



LIFE SCIENCES UPDATE

TRAVERSING THE PATENT CLIFF

Pfizer's strategic response to the threat of generic competition upheld by the Federal Court

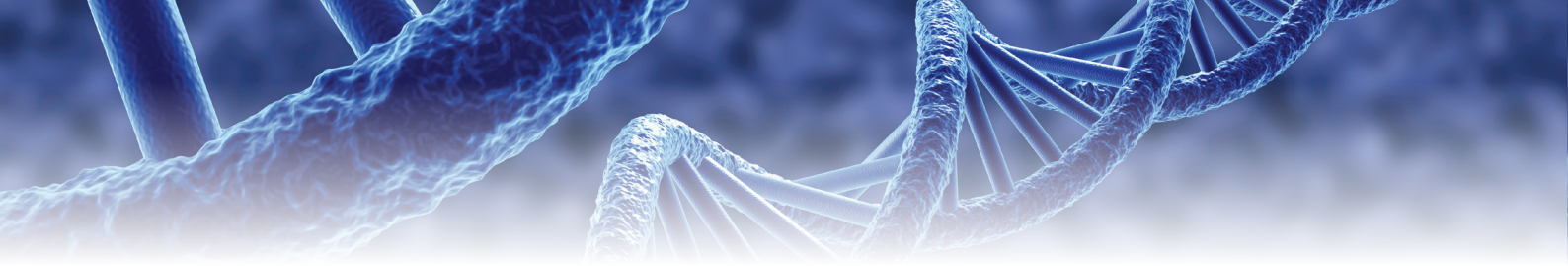
On 25 February 2015, the Federal Court handed down its much-anticipated judgment in the matter of *ACCC v Pfizer Australia Pty Ltd*. In dismissing the Australian Competition and Consumer Commission's (ACCC) allegations, Justice Flick held that Pfizer neither misused its market power, nor engaged in exclusive dealing, in relation to its supply of atorvastatin to pharmacies in Australia. The ACCC has since lodged a Notice of Appeal, publicly stating that the Commission "seeks clarity from the Full Court on issues of market power and anti-competitive purpose."

This update provides a summary of the decision and identifies the key implications for clients, as the life sciences sector encounters increasing regulatory scrutiny of the commercial strategies and practices employed by patent holders confronting the inevitable "patent cliff". Due to the significant public interest issues raised by such conduct, regulators around the world are testing the legal boundaries of legitimate competitive conduct when originator manufacturers vigorously.

KEY IMPLICATIONS FOR LIFE SCIENCES SECTOR CLIENTS

The following are the key implications of the decision for life sciences sector clients:

- *ACCC v Pfizer* is the first case in Australia to test the legal boundaries of legitimate competitive conduct when originator manufacturers take steps to remain competitive after patent expiry.
- Unless the decision is overturned on appeal, the result in this case indicates that there is scope for:
 - originator manufacturers to vigorously compete and improve their ability to defend volume and price erosion after losing exclusivity (e.g., rationalising the supply chain, offering rebates and discounts or bundling business products); and
 - generic manufacturers to vigorously compete and effectively position themselves for market entry prior to patent expiry (e.g., offering discounts, product ranges and tailored services, selling below cost during the launch-phase or negotiating bulk sell-ins to coincide with patent expiry).
- When formulating and implementing commercial strategies, businesses should ensure that the reasoning behind decisions and actions of key decision-makers are properly recorded and understood.
- Statements in internal business documents may imply a business' purpose, but they are not conclusive evidence. Negative inferences that may be drawn from internal documents can be defeated by credible oral evidence of actual purpose.
- Competition regulators will continue to closely scrutinise the responses of originator manufacturers to the threat of generic competition. There are now several decisions, across multiple jurisdictions, considering the application of competition law to the life sciences sector.
- There is still a material risk that commercial strategies designed to deter, prevent or delay the entry of generic competitors (for example, "pay-for-delay" and "product hopping" arrangements) will result in an investigation and may attract allegations of anticompetitive conduct. Comprehensive legal advice should be sought prior to engaging in conduct of this kind.
- In Australia, the ACCC has released its Compliance and Enforcement Policy for 2015. Competition and consumer issues in the "health and medical sector" are an on-going priority for the ACCC.



PATENT CLIFF: THE CATALYST FOR PFIZER'S CONDUCT

Pfizer needs no introduction. Headquartered in New York and listed on the New York Stock Exchange, Pfizer is a major manufacturer and supplier of pharmaceutical products in Australia.

The product at the heart of the matter is the world's best-selling drug of all time, marketed and sold by Pfizer under the trade name *Lipitor* (see *Figure 1*). The molecule, *atorvastatin*, blocks an enzyme in the liver, which the human body uses to make cholesterol, resulting in lower levels of cholesterol.

Figure 1



The patent over the molecule, ultimately owned by Pfizer, was in effect from 18 May 1987 to 18 May 2012 (an extended patent term of 25 years). However, as a consequence of settling a patent dispute, Ranbaxy (a generic manufacturer) was able to enter the market in February 2012, three months prior to patent expiry. Once the patent expired in May 2012, other generic manufacturers were then legally entitled to supply generic atorvastatin products in Australia.

For several years leading up to the loss of patent protection, Lipitor was the highest-selling prescription medicine (in terms of both volume and monetary value) subsidised under the Pharmaceutical Benefits Scheme in Australia. Therefore, the threat of impending generic competition faced by Pfizer cannot be overstated: in 2009, the company forecast that, after the patent expired, the value of sales of Lipitor would fall from \$771 million to \$70 million by 2015. Compounding that commercial reality was the fact that Pfizer also anticipated an abrupt decline in revenue from other pharmaceuticals products (such as the blockbuster Celebrex) because a number of its patents were coming to an end.

