

Agenda

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Competition law in pharmaceuticals: a moving target?

The European pharmaceutical sector has long been a priority market for the competition authorities. The high level of public spending and acute consumer welfare aspect mean that the sector is continually under review—indeed the European Commission has been conducting a sector inquiry since January. Pat Treacy, Sophie Lawrance and Helen Hopson of law firm, Bristows, consider the inquiry in its competition law context, and examine some of the likely outcomes of the recently published interim findings

Historically, the main focus for competition authorities has been ensuring that pharma companies do not restrict parallel trade in pharmaceutical products. The disparate pricing of pharma products across the EU due to differing pricing regulation by Member States creates opportunities for parallel traders to buy pharmaceutical products in low-priced countries and sell them in higher-priced countries. Although this can generate savings for national health authorities, pharma companies' profit margins may be eroded, which has led some to take measures that have been found to breach the competition rules.¹

However, the main focus of the authorities has shifted of late. In 2006, when addressing European Parliament, Competition Commissioner Neelie Kroes stated that:

generic competition is an area which has suffered from under-enforcement in the past ... the Commission will give greater priority to competition in the generic sector in the immediate future.²

The European Commission inquiry into the pharma sector, which commenced in January 2008, is not concerned with parallel trade within Europe.³ The Commission is examining the extent of competition between originator companies, and originator and generic companies, and whether competition is working as it should.

The inquiry is the latest event in a flurry of activity by the Commission in the pharma sector. In 2005, the Commission found that AstraZeneca had abused its dominant position by misusing the patent and regulatory regimes.⁴ In particular, AstraZeneca was held to have abused its dominant position for providing misleading supplementary protection certificate (SPC) information

for its Losec product to the regulatory authorities, and by withdrawing a marketing authorisation for the capsule form of Losec. The Commission found that both practices had inhibited generic entry. More recently, the Commission commenced proceedings against Boehringer Ingelheim for possible 'misuse of the patent system in order to exclude potential competition in the area of chronic obstructive pulmonary disease'.⁵

The Commission published an interim report of its findings in the sector inquiry in November and is due to publish its final report in the spring/summer of 2009. In some respects the timing of the inquiry is surprising. A final decision in *AstraZeneca* is unlikely to be forthcoming for at least a couple of years,⁶ and until it is received, the application of competition law in this area remains inherently uncertain. However, the inquiry's significance is unprecedented. It has re-ignited the debate surrounding pharma regulation, in particular the role of competition law in such an atypical market. In this article, we aim to place the pharma sector inquiry in its competition law context, and to analyse some of the likely outcomes of the report.

The pharma sector: special rules for a special market?

The European pharmaceutical market can be distinguished from more conventional economic markets in many ways.

First, Member States control the fundamental boundaries of competition in the EU pharmaceutical sector, namely price, supply and expenditure. These controls distort both the supply side (by controlling prices) and demand side (through physicians' prescribing budgets or monopsonist Member States' national health policies). Second, pharmaceutical companies spend more on R&D

than any other industry.⁷ The costs of developing and launching a new product are extraordinarily high and have increased substantially over the past few decades. The huge R&D costs reflect the inherently risky nature of successful discovery and launch of new products; the cost of one successful product includes the costs of countless failures.

This medley of distorted incentives and competition reflects the ‘special nature’ of the pharmaceutical market. Innovator companies argue that this is critical to assessing whether competition ‘is not working well’, as has been alleged by the Commission. However, the European courts’ position on the special nature of the pharmaceutical market when considering competition law is less clear. The Court of First Instance (CFI) in its 2006 judgment in an Article 81 case relating to GlaxoSmithKline’s (GSK) pricing systems took into account the peculiarities of the markets for the sale and distribution of pharmaceuticals in finding that the Commission had erred in its assessment of whether GSK’s pricing arrangements were eligible for exemption under Article 81(3).⁸ The CFI considered that the unique characteristics of this sector meant that the normal principle that a restriction on parallel trade has the object of restricting competition cannot be assumed without further consideration of the legal and economic context. Furthermore, while not reaching a conclusion on this issue, the CFI seemed to imply that the characteristics of the industry may be sufficient to justify an exemption on efficiency grounds for an arrangement that restricts parallel trade.⁹ However, in the recent judgment of the European Court of Justice (ECJ) in *Glaxo Greece*, the court was silent on the ‘special characteristics’ of the pharmaceutical market, indicating its reluctance to accept that such characteristics affect competition to any real extent.¹⁰

