Competition law scrutiny of patent settlements - a new focus in Australia?

Competition and Market Regulation Update

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Settlement agreements in patent disputes between pharmaceutical companies may soon face greater competition law scrutiny in Australia. The Productivity Commission has put ‘pay for delay’ patent settlements between originator and generic pharmaceutical companies in the spotlight in its recent inquiry into intellectual property arrangements in Australia. Although the final outcomes of that inquiry are yet to be seen, the issue will be front of mind for Australia’s competition regulator (ACCC) and pharmaceutical companies could find themselves subject to a new reporting and monitoring regime to detect anti-competitive patent settlements.

What is a ‘pay for delay’ settlement?

A pay for delay settlement generally involves the following, as part of the settlement of a patent dispute:

- An originator/patent holder paying a generic pharmaceutical manufacturer (or providing some other form of non-monetary benefit)
- The generic manufacturer agreeing to limit or delay the entry of a generic product into a market.

Such agreements are also referred to as ‘reverse payment’ settlements because the payment is arguably going in the ‘reverse’ direction to what would be expected in the settlement of a patent dispute (i.e., under such agreements, the patent holder pays the alleged infringer of the patent to settle a dispute, rather than vice versa).

**SETTLEMENT OF PATENT DISPUTE – ‘PAY FOR DELAY’/REVERSE PAYMENT**

Examples of overseas ‘pay for delay’ developments

- June 2013 – US Supreme Court holds that pay for delay agreements can contravene competition/antitrust law, adopting
a ‘rule of reason’ approach in Actavis

- June 2013 – European Commission imposes fines of about €146 million on Lundbeck and generic companies in relation to agreements relating to an anti-depressant, citalopram
- July 2014 – European Commission imposes fines of over €400 million on Servier and generic companies in relation to settlements relating to a blood pressure medicine, perindopril (subject to appeal)
- February 2016 – UK competition regulator, the CMA, imposes total penalties of almost £45 million in a pay for delay case in the UK relating to an anti-depressant (subject to appeal)
- March 2016 – US Federal Trade Commission files a new pay for delay case challenging an agreement not to market an authorised generic as a form of reverse payment
- September 2016 – European General Court upholds European Commission’s finding in Lundbeck that pay for delay agreements are anti-competitive ‘by object’

**Competition law concerns**

‘Pay for delay’ patent settlements between originator and generic pharmaceutical companies have been a hot topic in antitrust/competition law in the United States, Europe and the United Kingdom in recent years.

The competition law concerns are that the settlements delay the entry of generic products into the market and therefore limit competition between the patented drug and generic versions. However, patent holders clearly need to have an ability to protect and defend valid patent rights, as otherwise innovation (and the rationale for a patent system) may suffer. Patent settlements also of course provide the benefit of avoiding potentially costly and lengthy litigation.

The difficulties that competition regulators and courts have faced in drawing the line between legitimate conduct to defend valid patent rights and anti-competitive conduct that keeps competition from the market are illustrated in overseas cases.

One approach, which was a feature of the US case law for a number of years, is the ‘scope of the patent’ test. Under this test, if the terms of the settlement mean that the generic is only prevented from entering the market within the exclusionary scope of the patent, the agreement will not be anti-competitive (as the patent holder is simply protecting its rights). Another approach, adopted by the US Supreme Court in its landmark decision in Actavis, is the ‘rule of reason’ approach. This means that the competitive effects of the settlement agreement are considered (regardless of whether the agreement meets the scope of the patent test), but the agreement is not considered to be anti-competitive per se. Conversely, the European Commission, and more recently the European General Court, have considered pay for delay settlements to be anti-competitive ‘by object’ (which means that the competitive effects of the agreement are not considered).

In Australia, the ACCC has not yet taken a case relating to a pay for delay settlement. However, if such settlement agreements were entered into by Australian businesses, they are likely to breach Australian competition law in some circumstances. For example:

- Pay for delay agreements could amount to a cartel arrangement. This would mean that the agreement would be treated as illegal per se (and the actual impact that the agreement has on competition would not be considered) – provided the ACCC could establish that the originator and generic manufacturer are competitors or potential competitors in the relevant market (despite the existence of the patent) and that the arrangement contained a cartel provision, such as a provision restricting or limiting the supply of goods by the generic manufacturer. The application of the current exception relating to licences or assignments of intellectual property rights, discussed further below, would also need to be considered.
- If not a cartel arrangement, a pay for delay agreement could also be considered under the general prohibition on arrangements that substantially lessen competition (which would mean that the competitive effects of the agreement would be considered).
- The conduct of the originator could also be considered under the misuse of market power prohibition, which currently prohibits a corporation with market power from taking advantage of that power for a proscribed purpose (such as deterring or preventing a person from engaging in competitive conduct in a market or preventing the entry of a person into a market). If proposed changes to the misuse of market power prohibition are introduced, the conduct of the originator would be subject to a substantial lessening of competition test.