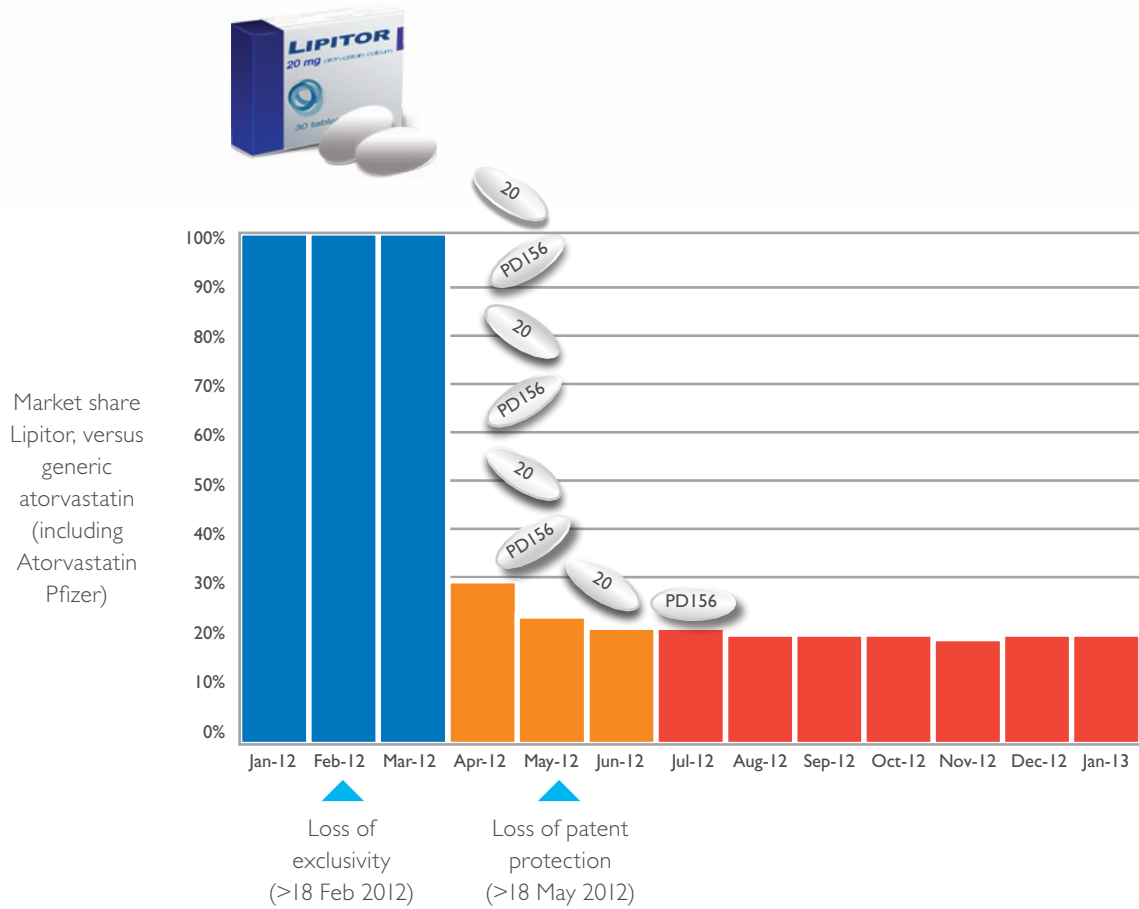
The phenomenon of patent expiry, and the dramatic loss of market share and sales to generic competitors, is (aptly) referred to in the sector as a “patent cliff.” How to effectively respond to the inevitable patent cliff represents one of the most critical strategic decisions in the life cycle of a pharmaceutical product (see *Figure 2*). This is true for both originator manufacturers (to protect an incumbent position) and generic manufacturers (to enter the market). However, since the conduct of originator manufacturers may affect the entry of generic manufacturers into the market, complex competition issues arise for careful consideration.

Figure 2



Anticipating the “patent cliff” in respect of atorvastatin, Pfizer began manufacturing its own generic version of atorvastatin, *Atorvastatin Pfizer*. This generic alternative was to be sold alongside, and as an alternative to, branded Lipitor. After receiving strategic advice from a business consultancy firm, Pfizer decided on, and ultimately implemented, a number of commercial steps in response to the threat of competition from generic manufacturers. These steps formed the components of a commercial strategy known internally as “Project LEAP.” Although Project LEAP made it harder for generic manufacturers to compete with Lipitor and *Atorvastatin Pfizer*, Pfizer’s loss of exclusivity over the commercial exploitation of the atorvastatin molecule nevertheless had a substantial impact on Lipitor’s market share and sales revenue (see *Figures 3*):

Figure 3



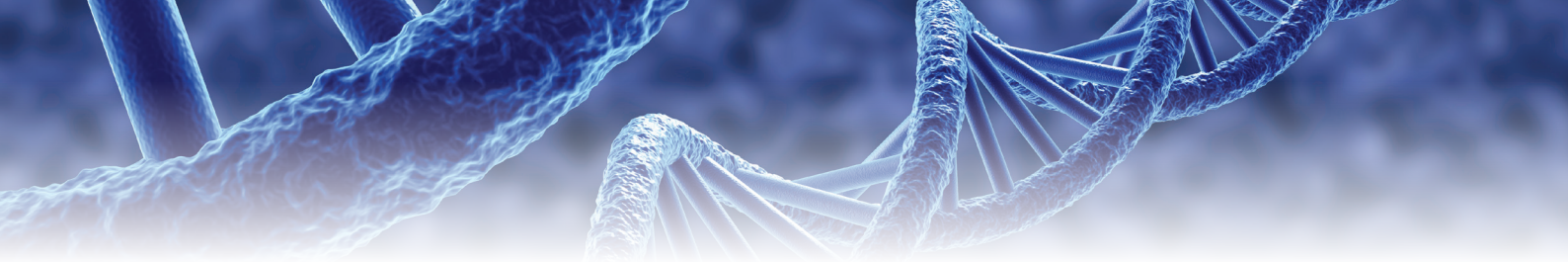
In 2014, the ACCC brought proceedings against Pfizer, claiming that its conduct in implementing Project LEAP contravened the provisions of the *Competition and Consumer Act 2010* (Cth) (CCA) prohibiting the misuse of market power and exclusive dealing. Specifically, the ACCC claimed that Pfizer:

- had a substantial degree of market power in the relevant market, and took advantage of that power for a purpose proscribed by section 46(1)(c) of the CCA (First Claim); and
- engaged in a course of exclusive dealing, pursuant to sections 47(1)(d) and (e) of the CCA, for the proscribed purpose of substantially lessening competition in the relevant market (Second Claim).

