

Chemicals under the cosh

Pharma companies face harsh treatment by competition authorities

by *Isabelle Rahman**

On 9 December 2009, the European Commission published a press release confirming it had conducted another wave of dawn raids at the premises of several pharmaceutical companies. This is the fourth time the Commission has carried out dawn raids against pharmaceutical companies since it began its sector inquiry into the pharmaceutical industry in January 2008.

The sector inquiry

The Commission's current investigation is focused on the potential misuse of patents and patent settlements by originators in order to prevent entry of generic competition. The Commission justified the launch of the inquiry by pointing to the decline in medical innovation in Europe (measured by the decreasing number of novel medicines reaching the market), as well as to increasing instances of delayed market entry by generic medicines.

As a result of its findings, the Commission has identified various tactics used by originators to delay or hamper generic competition. These include:

- filing for a large number of patents in relation to a single medicine (forming "patent clusters");
- launching expensive and protracted patent litigation against generic companies;
- concluding patent settlement agreements with generic companies that restrict generic entry and involve value transfers from the originator to the generic company;
- pursuing life-cycle strategies for follow-on products aimed at switching patients to new medicines prior to market entry of a generic version of a first-generation product; and
- intervening in national procedures for the approval of generic medicines, claiming that generic products are less safe, less effective or of inferior quality.

The Commission has also identified defensive patent strategies used by originator companies to interfere with the development of competing medicines by other originator companies.

Focused monitoring of patent settlements

In its final report on the pharmaceutical sector inquiry published on 8 July 2009, patent settlements appear to have been singled out for special treatment by the Commission. The Commission says that it will engage in what it calls "focused monitoring" of patent settlement agreements, which it continues to view with suspicion, for a limited period of time until it has gathered sufficient information on this type of practice. It is possible the Commission may want to delay making any final decision while it watches how current dissension on the legality of certain patent settlement agreements resolves itself in the US. Such co-ordination between competition authorities would be encouraging, as it could well lead to more consistent enforcement action and greater legal certainty. Greater consistency might in turn

promote more efficient global settlements, since patent litigation on the same drug is often pursued in multiple jurisdictions around the world.

Dawn raids

The sector inquiry itself was initiated with dawn raids in January 2008 on several originator and generic pharmaceutical companies. The use of unannounced inspections at these companies' premises as its first investigation tool was an unusual – and aggressive – step by the Commission. Sector inquiries are meant to be a learning tool for the Commission, enabling it to perform an extensive fact-finding exercise in the context of a specific industry. They are not meant to target specific companies suspected of wrongdoing.

The recent spate of dawn raids may be part of the Commission's focused monitoring of patent settlements, although, given the invasive nature of a dawn raid, it would seem that the Commission is not engaging in mere monitoring, but actually has clear suspicions of wrongdoing. In the past, the Commission's dawn raid powers have usually been reserved for hardcore cartel or abuse of dominance cases, and have been exercised with the aim of obtaining and preserving evidence that might not otherwise be volunteered by companies.

Armed with its improved knowledge of the pharmaceutical sector and a wealth of empirical evidence collected during its 18-month inquiry, the Commission's message is loud and clear: it will take action against company behaviour that it feels is contributing to competitive problems in the pharmaceutical sector. The recent wave of dawn raids is a clear and timely illustration of the seriousness of the Commission's enforcement intentions. The Commission has confirmed that it has launched a formal investigation against a number of pharma companies in respect of conduct aimed at hindering the entry of a cardiovascular generic medicine.

Increased antitrust scrutiny

In practice, pharmaceutical companies should therefore be prepared for increased antitrust scrutiny and enforcement action in relation to their patent strategies and agreements with competitors. Enforcement action will concern both originator and generic companies alike and will probably be taken by the Commission and/or the national competition authorities.

Interesting times lie ahead for all companies having to work in this new enforcement climate. Companies may have the awkward task of assessing whether litigating a patent is legal (as the Commission could decide it is vexatious and aimed at deterring generic entry) and, at the same time, considering whether entering into settlement agreements to avoid litigation might not also attract the Commission's wrath. In any event, pharmaceutical companies would do well to put their house in order now in case a dawn raid team knocks at their door.

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