Unsettling patents?
The EU pharmaceutical sector inquiry

by Simon Albert*

According to the European Commission, branded pharmaceutical manufacturers (“originators”) have deployed a toolbox of tactics to further their overall strategy of delaying the entry of generic drugs into European markets. While the sector inquiry may hold certain risks for the generic sector, the Commission’s actions may offer generic firms the chance to challenge the status quo and ultimately to increase the sales of generic pharmaceuticals across Europe.

Investigation to date
In January 2008, the Commission launched a sector inquiry, prompted by information suggesting that competition between innovative and generic medicines may be restricted or distorted. Symptoms included a decline in innovation measured by the number of novel medicines reaching the market, and instances of delayed market entry of generic medicines, as compared to what might be expected. The inquiry relates to 2000 to 2007 and has investigated a sample of 219 medicines. It was also prompted by the Commission’s decision to fine AstraZeneca €60m in June 2005 for abusing the patent system and pharmaceutical marketing procedures to block or delay market entry for generic competitors to its ulcer drug Losec, and by the Commission’s investigation into Boehringer’s conduct, launched in February 2007.

€3bn: all to play for?
The Commission found that originators use a variety of strategies to maintain revenue streams, in particular from blockbusters, for as long as possible. The report considered that these practices delay generic entry and lead to healthcare systems and consumers paying at least €3bn more than they would otherwise have done for medicines. Those lost sales represent a considerable opportunity for generic companies to pursue (see further diagram below).

Unsettling patents?
The Commission identified five tactics in the originators’ toolbox which are often used, in isolation or in combination, to prevent or delay market entry by generic medicines. These tactics are: (1) strategic patenting; (2) patent litigation; (3) patent settlements; (4) interventions before national regulatory authorities; and (5) life cycle strategies for follow-on products.

* Simon Albert is an associate with Berwin Leighton Paisner LLP (London)
Pharmaceutical sector inquiry

Given the potential opportunities for generic medicines detailed above, and that patent settlements are a source of international controversy, this article will focus narrowly on patent settlements and their repercussions.

“In the USA,” the Commission drily notes, “the Federal Trade Commission has scrutinised patent settlements that contained a direct payment made by the originator company to the generic company combined with a restriction on the generic company to enter the market with its own medicine.”

The report coyly adds that:

“as shown by the enforcement action of the USA competition authorities, in particular the [FTC], it might also be argued that settlements contain arrangements that could fall within the scope of competition rules. A patent settlement agreement might, for example, lead to a delay in a generic product’s entry in a specific market in return for a payment by the originator company to the generic company. Ultimately, it is the consumer who pays the price for such a delay in market entry.”

The report then forensically analyses the issue, while stressing that “the aim of this chapter is not to provide guidance on whether certain types of settlement agreements could be deemed compatible or incompatible with EC competition law.”

The Commission’s cautious approach does not reflect the vigour with which the FTC pursues the issue, nor the potential that the Commission may itself identify this as one of its primary enforcement areas. The Commission may feel it has some catching up to do. The US Medicare Prescription Drug, Improvement, and Modernization Act (MMA) 2003 requires the FTC to produce an annual report, detailing all patent settlement agreements filed with the FTC during the relevant period.

In May 2008, commenting on the Federal Trade Commission’s annual report for 2007, the FTC chairman William Kovacic stated that:

“this report confirms that settlements with potentially anticompetitive arrangements continue to be prevalent […] The Commission remains committed to ensuring that brand and generic companies do not use such settlements as a way to deny consumers the benefits of competition.”

Commissioner Jon Leibowitz added:

“as our report today sadly demonstrates, pay-for-delay settlements continue to proliferate. That’s good news for the pharmaceutical industry, which will make windfall profits on these deals. But it’s bad news for consumers, who will be left footing the bill. These agreements inflict special pain on the working poor and the elderly, who need effective drugs at affordable prices.”

During his campaign, Barack Obama officially stated:

“I will encourage the increased use and development of generic alternatives. Some drug manufacturers are explicitly paying generic drug makers not to enter the market so that they can preserve their monopolies and charge Americans exorbitant prices for brand name products. My healthcare plan will ensure that market power does not lead to higher prices for consumers. My plan will increase the use of generic drugs [and] prohibit large drug companies from keeping generics out of the marketplace.”

While the Department of Justice (DoJ) takes a more moderate approach to the issue, and the 11th Circuit Court opposed the FTC’s views in Schering Plough (2005), the FTC has continued to prosecute the issue vigorously. The Commission notes that, in February 2008 the FTC sued Cephalon, which had signed restrictive settlement agreements with four generic firms. In June, the FTC explained this was “a straightforward story of anticompetitive conduct,” where even Cephalon’s CEO admitted “we were able to get six more years of patent protection. That’s $4bn in sales that no-one expected.”