In respect of Pfizer’s conduct, Flick J framed the dispute between the parties:

- the real dispute was confined to whether the facts (that is, Pfizer’s conduct in the circumstances) fell within the relevant provisions of the CCA. Unlike other competition law cases, there was no real dispute as to the meaning and ambit of the relevant provisions; and
- the objective facts flowing from Pfizer’s conduct, and the inferences that may have been drawn from the documents circulating internally within Pfizer (if accepted by the Court), may well have supported a finding that Pfizer’s purpose, and hence its conduct, was anti-competitive.

It is therefore vitally important to understand Pfizer’s conduct and the reasons why the Court ultimately dismissed the ACCC’s claims of anti-competitive conduct. These issues are examined in detail on the following pages.



PROJECT LEAP: THE IMPUGNED CONDUCT

In 2009, Pfizer had little experience in marketing and supplying generic medicines. It is common knowledge that, historically, the company focussed on exploiting patented drugs and researching and developing new prescription medicines.

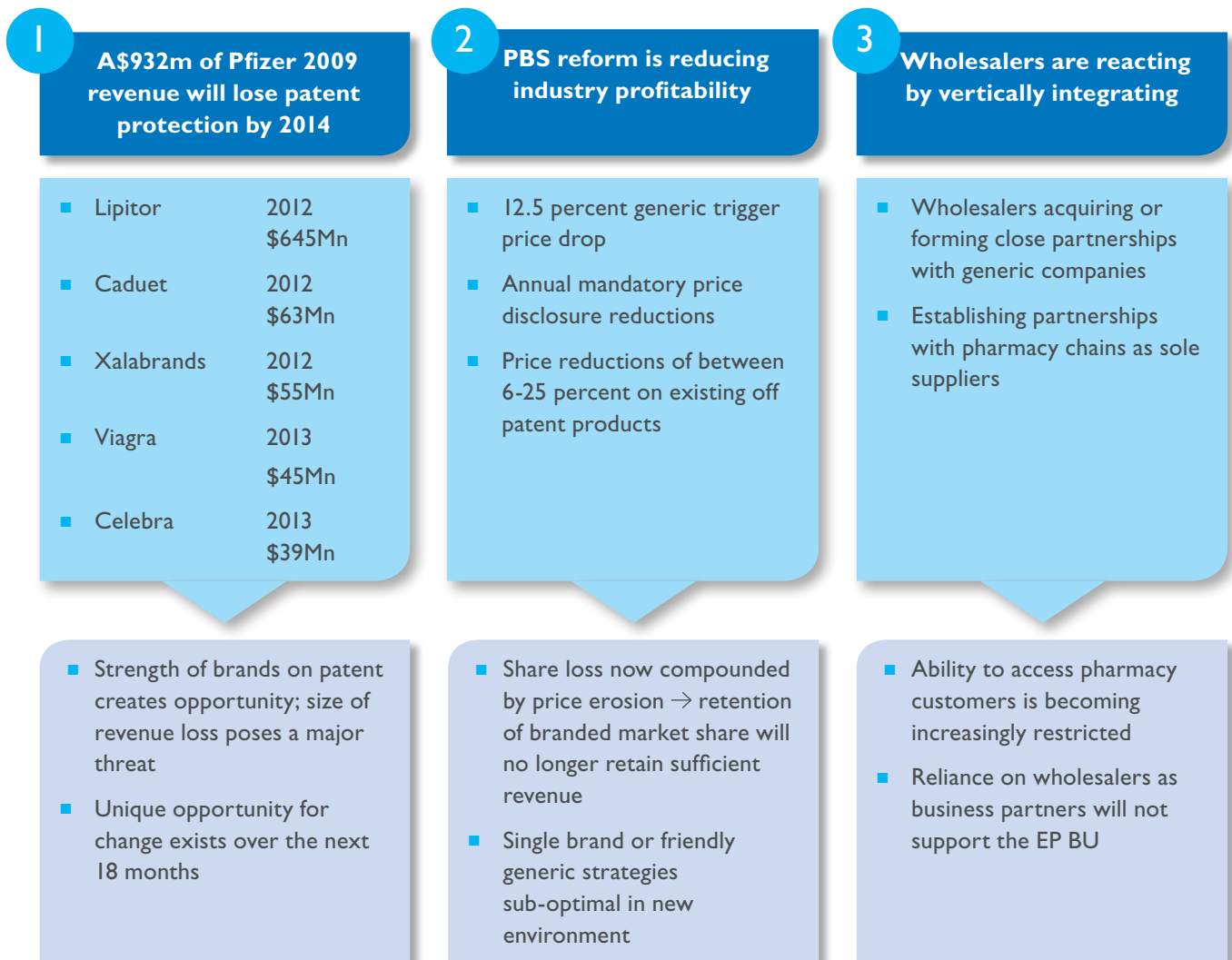
However, the impending expiry of several valuable patents forced Pfizer to formulate its best strategy for remaining competitive after the loss of exclusivity and entrance of major generic competitors. To that end, Pfizer acquired strategic advice from Sinapse, a consultancy firm with practical experience in retail pharmacy supply chains and direct distribution.

