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COMPETITION AND REGULATION UPDATE

CAN REVERSE PAYMENTS IN PATENT SETTLEMENTS CONSTITUTE CRIMINAL CARTEL CONDUCT?

It is a well-established and universally accepted principle of competition law that a payment by one competitor to another competitor not to enter a market is anticompetitive, and in Australia since 2010 a criminal offence. In the United States (US) over the past decade, drug companies, the Federal Trade Commission (FTC) and class action applicants have battled the question of whether this established principle of competition law applies in the context of a *settlement* of a *patent dispute*. The answer is now clearly and unequivocally yes.

Recent decisions of the US Supreme Court and the Director General (DG) of competition in the European Union (EU) have confirmed that reverse payments in patent settlements are subject to competition law and are potentially anticompetitive. If the Australian Federal Court were to follow these two clear decisions then a reverse payment could constitute criminal cartel conduct under *the Competition & Consumer Act* (CCA), in addition to potentially constituting an anticompetitive agreement.

Therefore, such settlements are at risk of criminal sanctions, pecuniary penalties and damages claims by private parties including class actions.

Whilst there is no Australian authority on this issue the jurisprudence in the US is now very clear and strong, the EU whilst not having jurisprudence has a very clear and strong prosecution by the DG of competition consistent with the US Supreme Court. Accordingly, it is inconceivable that the Australian Competition and Consumer Commission (ACCC), State Governments, private health insurers and class action law firms can ignore the clear legal position now being adopted in the both the US and the EU that reverse settlement payment are subject to competition law and are potentially anticompetitive. It can only be a matter of time before enforcement proceedings are bought by the ACCC or private proceedings by an affected party that a reverse payment is in breach of the CCA.

WHAT'S NEXT?

Submissions on the Australian Energy Regulator (AER) draft guidelines are due by close of business 11 October 2013. The AER (and Economic Regulation Authority (ERA)) are required to publish final rate of return guidelines by 29 November 2013.

The AER suggests that its final guidelines, while not specifying the rate of return that it would determine at that time, will specify some parameters and is intended to allow regulated businesses to determine a 'starting point' for the rate of return estimate with a reasonable degree of precision.

Contact us if you have any queries regarding the consultation process or the AER's proposed approach to determining the rate of return under the revised provisions of the National Electricity Rules (NER) and National Gas Rules (NGR).

FTC v Actavis, Inc (Androgel) **US Supreme Court 17 June 2013**	**Lundbec (Citalopram) European Commission 19 June 2013**
Offending reverse payment settlement terms: ▪ Generic Androgel would be marketed for nine years with period ending sixty five months before the patent expired. ▪ Generic company agreed to promote Androgel to urologists. ▪ Generic company receives annual payment of between US$19 million and $30 million for nine years for 'other services.'	Offending reverse payment settlement terms: ▪ Generic companies agreed not to market generic citalopram for agreed period. ▪ Generic companies received guaranteed profit for distributing Citalopram. ▪ Lundbeck (originator) acquired generic citalopram stock for destruction.
US Supreme Court finding ▪ The restraint has the 'potential for genuine adverse effects on competition.' ▪ Payment in return for staying out of the market - simply keeps prices at patentee-set levels, potentially producing the full patent-related $500 million monopoly return while dividing that return between the challenged patentee and the patent challenger. The patentee and the challenger gain: the consumer loses. ▪ Such payments are subject to antitrust scrutiny under a rule of reason approach and not immune under 'scope of the patent' projection. Matter remitted to District Court to apply rule of reason test to the settlement terms.	European Commission finding ▪ It is unacceptable that a company pays off its competitors to stay out of its market and delay the entry of cheaper medicines. Agreements of this type directly harm patients and national health systems, which are already under tight budgetary constraints. The Commission will not tolerate such anticompetitive practices. ▪ Lundbeck fined €93.8 million and each of the four generics fined €52.2 million.

IN A NUTSHELL WHAT IS THE PROBLEMATIC CONDUCT?

Both the US Supreme Court and the European Commission (EC) have ruled that a settlement of patent litigation proceeding which involves the originator paying consideration for the delay of the entry of competing generic drugs raises competition law issues (pay for delay).

However, 'where a reverse payment reflects traditional settlement considerations, such as avoided litigation costs or fair value for services, there is not the same concern that a patentee is using its monopoly profits to avoid the risk of patent invalidation or a finding of non-infringement.' Accordingly, where justifiable consideration is paid a limitation on the ability of generic company to enter is unlikely to raise competition concerns.

EXAMPLES OF PROBLEMATIC REVERSE PAYMENT SETTLEMENTS

Problematic reverse payment settlement agreements have two essential terms:

- Settlement agreement that the generic company will:
  - refrain from challenging the validity of the originator company's patent(s) (non-challenge clause); and/or
  - refrain from entering the market until the patent has expired (non-compete clause); and/or
  - solely be a distributor of the originator product concerned; and/or
  - source its supplies of API from the originator company.
- Unjustifiable consideration is paid by the originator company to the generic company, which can take many forms:
  - Payment of a lump sum for unspecified services.
  - Payment for purchasing the generic company's stock of the generic drug.
  - Annual payments for distribution services.

HOW WIDE SPREAD IS THE PROBLEM?

The EC over the period 2009 to 2011 reviewed a large sample patent litigation settlements in the EU. The EC's analysis indicates that of the patent settlements it reviewed in 20011, 11 percent are likely to be problematic from an antitrust perspective. Therefore, these issues are not one off and reasonably prevalent in the industry to attract scrutiny.

WHAT IS THE RISK?

The delay of entry by a competing generic drug permits the continued exploitation of the patent's monopoly. These monopoly returns are arguably the benefit the originator and generics retain as a result of the reverse payment settlement and the damage/loss suffered by the purchasers of the drugs. The EC has estimate that prices can be 90 percent higher without generic drug entry meaning monopoly profits are likely to be very high, attracting scrutiny.

> '*Experience shows that effective generic competition drives prices down significantly, reducing dramatically the profits of the producer of the branded product and bringing large benefits to patients. For example, prices of generic citalopram dropped on average by 90% in the UK compared to Lundbeck's previous price level once wide*.'

EXPOSURE IS TO PAST AND FUTURE REVERSE PAYMENT SETTLEMENTS

Both past and future reverse payment settlements are potentially subject to the CCA. Therefore, all past reverse payment settlements should be carefully reviewed to assess competition law risk, as it can only be a matter of time before the ACCC, State Governments, Private Health Insurers or Class Action Applicants follows the clear and strong jurisprudence set by the US Supreme Court and the EC in June 2013.

MORE INFORMATION

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