**Proposed new monitoring regime**

The Productivity Commission’s inquiry into Intellectual Property Arrangements has raised pay for delay settlements as a potential issue in Australia. In its draft report published earlier this year, the Productivity Commission recommended
introducing a new reporting and monitoring regime (administered by the ACCC) for pay for delay settlements.

The draft report does not contain details of the proposed new regime, but it would likely require pharmaceutical companies in Australia to lodge patent settlement agreements with the ACCC. This recommendation was made despite the Productivity Commission acknowledging that there is no evidence of such settlements in Australia, on the basis that the lack of evidence may "reflect the lack of monitoring arrangements, rather than the absence of such activity" and that monitoring arrangements would "detect and deter such behaviour".

The ACCC already has powers to investigate potential breaches of Australia’s competition law – for example, by requiring companies to provide information and documents through a ‘section 155 notice’. However, before issuing such notices, the ACCC must have reason to believe that the person to whom the notice is directed is capable of providing information/documents relating to a matter that constitutes, or may constitute, a breach of competition law.

The proposed new monitoring regime would therefore mean that the ACCC would have greater visibility of the extent to which pay for delay agreements are being entered into in Australia and the terms of those agreements, without needing to rely on its investigative powers to seek that information. The proposal is based on the regime in the United States, which requires that brand-name drug manufacturers and generic drug applicants file certain agreements with antitrust agencies. The European Commission has also carried out annual patent settlement monitoring exercises in recent years.

The proposal for a reporting and monitoring regime in Australia naturally raises concerns about the compliance costs and burden that it will put on companies subject to the regime, and whether there is any real need for increased monitoring (beyond the ACCC’s existing investigative powers) in the Australian context. During the Productivity Commission’s consultation process, for example, several submitters queried the need for the regime based on a lack of evidence that pay for delay agreements are an issue in Australia. Medicines Australia noted that the mandatory reporting regime would be "superfluous" and "constitute significant regulatory overreach". The Intellectual Property Committee of the Law Council of Australia similarly noted:

"...there is no empirical evidence relied upon in the Draft Report to support the proposition that pay-for-delay settlements are occurring with any frequency in Australia which might justify any special or particular enforcement procedures to be deployed by the competition regulator..."

The ACCC, however, has expressed support for the proposed new regime, noting that it could aid the ACCC to detect anti-competitive conduct that might otherwise go undetected. The ACCC’s submission to the Productivity Commission also indicates that the ACCC wishes the monitoring regime to apply to a broad range of agreements, including agreements entered into outside Australia that have an effect in Australia.

"In order for the scheme to be most effective, the ACCC considers that it would need to capture agreements with an effect on markets in Australia, which may include agreements reached in other jurisdictions … it will be important that the ACCC has the ability to monitor and report on settlements that cover a diverse range of agreements that delay generic drug market entry to the detriment of consumer welfare." (ACCC, Submission to the Productivity Commission’s Draft Report into Australia’s Intellectual Property Arrangements, 6 June 2016).

Draft report also recommends repeal of intellectual property exception

The Productivity Commission’s draft report also proposed (in line with a recommendation in the recent Harper Competition Policy Review) that the intellectual property exception in Australia’s competition law be repealed. There is currently a limited exception from most of the restrictive trade practices prohibitions for conditions in licences or assignments of intellectual property rights such as patents. If implemented, intellectual property agreements that were previously protected from competition law consideration by the operation of the exception may come under greater scrutiny.

Next steps

The Productivity Commission handed its final report to the Australian Government in late September 2016, but the report has not yet been tabled in Parliament or released to the public. During its consultation process, the Productivity Commission noted that it was seeking to determine whether there was something structurally different in the Australian market that would mean that pay for delay settlements may not occur, and indicated that further consideration would be given to the costs and benefits of the proposed change.

However, even if a different course is recommended in the final report, there is still likely to be an increased focus by the ACCC on patent settlements in the life sciences sector. The ACCC has shown that it will take action when concerned
about alleged anti-competitive activity by an originator prior to the expiry of a patent (in the recent Pfizer case, for which judgment on the ACCC’s appeal is currently pending), and competition issues in the health sector generally are one of the ACCC’s priority areas.

The size, nature and importance of the life sciences sector means that it will always be a sector of interest for competition regulators. Even greater attention on competition issues in the sector looks likely in Australia in coming years. Life sciences companies should therefore be prepared for ACCC investigations into their conduct, including in the area of patent settlements.

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