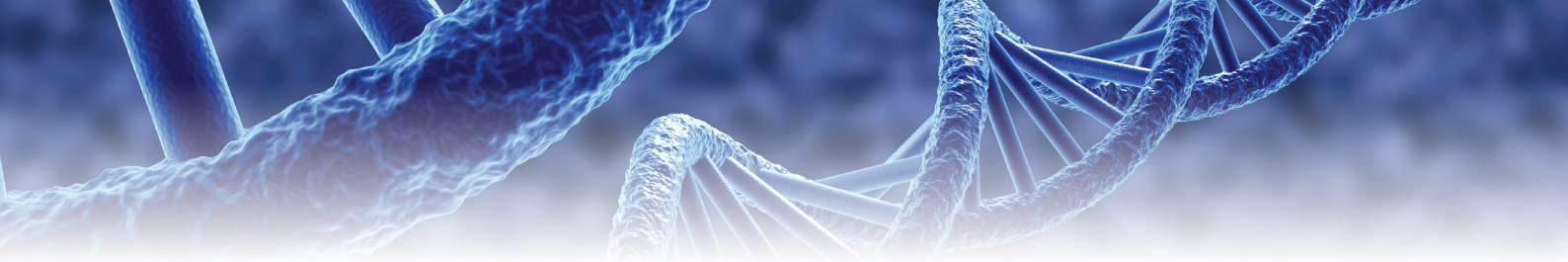
Sinapse identified Pfizer's "three key drivers for change", which are set out in a document tendered as evidence during the hearing (see *Figure 4*):

Figure 4

RECAP: THREE KEY DRIVERS FOR CHANGE

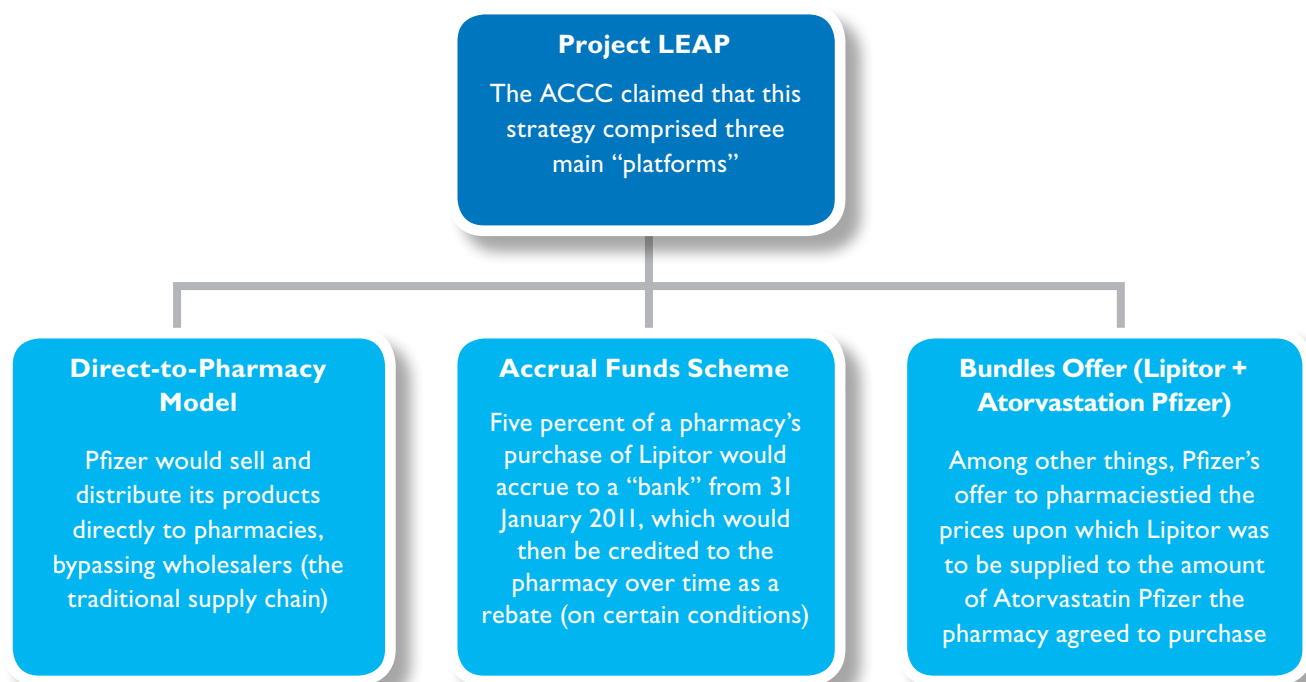
Equal measures of threat and opportunity





Pfizer's plan to combat these changes in the marketplace was Project LEAP, which received final approval on 14 July 2010. The ACCC claimed that Project LEAP, as approved by Pfizer, involved three major 'platforms' (see Figure 5), the "cumulative" operation of which raised competition concerns.