The sector inquiry: the Commission’s areas of concern

The Commission gave two main reasons for launching its sector inquiry: (i) an apparent decline in innovation, as evidenced by a reduction in the number of new medicines reaching the market (the average number of new molecular entities launched each year during the periods 1995–99 and 2000–04 was 40 and 28, respectively); and (ii) delays to market entry by generic competitors.

In its press release announcing the inquiry, the Commission stated its intention to look at whether there were restrictive agreements in place in the industry which could be producing the identified effects.¹¹ In particular, the Commission wanted to look at settlement agreements between originator and generic companies. In Europe (in contrast to the USA) there is no mandatory requirement to notify settlements to the Commission.¹²

The Commission has therefore had less opportunity than its US counterparts to review settlement agreements, or to consider the correct approach under competition law.

The Commission also stated that it intended to consider whether companies:

may have created artificial barriers to entry, whether through the misuse of patent rights, vexatious litigation or other means, and whether such practices may infringe the EC Treaty’s ban on abuses of dominant market positions (Article 82).

As well as gathering data for its preliminary report via inspections and questionnaires to industry participants, the Commission also received submissions from industry stakeholders, in particular the European Federation of Pharmaceutical Industries and Associations (EFPIA) and the European Generic Medicines Association (EGA). The EGA was supportive of the Commission’s intervention. However, it is of note that its report focused on the ways in which the European patent (including patent litigation) and regulatory systems should be reformed, rather than on breaches of the competition rules.¹³

While regretting the way in which the inquiry had been started (with ‘dawn raids’ of a number of pharmaceutical companies), EFPIA also welcomed the Commission’s inquiry, perceiving it as an opportunity for the Commission to gain a deeper understanding of the industry.¹⁴ However, EFPIA questioned whether the Commission’s initial assumptions were correct, noting that ‘there is no evidence of a marked decline in innovation’ in the industry. EFPIA questioned whether measuring innovation by reference to the number of new molecules entering the market—the Commission’s chosen method—is an adequate method of assessing innovation. It tests only numeric output rather than the value created. However, the report did find that there had been some decline in productivity as measured by the cost of bringing a new molecular entity to the market. Despite an increase in R&D spend, the output of new medicines was not keeping pace. Three primary causal factors were identified for this decline:

- industry retooling to exploit a growing proportion of biotechnology products;
- increased costs of product development (in particular due to spiralling costs of clinical trials);
- higher commercial attrition rates due to indications from state buyers that they are not prepared to pay for the development of certain types of new medicines.

The content of the Commission’s preliminary report

The Commission’s preliminary report runs to over 400 pages. It contains an overview of the structure of the

pharmaceutical market, a long section on the state of competition between originator and generic companies, a shorter section on competition between originator companies, and concludes with some comments on the regulatory framework (including the patent system, marketing authorisations and the pricing and reimbursement system). The Commission has gathered a large amount of data, and presents an array of statistics on topics such as the number of patents (from the set selected by the Commission) subject to litigation or opposition proceedings; the outcome of those proceedings; the relationship between patent expiry dates and the start of patent litigation; the relative incidence of settlement agreements; and the average number of patents applicable to a particular drug. Many of the statistics are presented in a number of ways—for example, by company, by drug or by EU Member State.

However, the report is arguably as noteworthy for what it does not cover as for what is included. It does not attempt to assess at all the contribution that company conduct makes either to any decline in innovation or to any delay in generic entry and thus possible consumer harm. Despite citing a decline in innovation as one of the two key reasons for carrying out the study, the Commission does not analyse the extent of this supposed decline, nor does it address EFPIA's analysis of the reasons for the decline. Rather, the report approaches the issue indirectly, suggesting that an inference should be drawn from the fact that, on average, a relatively larger proportion of drug companies' budget goes to promotion and marketing than on R&D (and of that R&D spend, a minority goes to what the Commission styles 'basic' research as opposed to development activities such as clinical trials). In a similar vein, the report also emphasises the tendency of pharmaceutical companies to patent 'defensively', securing a large number of patents around a particular area of interest. The Commission suggests that this is a source of undue hold-up in the industry, fettering other originator companies' freedom to operate.

