Article Information

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Service: Competition & Consumer

ACCC v Pfizer – Judgment summary and ramifications

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On 25 February 2015, Justice Flick of the Federal Court of Australia ruled in favour of Pfizer Australia Pty Ltd (Pfizer), dismissing the Australian Competition and Consumer Commission (the ACCC)'s case that Pfizer's sales and marketing conduct immediately prior to the expiration of its Lipitor patent breached sections 46 and 47 of the Competition and Consumer Act 2010 (the CCA).

Australian Competition and Consumer Commission v Pfizer Australia Pty Ltd [2015] FCA 113

Background

From around 2000, Pfizer supplied a cholesterol lowering pharmaceutical item called atorvastatin, which it marketed under the name 'Lipitor'. Pfizer was the sole supplier of atorvastatin in Australia, by virtue of the patent protection it enjoyed over the molecule (Patent).

Atorvastatin was (and remains) a prescription pharmaceutical subsidised under the Pharmaceutical Benefits Scheme (the PBS). The PBS, which is regulated by Part VII of the *National Health Act 1953* (Cth), provides for the Government to subsidise the cost of prescription medicines available to members of the general public. As at January 2012, atorvastatin was the highest-selling pharmaceutical item on the PBS, in terms of both its volume and value.

The Patent was due to expire on 18 May 2012 and, in settling a patent dispute, Pfizer granted Ranbaxy Australia Pty Ltd (Ranbaxy) a licence (the only such licence to be granted), allowing it to release a generic version of atorvastatin from 18 February 2012.

Not surprisingly, the expiration of the Patent was highly anticipated by generic manufacturers who wanted to sell their own atorvastatin products. By mid-2011, there were already 12 different generic atorvastatin products listed on the Australian Register of Therapeutic Goods (ARTG).

The traditional pharmaceutical supply chain is such that a pharmaceutical company supplies its product to a wholesaler, which on-sells to pharmacies (Community Pharmacies). Pfizer supplied Lipitor under this model in Australia until around 18 months prior to the expiry of the Patent, when it significantly adjusted its sales and marketing strategies, prompting the ACCC's investigation.

Pfizer's conduct prior to January 2012

In preparation for the expiry of the Patent, as well as a number of other of Pfizer's patents, in 2010, Pfizer implemented various changes to its marketing strategies, including:

- the Direct-to-Pharmacy Model, involving the sale and distribution of its products directly to pharmacies rather than through wholesalers (Pharmacy Supply Arrangements)
- the Accrual Funds Scheme, involving the accrual of 5% of a pharmacy's purchase of Pfizer's patented products (including Lipitor) from 31 January 2011 to be credited as a rebate on conditions
- a "bundled offer" to pharmacies which (inter alia) tied the prices upon which Lipitor was to be provided to the amount of Pfizer's generic atorvastatin that the pharmacy agreed to purchase.

Under the Accrual Funds Scheme, Pfizer established an account for each Community Pharmacy (Accrual Account). Rebates

on purchases of Pfizer's non-generic prescription pharmaceuticals were credited to the Accrual Accounts of purchasing pharmacies, calculated as a percentage of the purchase price, including a rebate of 5% of the purchase price of Lipitor (Lipitor Credits). In addition, up until the Patent expired, the "bundled offer" was made to Community Pharmacies. Pfizer's marketing documents stated that the aim of the "bundled offer" was to "block" the ability of pharmacies to obtain and sell the generic products of other manufacturers.

Pfizer's conduct post January 2012

On 12 January 2012, Pfizer released its own generic atorvastatin which was the same size, shape and colour as Lipitor (Atorvastatin Pfizer). On 16 January 2012, Pfizer offered virtually all Community Pharmacies the chance to redeem some or all of the Lipitor Credits in their Accrual Account and obtain discounts on Lipitor and Atorvastatin Pfizer.

To access these benefits, the Community Pharmacies had to agree to purchase 75% of their generic atorvastatin requirements from Pfizer for the following 6, 9 or 12 months by 24 February 2012, and take delivery of it in one shipment before 30 April 2012 (Atorvastatin Pfizer Offer). By nominating a longer supply period, pharmacies could redeem more of their Lipitor Credits and received a greater discount. They were also able to redeem a higher percentage of their Lipitor Credits by accepting the Atorvastatin Pfizer offer before 24 February 2012. The Lipitor Credits could not be redeemed after 24 August 2012. The discount offered on Atorvastatin Pfizer and Lipitor was calculated with reference to each pharmacy's estimation of the percentage of their Lipitor sales which would be converted to generic atorvastatin sales.

By 24 February 2012, 2346 pharmacies had accepted the Atorvastatin Pfizer Offer (with 2100 signing up for the Platinum offers with a 12 month supply period). This had increased to 3300 pharmacies by the time the Patent expired on 18 May 2012.

The decision

In February 2014, the ACCC instituted proceedings against Pfizer claiming that it had misused its market power (section 46(1)(c)) and breached the exclusive dealing provisions(section 47) of the CCA. In August 2014, it sought leave to amend its case to include a claim that Pfizer had sold Atorvastatin Pfizer at lower than cost price for a sustained period.