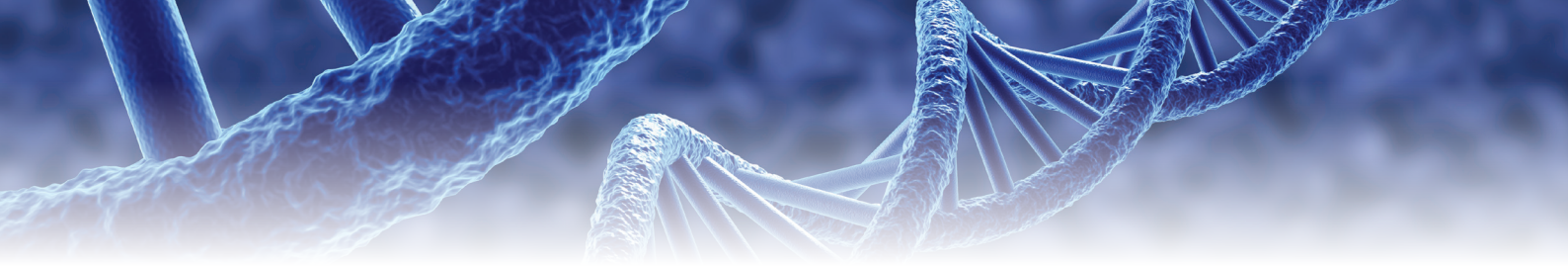
Figure 5



Importantly, only Pfizer could supply both branded and generic atorvastatin (as a "bundle") to pharmacies. In this regard, Pfizer's position was "unique" and it was that unique position that Pfizer decided to leverage. If successful, Pfizer envisaged that it would gain a commercial advantage over generic manufacturers *prior* to the loss of exclusivity. The efficacy of Pfizer's strategy depended on tying financial incentives to a bulk "sell-in" of Atorvastatin Pfizer into community pharmacies (i.e. 75 percent of the pharmacy's anticipated supply requirements of generic atorvastatin over six, nine or 12 months). The offers made to community pharmacies in January 2012 were categorised as Silver, Gold and Platinum, respectively, depending on:

- the duration of the atorvastatin supply contract; and
- the percentage of atorvastatin sales constituted by Atorvastatin Pfizer.

Several internal Pfizer documents made reference to "blocking" competition from generic manufacturers by offering the Lipitor/Atorvastatin Pfizer bundle to pharmacies in January 2012. The ACCC's anti-competitive conduct case focussed primarily on the language used to express Pfizer's objective within such documents, and changes to the structure and implementation of Project LEAP over time.



THE FIRST CLAIM: MISUSE OF MARKET POWER

Summary

To succeed in respect of its First Claim, the ACCC needed to prove that:

- Pfizer had power in a market;
- that market power was substantial;
- Pfizer took advantage of that market power; and
- Pfizer took advantage of that power for a proscribed purpose (and that purpose was a substantial purpose).

In dismissing the First Claim, the Court held that:

- the relevant market was the Australia-wide market for the supply of atorvastatin to, and acquisition of atorvastatin by, community pharmacies (the reference to atorvastatin including both branded and generic versions);
- until late 2011, Pfizer had a substantial degree of market power in that market, but no longer maintained a substantial degree of market power from January 2012;
- Pfizer took advantage of:
 - its substantial market power until late 2011, by distributing its products through the Direct-to-Pharmacy Model and establishing the Accrual Funds Scheme, and
 - its limited market power from January 2012, by making its offers to community pharmacies; however,
- despite the above findings, Pfizer did *not* engage in conduct for the proscribed purpose of “detering or preventing a person from engaging in competitive conduct in that or any other market.”

These findings are examined in more detail below.

The Australia-wide atorvastatin market

The geographic dimension of the market was not in dispute: the parties agreed that any market was Australia-wide. Rather, the dispute concerned how the “market” should otherwise be defined, and over what period of time. The divergent expert evidence assisted the Court in resolving this issue.

Pfizer unsuccessfully contended that there was “a market for the wholesale supply of pharmaceutical products and over-the-counter products to Community Pharmacies.” The fact that atorvastatin had long been offered as part of a range of other products did not detract from the conclusion that atorvastatin formed its own market prior to mid-2012.

The Court held that “many facts dictate the conclusion that the ‘market’ is the market for atorvastatin as identified by the ACCC.” The main reason identified was that, irrespective of how a “range” of pharmaceutical products was purchased from generic manufacturers and/or pharmaceutical wholesalers, the fact remains that a prescription for atorvastatin issued by a medical practitioner cannot be “filled” by the supply of any other product. In economic terms, at all relevant times, there was neither demand-side substitution nor supply-side substitution for atorvastatin.

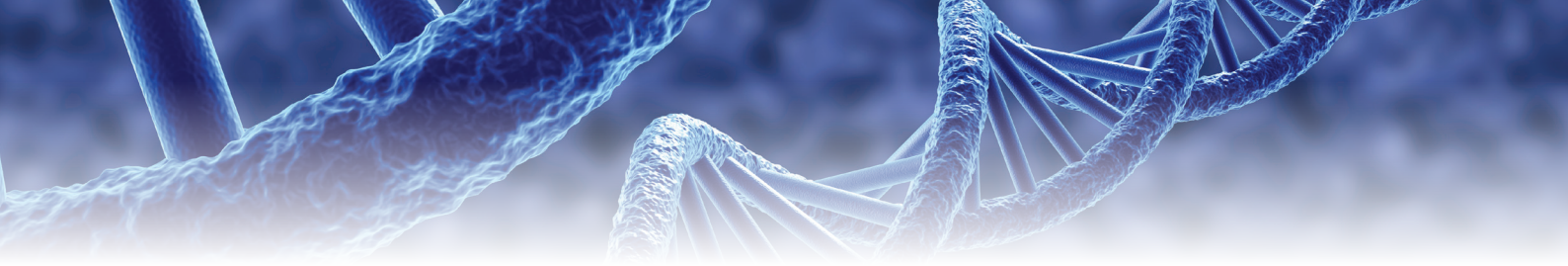
In addition, Flick J found that, within the industry, “atorvastatin was being seen to be – and being marketed as – a separate pharmaceutical product in its own right for which there was no substitute throughout the period in question.” As such, the relevant market was held to be the Australia-wide market for the supply of atorvastatin to, and acquisition of atorvastatin by, community pharmacies.