The FTC concluded that:

“shielding exclusion payment settlements by drug companies from antitrust scrutiny would grant monopolists the ability to buy more protection from competition than their Congressionally-granted patent rights provide and would retard – rather than foster – innovation. Drug companies, like Cephalon, will use this power not to preserve legitimate patent monopolies, but rather to extinguish challenges to the weakest patents which would otherwise generate billions of dollars in consumer savings.”

Separately, in December 2008, the FTC challenged Ovation Pharmaceuticals’ January 2006 acquisition of the drug NeoProfen, which eliminated its only competitor for the treatment of a serious congenital heart defect.

In Europe, the Commission has found that, in 2004 and 2005, “there were substantially more settlement agreements for the EU than for the USA,” and concluded there are “more similarities than differences between the two systems.” The report details a large number of anonymised settlement agreements, involving over €200m in direct payments (the UK had the second highest number of settlement agreements in the relevant period, after Germany). Despite certain procedural concerns, given that the FTC and the Commission have been in regular contact in this regard, these findings might provide the Commission with an ideal opportunity for enforcement action.

Dawn raids: procedural concerns

However, the Commission may have already pre-empted itself by launching dawn raids in November against Teva UK, Servier (France) and Krka (Slovenia). The Commission stated in its press release that:

“The inspections are not related to the pharmaceutical sector inspections in January 2008 nor part of the pharmaceutical sector competition inquiry […] However, the knowledge acquired during the sector inquiry has allowed the Commission to draw conclusions on where Commission action based on competition law could be appropriate and effective.”
However, despite the Commission’s carefully worded press release, article 28 of Regulation 1/2003 clearly states that “information collected pursuant to [a sector inquiry] shall be used only for the purpose for which it was acquired” – ie the Commission is unable simply to recycle information gathered in a sector inquiry for use in enforcement action. Indeed, the Commission assured the industry in January 2008 that “if any specific cases against companies are opened, these cases will be launched in their own right, outside of the framework of the sector inquiry”.

However, the industry may be concerned that enforcement action is running in parallel to, rather than following the conclusion of, the sector inquiry. It may also ask how the respective case teams are maintaining the necessary information barriers to ensure sensitive information (for example, regarding the most controversial patent settlement agreements) is not inappropriately recycled to the detriment of individual companies. These procedural concerns may even feature in potential challenges to future Commission enforcement decisions in the Court of First Instance.

The November raids followed the initial January raids at the inquiry’s launch, which the Commission admitted was “the first time a sector inquiry [had started] with unannounced inspections”. The Commission ordered the unprecedented dawn raids to gain “immediate access” to “information … concerning the use of intellectual property rights, litigation and settlement agreements covering the EU, [which] by its nature … companies tend to consider highly confidential [and] may also be easily withheld, concealed or destroyed.”

The Commission’s use of its information-gathering powers may therefore mean that its enforcement timetable begins earlier than otherwise predicted.

“The need for a strong and fast Central Patents Court for Europe sticks out a mile”
Lord Justice Jacob

Be prepared
Given the Commission’s stance, firms may wish to prepare themselves accordingly, reviewing their competition compliance programmes, dawn raid preparedness, and involvement in areas of concern such as patent settlement agreements. Certain firms may even consider the strategic value in making leniency applications to the relevant competition authorities. This process may be an opportunity as much as a threat, depending on which side of the branded divide one sits. Certain generic firms may see an opportunity in approaching the relevant competition authorities to challenge certain originators’ business practices and so help increase generic sales in Europe. However, there may be a potential legal risk for certain generic firms party to settlement agreements with originators which the Commission subsequently regards as infringements. The Commission has the power to impose fines, declare agreements to be unenforceable, and issue an infringement decision which third parties could use in follow-on damages actions.

Reform proposals: unanimity
The Commission has also consulted widely on the need for regulatory reforms. A near unanimity has emerged over a single European patent court and a harmonised patent judiciary across Europe, to avoid the examples which the Commission identified of several national courts arriving at different conclusions on the validity of the same patents. This received powerful backing at the official presentation of the Commission’s findings on 28 November, where the leading UK IP judge Lord Justice Jacob urged that “one thing is clear […] the need for a strong and fast Central Patents Court for Europe sticks out a mile […] It is particularly that last proposal which matters for European industry as a whole.”

Comments please
The Commission has invited comments by 31 January 2009, with a view to publishing the final report by Spring 2009. Enforcement action against individual firms may well follow.

Conclusion
The Commission clearly believes it has identified some serious issues, that a significant likelihood of enforcement action exists as a result, and that any potential penalties could reflect the large turnovers involved. Further close analysis of the issues is recommended, as is engaging with the authorities at an early stage. Doing so may well be an opportunity for some, as much as the inquiry may pose a threat to others.

References
FTC’s Bureau of Competition Issues FY 2007 Summary of Pharmaceutical Company Settlement Agreements: Nearly Half Involved Payment to Generic Firms, Restricted Generics’ Ability to Enter the Market (at http://www.ftc.gov/opa/2008/05/drug.shrm)