Moreover, the Commission's report looks only at two out of the three relevant aspects of the inter-company relationships within the industry. While it covers originator–generic and originator–originator conduct in considerable detail, generic–generic conduct is entirely absent. Given that cost savings to health authorities from generic entry become particularly significant only after the second generic company has entered the market (as the first company is likely to undercut the price of the branded product only by a fairly small amount), conduct by the first generic company in each case to try to remain in that position for as long as possible may be equally relevant to the question of whether purchasers of medicines are being denied cost savings.

Most importantly, the Commission report does not identify whether the practices described may infringe competition law. Indeed, the ultimate purpose of the report is unclear. The Commission may decide to use the information it has gathered to commence legal actions against some or many industry participants (indeed, it carried out a number of dawn raids on pharmaceutical companies shortly before publication of the preliminary report, although it has not confirmed any connection with the report's findings),¹⁵ or it might choose instead to issue guidance to the industry as to what it regards as acceptable conduct. The status that any such industry-specific guidance would have is unclear.

Nevertheless, the rules on anti-competitive agreements (Article 81 EC) and abuse of dominance (Article 82) form the backdrop to the report. Infringement of these rules is a very serious matter: companies may be fined up to 10% of group worldwide turnover (although it is also the case that the Commission's fining guidelines suggest that the maximum is unlikely to be applied for a 'novel' breach of the rules).

Despite the Commission's assertion that it does not seek to identify wrongdoing by individual companies, or to determine whether conduct described in the report infringes EC competition law, the report's tone is indicative of the Commission's view of the practices described in it. Throughout the report, the practices used by originator companies to remain competitive and to obtain a return on R&D are described in a negative light. For example, the Commission refers to originators' 'tool box' of strategies for delaying generic entry. The tool box described by the Commission includes actions such as the filing of secondary patents (ie, those which protect new formulations or other modifications to the primary therapeutic molecule); the creation of patent clusters (ie, a large number of such secondary patents); patent litigation against generic companies; challenges to marketing authorisation or pricing and reimbursement decisions; withdrawals of products shortly before patent expiry; product promotion to prescribers; and the practice of entering into agreements with generic companies. Generic companies allege that such strategies—which they often refer to as patent 'evergreening'—unfairly and unlawfully prevent them from being able to enter the market once the basic patent expires.

The Commission does not explain how or when such practices, which are in themselves in most cases likely to be a reasonable and commercially rational way of proceeding given the enormous risk and cost of bringing new drugs to market and the relatively short exclusivity available under the patent system (even when a patent can be extended by an SPC), would constitute competition law wrongs. Aside from the parts of the

report concerning agreements, the actions listed could constitute conduct prohibited by the competition rules (if indeed they are prohibited at all) only if they were carried out by dominant companies. The analysis to be undertaken to determine if a pharmaceutical company is dominant is now reasonably well established (although it could be affected by appeals in the *AstraZeneca* case), and in many cases holding a patent-protected product with significant sales will confer a dominant position on its proprietors. However, a very detailed analysis of the surrounding facts and market is still required in order to ascertain whether a given company is in fact dominant in a particular market. Similarly, it is unclear whether many of the actions in the tool box would in fact constitute an abuse of a dominant position. For example, the Commission goes into some detail on the way in which pharmaceutical companies carry out litigation against generic companies. The Commission impliedly draws into question whether it is legitimate for originators to bring proceedings on secondary patents. Yet it does not refer to the existing case law of the European Courts (which will take legal precedence over any Commission decision or guidance) on the circumstances in which the bringing of legal proceedings could amount to unlawful vexatious litigation. It is clear from this case law (in which an infringement of this kind has never been found) that companies' right of access to the courts can be tampered with only in exceptional circumstances.¹⁶

The hostile tone of the report, coupled with the lack of legal analysis, means that there is a risk that the report

could itself chill innovation in the industry. Originator companies will be uncertain as to the extent to which they remain entitled to use their tool box without running unacceptable risks under the competition rules: can they use one or two tools only, or must they refrain altogether? Budgets based on current estimates of when generic entry is likely to take place may need to be rewritten. Global companies may consider scaling back their European operations to concentrate on markets where there is less legal uncertainty (although it should be noted that US President-Elect, Barack Obama, has indicated that any pharmaceutical company practices that delay generic entry will be targeted under his regime).

