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Australian competition regulator brings proceedings for alleged misuse of market power in pharmaceutical industry

In recent years, the Australian Competition and Consumer Commission (ACCC) has vigorously enforced its competition laws in cases of alleged misuse of market power, cartel conduct and anti-competitive agreements. Continuing this trend, in February 2014 the ACCC filed civil proceedings in a superior Australian court against multinational pharmaceutical company Pfizer for alleged misuse of market power and exclusive dealing in relation to its anti-cholesterol drug Lipitor shortly before patent expiry. Pfizer strenuously denies that its conduct contravened the law.

Key issues

- the ACCC has brought the proceedings against Pfizer and indicated that the pharmaceutical industry and the use of patents are areas it is paying close attention to
- in an environment of increased regulatory enforcement, it is important for pharmaceutical and other companies to be aware of the competition law interaction with intellectual property rights.

Significance of ACCC misuse of market power cases

Misuse of market power cases are extremely difficult in concept, having regard to the possibility of incorrectly prosecuting pro-competitive and vigorous competitive conduct. Nevertheless, the ACCC has brought the proceedings against Pfizer and indicated that the pharmaceutical industry and the use of patents are areas it is paying close attention to.

Accordingly, in an environment of increased regulatory enforcement, it is important for pharmaceutical and other companies to be aware of the competition law interaction with intellectual property rights.

The tension between competition law and intellectual property rights

Intellectual property rights (IPRs) include patents, trademarks, copyright, designs, database rights, domain names, and trade secrets. Competition law and IPRs share the same basic objective of promoting economic efficiency and innovation. Competition law does this by helping to promote competitive markets, thereby spurring firms to be more efficient and innovative. Intellectual property law does this by establishing a legal monopoly for the creators of new and improved products to incentivise innovation and the significant investment involved in research and development (R&D). IPRs are not treated for competition law purposes any differently to any other agreement or conduct.

A tension exists in finding a balance between innovation and incentives. For example, a pharmaceutical company may be entitled to patent protection for a novel and inventive drug thereby rewarding them for the significant time and costs invested in

the R&D of the drug. For the duration of the patent, the company is often able to exercise a legal monopoly over the drug or to capitalize on the commercial value of the patent through pro-competitive licensing arrangements. However, licensing arrangements should be drafted carefully to ensure that they are not anti-competitive or that they fall within the limited exemption for intellectual property licences contained in Australia's competition legislation. Licensing arrangements which could raise competition issues include those which directly or indirectly restrict the ability or incentive of any parties to carry out independent R&D, contain grantbacks which substantially reduce the incentives of the licensee to engage in R&D, involve exclusivity or non-compete clauses which impact market dynamics, or establish technology pools.

It is generally not a misuse of market power for a company with market power to exercise IPRs in the market for the product which incorporates the IPR. However, there may be competition concerns where a company with market power attempts to extend the IPR beyond the scope granted by law or attempts to prevent or restrict the use of the products or processes formerly subject to the IPR once the IPR has expired. There may also be anti-competitive effects where a company with market power acquires exclusive rights to competing technology. A further category of potential concern is the refusal to supply a license to essential facilities on the (rare) occasion where there are no potential substitutes.

The ACCC proceedings against Pfizer

On 13 February 2014, the ACCC lodged a claim against Pfizer in the Federal Court of Australia alleging misuse of market power in relation to the anti-cholesterol drug Lipitor. The ACCC alleged that Pfizer offered discounts and rebates to pharmacists in Australia paid through revenue accrued from Lipitor sales, on the basis that those pharmacies purchase a year's supply of Pfizer's generic version of Lipitor. The agreements were finalised shortly before the Lipitor patent expired in May 2012. Pfizer has announced that it will vigorously defend the proceedings and strongly denies any anti-competitive conduct on its part.

The proceedings against Pfizer appear to be the first high profile ACCC misuse of market power action involving intellectual property rights in recent times. It is anticipated that the proceedings will turn on whether the ACCC is able to prove that Pfizer took advantage of its position in the market by offering discounts on the generic version of the patented drug shortly before the Lipitor patent expired. ACCC Chairman Rod Sims has said publicly that the proceedings raise an important public interest issue regarding the conduct of a patent holder nearing the expiry of that patent and what constitutes permissible competitive conduct.

The proceedings raise some complex questions under Australian competition law and highlight the difficulties in competition agencies bringing misuse of market power cases and differentiating between anticompetitive conduct and conduct that could also be characterised as pro-competitive conduct.

The agreement that the ACCC alleges to be problematic arises against the context of an industry structure where specific generics are tightly aligned with distributors. Accordingly, Pfizer has an argument that its conduct was legitimate business conduct in order to compete effectively. Such an argument may also be a good defence to the ACCC's case which is based on an anticompetitive purpose for the conduct, not an anticompetitive effect.

An international perspective

The pharmaceutical sector has experienced particular scrutiny in recent times. In particular, the EU and US antitrust authorities have continued their enforcement focus on "pay for delay" cases with major decisions on this area in both jurisdictions in 2013. Pay for delay is said to occur if an originator company settles patent litigation with a generic manufacturer and makes a transfer of value to the generic manufacturer in return for a delayed entry to the market.

The most recent decision by the European Commission involved fines in December 2013 totalling EUD16 million on US pharmaceutical company Johnson & Johnson and Switzerland's Novartis AG for entering into an anti-competitive agreement to delay the market entry of a generic version of the painkiller Fentanyl. Earlier that year in June 2013 the European Commission imposed on five pharmaceutical companies fines totalling EUD145 million in relation to

the anti-depressant Citalopram where Lundbeck had paid the other pharmaceutical companies sums equivalent to what they would have earned had they entered the generics market. The European Commission continues to investigate a number of similar cases, including the Servier case regarding Perindopril and Cephalon and Teva regarding Modafinil. The US Supreme Court's June 2013 judgment in *FTC v Actavis* held on a rule of reason basis that an agreement to delay entry of a generic version of Solvay's AndroGel in exchange for payment was anti-competitive. In December 2013, the Federal Trade Commission in the US moved to join Teva to its suit against Cephalon over patent settlement agreements in relation to the narcolepsy drug Provigil.

Looking forward

ACCC Chairman Rod Sims has said publicly that there are many patents in Australia and judicial guidance would be helpful not only in the proceedings against Pfizer but also in respect of other drugs manufactured by pharmaceutical companies. This may indicate that the ACCC will adopt a similar position to that being taken currently in the EU and US. It is therefore important for pharmaceutical companies (as well as other companies that rely on intellectual property rights to protect their economic interests) to be aware of the associated competition risks and to review business practices in light of the likely increased competition law scrutiny.

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