Whilst the Court recognised that the dimensions of a market may change over time and that the defined market may well have been in a state of flux between January/February and May/June 2012, it was nonetheless concluded that the dimensions of that “market” had not changed by mid-2012. The Court did not need to consider whether the marketing and supply of atorvastatin after May 2012 would lend support to a different definition of the market. As Flick J concluded on this point, “Whether atorvastatin has, for example, now entered a more generalised ‘wholesale market’ may be a question for another day.”

Pfizer possessed substantial market power

In assessing the extent or degree of market power possessed by Pfizer, the Court held that the conclusion depended on the period of time being considered.

In respect of the period *prior to late-2011*, Flick J held that “no conclusion is open other than that Pfizer possessed both ‘market power’ and that such power as it possessed was truly “substantial”... Pfizer had long been the sole supplier of atorvastatin.” The limited degree of regulation



by virtue of being subsidised under the Pharmaceutical Benefits Scheme was deemed insufficient to detract from the conclusion that Pfizer possessed substantial market power.

However, Pfizer's market power diminished with the passage of time. By 2010, several established generic manufacturers were planning their future sale of atorvastatin. In colourful terms, the Flick J described such plans as "circling the prey from an early date." As the expiry date approached, Pfizer's market power gradually decreased. This was primarily due to the significant influence that established generic manufacturers could exert over the market. On that view, the Court concluded that, *from January 2012*, the market power Pfizer retained could no longer be described as "substantial." That being said, the Court did not endeavour to identify a "clear or definitive point of time at which Pfizer's market power ceased to be *substantial*."

Pfizer took advantage of its market power

When its Direct-to-Pharmacy Model was implemented, Pfizer had a substantial degree of market power and took advantage of that market power in order to bypass wholesalers and supply directly to community pharmacies. Justice Flick held that, unquestionably, "the Direct-to-Pharmacy Model could not have been successfully implemented by Pfizer without the position it occupied as the sole supplier of atorvastatin prior to 19 February 2012." On the facts, the pharmacies received Pfizer's strategy unfavourably; however, they had no option other than to continue acquiring atorvastatin from Pfizer prior to the loss of exclusivity. In addition, although Ranbaxy could supply generic atorvastatin from March 2012, this alternative source of supply didn't become available under the Pharmaceutical Benefits Scheme until 1 April 2012.

The court then directed its attention to Pfizer's Accrual Funds Scheme. When Pfizer made its offer to pharmacies, the terms upon which a pharmacist could access its accruing rebate were not clear. "Notwithstanding the uncertainty as to the precise terms upon which a pharmacist could access its 'rebate' until January 2012," Flick J held, "it is nevertheless concluded that Pfizer took advantage of its market power in establishing the *Accrual Funds Scheme* in January 2011." Importantly, offering a rebate does not, on its own, involve nor require the taking advantage

of market power. Rebates and discounts are a common strategy in the pharmaceutical industry. In fact, offering financial incentives of this kind was a strategy open to any other manufacturer of pharmaceutical products. However, two facts weighed against Pfizer:

- Pfizer was able to implement the Accrual Funds Scheme without providing community pharmacies with any certainty as to how or when the accruing rebates were to be accessible; and
- even if pharmacies had accrued significant rebates in their "banks", their ability to access such rebates was linked to a commitment to purchase Atorvastatin Pfizer.

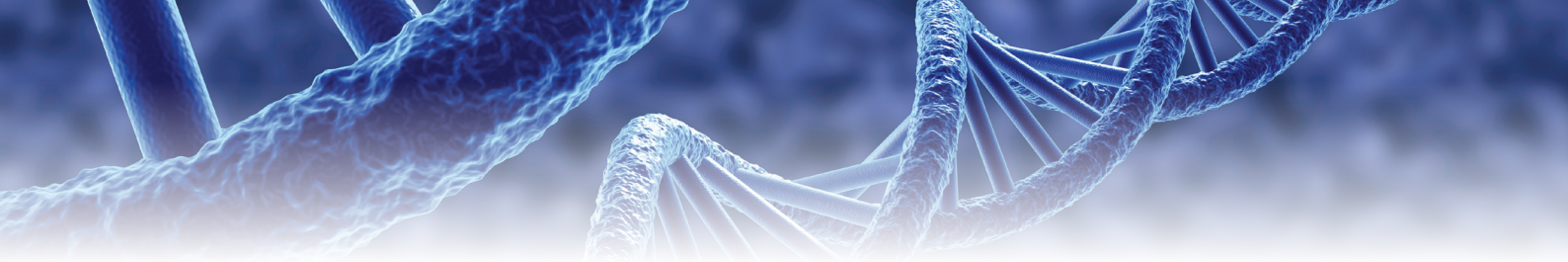
In the Court's view, Pfizer "was throughout 2011... developing the manner in which it could best take advantage of that [market] power in securing the greatest commitment of pharmacies to purchase its generic atorvastatin."

It was unnecessary to decide whether Pfizer took advantage of its market power in making its offers to community pharmacies in January 2012. The Court had already concluded that Pfizer did not possess a substantial degree of market power at that time. Notwithstanding that, Flick J expressed the view that, on the evidence, Pfizer's offers when first made did not involve the taking advantage of any market power that Pfizer may have retained as at January 2012. It was inconsequential that Pfizer may have been selling Atorvastatin Pfizer below cost. If it were, such conduct was during the launch phase of its generic product and only in the short-term.

Project LEAP was not implemented for a proscribed purpose

The ACCC failed to establish that Pfizer took advantage of its market power for the proscribed purpose of deterring or preventing a person from engaging in competitive conduct (section 46(1)(c) of the CCA).

Justice Flick candidly acknowledged that "it was plainly open to contend that Pfizer's conduct was undertaken for the purpose of 'deterring' the entry of other generic manufacturers – and for the purpose of 'deterring' the entry of other generic manufacturers for as long a period of time as possible." Pfizer admitted that its conduct incentivised pharmacies to accept its offers.



