, many will argue, it is the role of patent offices and national courts, rather than competition regulators, to judge.

By contrast, the patent settlements are agreements between two parties and as such are at least clearly capable of challenge under Article 81. This is why we believe the Commission is likely to focus on them in the first instance. And the fact that generics, as well as originators, were raided shortly before the report was published supports this view. But even here enforcement will not be easy, and the Commission is watching developments in the US, where complainants have had an uphill struggle to establish antitrust liability in this area.

This is clearly a case of “watch this space” and “more to follow soon”.

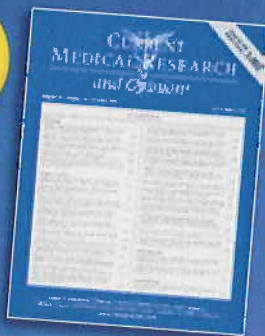
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**This is the second of two commentaries on the EU sector inquiry; the first, by Bill Batchelor of Baker & McKenzie, appeared in *Scrip* No 3423/24, pp 40-42.**

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