Misuse of market power – section 46 of the CCA

To succeed in its claim under section 46(1)(c) of the CCA, the ACCC had to prove that Pfizer had a substantial degree of market power in the relevant market, which it took advantage of for the purpose of deterring or preventing competition in that market.

Market power

His Honour accepted the ACCC's characterisation of the relevant market as the "Australia-wide market for the supply of atorvastatin to, and acquisition of atorvastatin by, community pharmacies." It was accepted that, although generic manufacturers often sell "ranges" of products, atorvastatin was sold as a separate pharmaceutical product for which there was no substitute.

Accordingly, Pfizer, as the sole atorvastatin supplier, was held to have "substantial market power" prior to January 2012, despite the limited degree of price regulation imposed its PBS listing. However, Justice Flick held that Pfizer's market power gradually decreased as a result of the preparatory activities undertaken by its competitors in anticipation of the expiry of the Patent. Accordingly, his Honour concluded that, by January 2012, Pfizer's market power was no longer "substantial".

Taking advantage of market power

The Court found that prior to January 2012, Pfizer took advantage of its substantial market power by establishing the Pharmacy Supply Arrangements and Accrual Accounts. Justice Flick found that it would not have been able to undertake these activities without its market power, because Community Pharmacies:

1. did not like the Pharmacy Supply Arrangements, but felt they had no option but to enter them in order to purchase atorvastatin prior to February 2012
2. did not know when or how they would be able to access their Lipitor Credits at the time the Accrual Accounts were established and, ultimately, the redemption of the Lipitor Creditors was conditional on the purchase of Atorvastatin Pfizer. Although his Honour noted that offering rebates does not, in itself, constitute taking advantage of market power, the context in which it occurs may support such a conclusion, as it did in this case.

His Honour further noted that, although it did not have the requisite market power at the time, Pfizer took advantage of its

remaining market power after January 2012 in making the Atorvastatin Pfizer Offer. However, his Honour found that, even assuming the Atorvastatin Pfizer Offer constituted selling Atorvastatin Pfizer below cost price, such short term behaviour at the launch of a product is not, without more, "anti-competitive".

Purpose

His Honour held that it would be "commercially naïve" to contend that Pfizer was attempting to "prevent" generic manufacturers from entering the atorvastatin market. On the other hand, his Honour found that the reference to "blocking" competition in the Pfizer marketing documents, on its face, suggested that Pfizer's purpose was to deter generic manufacturers from entering the atorvastatin market. However, the Court accepted the evidence, given by senior Pfizer employees, that the actual purpose was to prevent the erosion of Pfizer's market share, by strengthening its generic brand and relationship with Community Pharmacies. Noting that it is the corporation's subjective purpose for undertaking the conduct in question that is of relevance for section 46 of the CCA, his Honour held that marketing documents must be viewed with a degree of caution, as they are often prepared by those who do have ultimate decision making power in a corporation.

As a result, the ACCC's claim under section 46(1)(c) was dismissed on the basis that it was unable to establish that Pfizer engaged in the above conduct for a proscribed purpose.

"Legally incoherent" pleading

Justice Flick also held that the way in which the ACCC pleaded its claim under section 46(1)(c) of the CCA was "legally incoherent" and, on this basis, would have otherwise summarily dismissed its claim.

Exclusive dealing – section 47 of the CCA

The ACCC had alleged that the Atorvastatin Pfizer Offer constituted to a breach of section 47 of the CCA on the basis that the discounts were offered on the condition that Community Pharmacies purchase 75% of their anticipated non-generic atorvastatin requirements from Pfizer with the practical effect that non-Pfizer generic atorvastatin could not amount to greater than 25% of their total anticipated volume. This conduct was said by the ACCC to result in a substantial lessening of competition within the market.

Both limbs were rejected by the Court. Justice Flick held that the terms of the Atorvastatin Pfizer Offer did not positively place any restrictions on Community Pharmacies from acquiring any particular volume of generic atorvastatin. Interestingly, his Honour stated that while the practical effect may have been that the pharmacies acquired less generic atorvastatin, there was no condition per se within the meaning of section 47(2) of the CCA.

Just as the ACCC failed to establish purpose in its claim under section 46 of the CCA, the Court also found that the ACCC failed to establish that Pfizer's purpose for engaging in its pre-Patent expiry conduct was to cause a substantial lessening of competition within the meaning of section 47(10).

Important implications

The outcome of this case raises questions about the "purpose test" for misuse of market power in section 46 of the CCA. As noted above, to succeed in a claim under section 46, the ACCC must show the conduct in question was engaged in for an anti-competitive purpose, whereas it merely needs to show that the likely effect of the conduct was anti-competitive to establish exclusive dealing under section 47. Given his Honour's finding that Pfizer's purpose was not anti-competitive, but that the likely effect of its conduct was, it is possible that the ACCC would have succeeded in its claim under section 46 if it included a "likely effect test", regarding the establishment of the Pharmacy Supply Arrangements and Accrual Accounts. The ACCC has, in its submission to the Harper review, called for a "likely effect" test to be added to section 46 to strengthen the protection against misuse of market power. The final Harper review report is scheduled for release shortly, following a period of consultation, and it can be expected that it will recommend an amendment to section 46. It will remain to be seen whether the Government supports such a recommendation.