The Competition and Markets Authority (the “CMA”) announced on 12 February 2016 that it has fined GlaxoSmithKline plc (“GSK”) and certain suppliers of generic medicines for entering into anti-competitive agreements for the supply of paroxetine – an anti-depressant medicine.

This again raises the question at what point patent holders of branded medicines may violate competition law when they negotiate patent settlements.

**WHAT HAS HAPPENED?**

In 2001, pharmaceutical companies active in the supply of generic medicines, especially Generics (UK) Limited (“Generics”) and Alpharma Limited (“Alpharma”), were looking to enter into the UK market for the supply of paroxetine. GSK owned certain patents in relation to paroxetine and sold a branded version of it (called Seroxat) in the UK market. Seroxat was by far the largest selling product on the paroxetine market – its sale in the UK itself amounted to over £90 million in 2001.

GSK initiated a court challenge against Generics and Alpharma for alleged infringements of its patents. The cases were, however, settled before the trials began and both Generics and Alpharma agreed not to enter into the UK paroxetine market for a certain number of years. The terms of these agreements also included an obligation on GSK to make payments (including certain value transfers) of £50 million to Generics and Alpharma. According to the CMA, these payments were
aimed at delaying the potential entry of generic medicines into the UK market for paroxetine – the so called “pay-for-delay” arrangements.

The CMA’s investigation found that because of these “pay-for-delay” arrangements the UK’s National Health Service was likely denied the benefit of substantial reduction in prices that usually result from the introduction of generic competition. According to the CMA, following the introduction of generic paroxetine in the UK market the average price of paroxetine dropped by approximately 70% over the following two years.

The CMA has found that the arrangements between GSK and Generics and Alpharma breached the rules against anti-competitive agreements. In addition to this the CMA has also concluded that GSK’s conduct amounted to an abuse of its dominant position. Consequently, GSK was fined approximately £37.6 million whereas Generics and Alpharma were fined approximately £5.8 million and £1.5 million respectively.

COMMENT

Pharmaceutical companies incur considerable R&D costs to develop new medicines, and in order to allow them to recoup these costs they generally enjoy a period of patent protection. Once the patent expires, manufacturers/suppliers of generic medicines are free to enter the market which was earlier reserved to the patent holder. This period of protection is important to allow pharmaceutical companies to continually invest considerable resources and time in developing new medicines.

However, attempts by pharmaceutical companies to prolong the period of market-exclusivity, by mechanisms such as patent settlements, or patent clusters (web of overlapping intellectual property rights that a new entrant would have to negotiate) that result in high prices may amount to a violation of the prohibition against anti-competitive agreements1 and / or an abuse of a dominant position2.

In 2005, AstraZeneca was fined €60 million by the European Commission (the “Commission”) for abuse of the patent system and the system for authorisation of medicines. AstraZeneca was found to have abused its dominant position by firstly, providing misleading information to a number of EEA patent offices in order to obtain supplementary protection certificates and secondly, by misusing pharmaceutical regulatory system by selective withdrawal of certain market authorisations. According to the Commission, AstraZeneca’s aim was to delay competition to its blockbuster drug from generic and parallel imported medicines.3

“Pay-for-delay” provisions in patent settlement agreements are of particular interest to competition authorities.4 The CMA’s recent decision follows a number of high profile pay-for-delay fines imposed by the Commission in recent years: Servier was fined €330 million in 2014 (high blood pressure medicine – perindopril); Johnson &

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1 Article 101 of the Treaty on the Functioning of European Union and/or Chapter I of the Competition Act 1998.
2 Article 102 of the Treaty on the Functioning of European Union and/or Chapter II of the Competition Act 1998.
3 AstraZeneca’s appeals to both the Court of First Instance and the European Court of Justice were rejected.
Johnson and Novartis were fined €16 million in 2013 (pain-killer – fentanyl); and Lundbeck was fined €93.8 million in 2013 (anti-depressant – citalopram).\(^5\)

This is not to say that all pay-for-delay agreements are considered anti-competitive. Generally, only those agreements that unreasonably delay the generic entry and as a result cause consumer harm and maintain unnecessary high prices are likely to be considered anti-competitive. This is also evident in the latest monitoring report published by the Commission on 2 December 2015.\(^6\) The Commission found that only 12% of the total patent settlement agreements in the EU concluded between January 2014 and December 2014 were potentially problematic.\(^7\) Nevertheless, pharmaceutical companies looking to enter into any such agreements must be mindful that they do not fall foul of competition rules.

In the US, “pay-for-delay” agreements have also been one of the top priorities of the Federal Trade Commission (the “FTC”) in recent years. In a study published by the FTC in January 2013, it found that “pay-for-delay” agreements cost American consumers approximately $3.5 billion every year in higher drug costs.\(^8\) The FTC has also offered its support to the “Protecting Consumer Access to Generic Drugs Act of 2012”, which was introduced into the US Congress on 9 February 2012. This Bill intends to target patent settlements that include pay-for-delay provisions. The Bill has not yet been adopted into law.

There is one more important question that arises in pay-for-delay and other patent settlement cases: where is the boundary between legitimate protection of intellectual property rights and anti-competitive behaviour? The patent settlement cases are a classic example of the fine balancing required between the protection of intellectual property rights on one hand and competition rules on the other hand – a too interventionist approach may diminish the value of intellectual property rights to a mere entitlement to litigate (as opposed to a property right) which is likely to take away the incentives to innovate; conversely, if there are no restrictions on intellectual property rights, it may mean that competition prohibitions may not apply to an important area of commercial activities. Each case must be considered individually, on its own terms.

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\(^5\) The Servier and Lundbeck cases are currently under appeal.

\(^6\) Following the conclusion of sector inquiry into the pharmaceutical sector the European Commission has continued to carry out annual patent settlement monitoring exercises.


FOR MORE INFORMATION

Should you like to discuss any of the matters raised in this Briefing, please speak with a member of our team below or your regular contact at Watson Farley & Williams.

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