However, several factors weighed against the finding that Pfizer implemented Project LEAP for an anti-competitive purpose. In particular:

- a substantial purpose of Project LEAP was to ensure that Pfizer remained a supplier of pharmaceutical products in Australia, including both Lipitor and Atorvastatin Pfizer; and
- a substantial purpose of Project LEAP was to ensure that Pfizer remained competitive in the Australia-wide atorvastatin market.

On the evidence – attributing considerable weight to the credible testimony of Pfizer’s witnesses – the Court expressly rejected the ACCC’s allegations that Pfizer purpose was to deter or prevent generic manufacturers from engaging in competitive conduct or, more broadly, “block” competition in the atorvastatin market. An attempt to do so, Flick J appreciated, would have been “commercially naive.”

The colourful language in Pfizer’s internal documents (“blocking” competition), at the very least, provided a platform for an adverse inference to be drawn about

the purpose being pursued by Pfizer. However, the language in internal documents needed to be understood in its context. In all the circumstances, the evidence showed that Pfizer took the steps it did to avoid being “slaughtered” by generic competitors and to remain a viable competitor in the atorvastatin market into the future. As Mr Crotty of Pfizer explained, “Our strategy was we knew – when you have 100 per cent of a market because you’re patent protected, there’s only [one] way to go, down, and our strategy was to manage that market share erosion as best we could.”

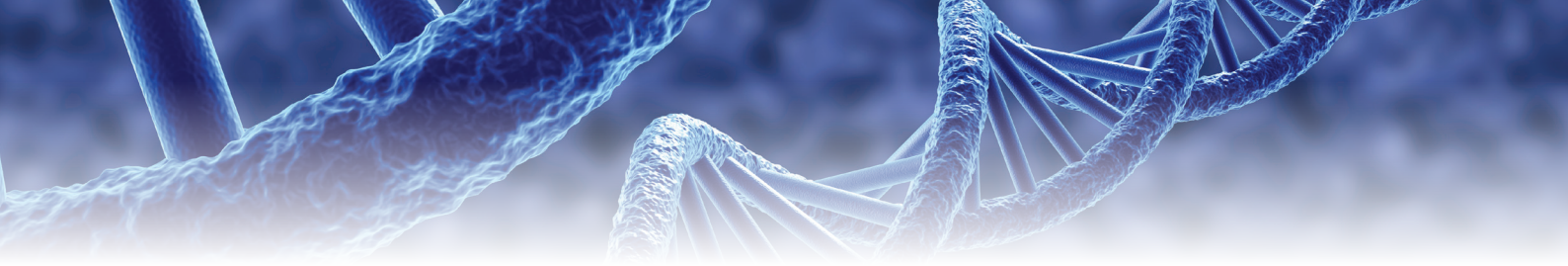
Even if the ACCC had persuaded the Court that Pfizer’s desire to gain a commercial advantage prior to the loss of exclusivity or render it more difficult for generic manufacturers to successfully enter the market fell within the ambit of section 46(1)(c), such a purpose would not have been a “substantial” purpose of Pfizer’s conduct.

In the absence of a substantial anti-competitive purpose, the ACCC’s First Claim was dismissed.

KEY TAKEAWAYS

- Strategies undertaken by originator manufacturers to seek to defend volume and price erosion after losing exclusivity (e.g., offering rebates and discounts to suppliers or bundling products) may not contravene section 46 of the CCA where it is clear that their purpose is not to deter or prevent generic manufacturers from engaging in competitive conduct, but rather to ensure the originator manufacturer remains competitive.
- When formulating and implementing commercial strategies, businesses should ensure that the purpose for those strategies is accurately recorded in documents.
- It may be more difficult for the ACCC to establish that an originator manufacturer has breached section 46 through its strategies to defend volume and price erosion where there is evidence of a significant erosion of the originator manufacturer’s market share following generic entry.





THE SECOND CLAIM: EXCLUSIVE DEALING

Summary

To succeed, the ACCC needed to prove that:

- Pfizer supplied/offered to supply its products or services on one or more of the *conditions* set out in section 47(2) of the CCA;¹ and
- the conditional supply/offer to supply was for the proscribed *purpose* of substantially lessening competition in the relevant market.²

In dismissing the Second Claim, the Court held that:

- as for the First Claim, the relevant market is the Australia-wide market for the supply of atorvastatin to, and acquisition of atorvastatin by, community pharmacies;
- only one relevant condition existed, which was admitted by Pfizer, being a condition found within the form completed by community pharmacies in accepting a Pfizer offer; however,
- despite the above findings, Pfizer did *not* engage in conduct for the proscribed purpose of “substantially lessening competition.”

These findings are discussed in more detail below.

Supply/offer to supply on “condition”

Importantly, the ACCC alleged that there were three “conditions” that fell within the ambit of section 47 of the CCA.

Pfizer admitted that it offered discounts on the condition that Community Pharmacies would not, except to a limited extent, acquire or re-supply atorvastatin from a generic manufacturer. For example, Pfizer’s Platinum Offer provided that, to be eligible for specified discounts, “you must comply with purchasing & dispensing at least 75 percent of your generic Atorvastatin requirements from Pfizer.” In the acceptance form, Pfizer expressly represented that ‘Lipitor discounts are subject to first line support of Atorvastatin Pfizer – at least 75 percent of your total generic atorvastatin volumes dispensed must be Atorvastatin Pfizer... If you do not meet

this requirement, your Lipitor discount will revert to 1.5 percent. The Court accepted that this “condition” fell within the ambit of section 47 of the CCA.

However, the alternative conditions pleaded by the ACCC were not accepted. Pfizer contended that:

- community pharmacies remained free to purchase atorvastatin from generic manufacturers; and
- the fact that pharmacists were less likely to buy as much atorvastatin from generic manufacturers as they would have, but for accepting an offer from Pfizer, did not prove that Pfizer engaged in exclusive dealing.