Whatever the internal response of originators, it is inevitable that some generic companies will seize on aspects of the report in their dealings with pharmaceutical companies. Since most disputes between generic and originator companies take place in the context of national courts or before the patent authorities, it is likely that the judiciaries of Member States will be some of the first to be asked to decide whether conduct which arguably has delayed generic entry should be punished under the competition rules. This could lead to inconsistent and inappropriate decision-making. It is therefore to be hoped that the Commission's final report, due in spring/summer 2009, takes a more measured view of the industry, and takes greater account of the incentives of originators to continue to invest and innovate.

Pat Treacy, Sophie Lawrance and Helen Hopson

¹ For a discussion on parallel trading, see Oxera (2008), 'Shades of Grey: Arguments For and Against Parallel Trade in Pharmaceuticals', *Agenda*, October. Available at www.oxera.com.

² Commissioner Neelie Kroes's reply to Oral Question put by the honourable member of the European Parliament Mr von Boguslaw Sonik (H – 0459/06).

³ See European Commission (2008), 'Pharmaceutical Sector Inquiry: Preliminary Report', November 28th, para 15. See also in this issue of *Agenda*, 'Drug Abuse? The Commission, the Sector Inquiry, and Generic Entry'.

⁴ Commission Decision 2006/857/EC, *Re: AstraZeneca Plc*, 2006 O.J. (L 332) 24.

⁵ Case COMP/B/39.246 – Boehringer Ingelheim (commenced February 22nd 2007).

⁶ One or both parties are likely to appeal the decision of the Court of First Instance (expected in around six months) to the European Court of Justice.

⁷ European Commission (2007), 'EU Industrial R&D Investment Scoreboard', October, p. 12.

⁸ Case T-168/01, *GlaxoSmithKline Services Unlimited v Commission*, judgment of the CFI.

⁹ The CFI judgment has been appealed by GSK, the Commission and two wholesalers' associations.

¹⁰ Cases C-468/06 to C-478/06 *Sot. Lélos kai Sia EE and Others v. GlaxoSmithKline AEVE Farmakeftikon Proïonton*, judgment of the ECJ.

¹¹ European Commission (2008), 'Commission Launches Sector Inquiry into Pharmaceuticals with Unannounced Inspections', press release, IP/08/49, January 16th.

¹² In the USA the Medicare Prescription Drug, Improvement, and Modernisation Act 2003 requires drug companies to file certain agreements (including patent settlement agreements) with the Federal Trade Commission and US Department of Justice.

¹³ European Generics Medicines Association (2008), 'Patent-related Barriers to Market Entry for Generic Medicines in the European Union', press release, May. Available at www.egagenerics.com.

¹⁴ European Federation of Pharmaceutical Industries and Associations (2008), 'Submission to the European Commission in Relation to the Pharmaceutical Sector Inquiry', June and CRA International (2008), 'The Current State of Innovation in the Pharmaceutical Industry', June; available at www.efpia.org.

¹⁵ European Commission (2008), 'Commission Confirms Unannounced Inspections at Pharmaceutical Companies', press release, MEMO/08/734, November 25th.

¹⁶ Case T-111/96 *ITT Promedia NV v Commission* [1998] ECR II-2937. In this case, the CFI held that litigation is lawful unless undertaken by a dominant company where (i) it 'cannot reasonably be considered to be an attempt to assert the right of the undertaking concerned and can only serve to harass the opposing party', and (ii) it is part of a plan to eliminate the competitor.

If you have any questions regarding the issues raised in this article, please contact the editor, Derek Holt: tel +44 (0) 1865 253 000 or email d_holt@oxera.com

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- drug abuse? the Commission, the sector inquiry, and generic entry
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