The alternative conditions may have had the effect or practical consequence that pharmacies were dissuaded from purchasing generic atorvastatin from a supplier other than Pfizer. However, no “condition” was imposed on pharmacies that inhibited their freedom to acquire generic atorvastatin from other suppliers.

For the purpose of substantially lessening competition

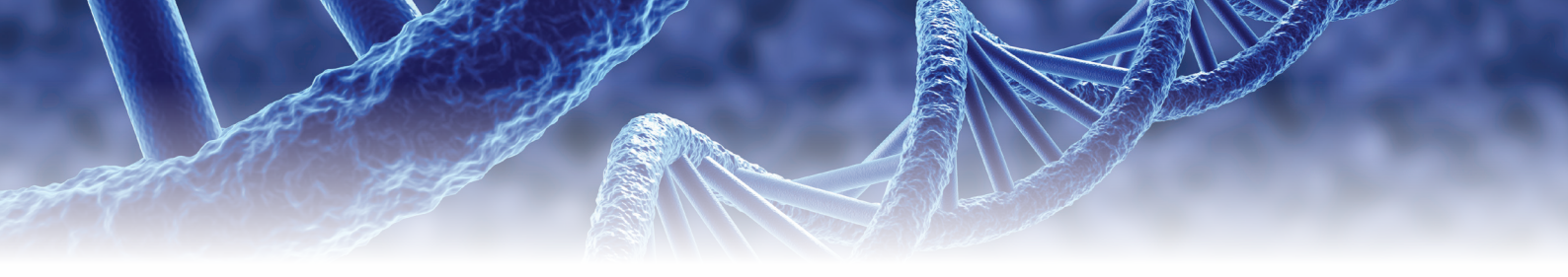
Having accepted that Pfizer supplied, or offered to supply, Lipitor and Atorvastatin Pfizer on “condition”, the Court again considered whether Pfizer did so for an anti-competitive purpose. Here, the ACCC alleged that Pfizer had the purpose of “substantially lessening competition” in the atorvastatin market.

Pfizer contended that the ACCC had not established that its purpose was to cause a substantial lessening of competition, having failed to “direct any real attention to the likely state of future competition in the market ‘with and without’ Pfizer’s impugned conduct.” Pfizer adduced credible evidence that the purpose of imposing the relevant condition was “to ensure its own corporate *survival*.” Such evidence was not displaced by the ACCC at trial. The Court therefore concluded that “It was no part of the ‘purpose’ of Pfizer in imposing this condition to substantially lessen competition.”

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¹ The ACCC’s pleadings were limited to paragraphs 47(2)(d), (e) and (f) of the CCA.

² The ACCC’s pleadings were limited to the “purpose”, rather than the “effect” or “likely effect”, of Pfizer’s supply/offer to supply to pharmacies.



For the purpose of substantially lessening competition

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Pfizer contended that the ACCC had not established that its purpose was to cause a substantial lessening of competition, having failed to “direct any real attention to the likely state of future competition in the market ‘with and without’ Pfizer’s impugned conduct.” Pfizer adduced credible evidence that the purpose of imposing the relevant condition was “to ensure its own corporate *survival*.” Such evidence was not displaced by the ACCC at trial. The Court therefore concluded that “It was no part of the ‘purpose’ of Pfizer in imposing this condition to substantially lessen competition.”

In the absence of a substantial anti-competitive purpose, the ACCC’s Second Claim was dismissed.

KEY TAKEAWAYS

- Originator manufacturers may not breach section 47 of the CCA by offering discounts or rebates on the supply of their products on the condition that the acquirer does not, or does not except to a limited extent, acquire or re-supply a generic product where they do not have the purpose of substantially lessening competition in a market, and the conduct does not have that effect or likely effect.
- In this case, Pfizer’s purpose was to remain competitive and maximise sales of its products and it did not have a purpose of substantially lessening competition. The ACCC did not allege that Pfizer’s conduct had the effect of substantially lessening competition.

FURTHER CONSIDERATIONS

Harper Review and proposed amendments to section 46

One of the most significant competition law reforms recommended by the Harper Review concerns section 46 of the CCA. Among other things, the Harper Review recommends that amend section 46 be amended to capture conduct with the purpose, effect or likely effect of substantially lessening competition. The push to reform section 46 comes after several high-profile cases involving misuse of market power have gone against the ACCC. This case provides yet another example and there is another case currently before the Federal Court (*ACCC v Visa*). However, unlike several earlier cases, where the ACCC encountered difficulties in proving that a corporation had “taken advantage” of its market power, *ACCC v Pfizer* fell over at the “purpose” stage. Interestingly, even under the new section 46 recommended by the Harper Review, the ACCC’s case would probably have failed for want of an anticompetitive purpose. In respect of its Second Claim, the ACCC did not plead an anticompetitive “effect” or “likely effect” – only purpose. Nonetheless, the result in *ACCC v Pfizer* (and the impugned conduct) may lend momentum to the reform campaign.

The Harper Review is also recommending the removal of the “IP licences” defence in section 51(3) relied on by Pfizer. Pfizer contended that the supply of atorvastatin to pharmacies granted a licence to the atorvastatin patent and therefore the exemption applied to excuse conduct that otherwise would breach section 47 of the CCA. Given that the Court concluded that the ACCC did not make out its Second Claim, it became unnecessary to consider the IP licences defence. However, the Court held that, had it been necessary to resolve the issue, it would have rejected Pfizer’s argument because:

- Pfizer’s supply of atorvastatin to pharmacies would not involve the granting of any “licence” at law; and
- even if the “condition” upon which Pfizer supplied atorvastatin had been contained within a licence, it would not have constituted a “condition” to which section 51(3) applies. Instead, the relevant “condition” was sought to gain “advantages collateral to the patent.”



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