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Refusals to License Patents under Australia's "New" Unilateral Conduct Prohibition

*By Arlen Duke & Rhonda L. Smith**

(University of Melbourne)

Edited by Barbora Jedlickova (University of Queensland)

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Both intellectual property ("IP") and competition policies aim to provide an incentive for creation/innovation. However, given the different approach of each policy, it is unsurprising that there may be tension between them. Refusals to license IP rights highlight this tension. While such a refusal may lessen competition in downstream markets (in that it prevents the entry of generic manufacturers), by their nature, patents give the owner the right to exclude. Prior to late 2017, firms with substantial market power were prohibited from "taking advantage" of their power for one of three prescribed purposes. The now repealed "take advantage" allowed the courts to take account of intellectual property policy when considering whether or not a refusal to license IP breached Australian competition laws. However, relatively recent changes mean that the courts can no longer do so. Now, a firm with substantial market power will breach competition laws if it engages in conduct (of any kind) that has the purpose, or has or is likely to have the effect, of substantially lessen competition in a market in which the firm possesses substantial market power, a market in which the firm supplies, or is likely to supply, goods or services, or a market in which the firm acquires or is likely to acquire goods or services. IP policies can now only be considered under the exemption processes administered by Australia's competition regulator, the Australian Competition and Consumer Commission ("ACCC").

A refusal to license a patent will not breach competition laws if the owner does not possess substantial market power. The decision of the Full Court of the Federal Court of Australia's decision in *Australian Competition and Consumer Commission v. Pfizer Australia Pty Ltd.*[1] provides guidance as to when a patent holder may be held to possess substantial market power. It suggests that the owner of a "blockbuster" patent is likely to be held to possess substantial market power, even in the lead up to patent expiry. Pfizer sells a pharmaceutical product known as Lipitor. The active ingredient in Lipitor is atorvastatin. Atorvastatin blocks an enzyme in the liver which the human body uses to make cholesterol and so lowers cholesterol levels.[2] From about the mid-1990s to 2012, Lipitor became the biggest-selling drug in the world.[3] For each of the financial years ending in June 2010 through to June 2012, atorvastatin was the highest selling prescription pharmaceutical product in Australia, with sales exceeding $700 million in each year.[4]

Pfizer's patent for atorvastatin expired on May 18, 2012. After this date, intense competition from generic manufacturers was inevitable.[5] Further, generic pharmaceutical manufacturers were planning the development of the generic products well before the impending patent expiry.[6] To make good its claim that Australia's unilateral conduct prohibition had been breached the ACCC needed to establish that Pfizer possessed substantial market power at the time of the challenged conduct,[7] that is, in January 2011 and in the early months of 2012. The ACCC argued that Pfizer possessed substantial market power at the time of the impugned conduct because until its expiry on May 18, 2012, the patent acted as a barrier to entry. Pfizer, on the other hand, argued that its market power gradually diminished prior to this date and that it did not have substantial market power in the first half of 2012.[8]

The grant of a patent over an originator molecule by no means confers substantial market power on its owner. Intellectual property rights give the owner the right to exclude, not an economic monopoly. As Morse has noted, "[w]hether or not a patent confers monopoly power depends on the availability of substitutes."[9] There is often "dynamic competition between multiple, differentiated, patent protected originator molecules."[10] However there was no such dynamic competition in this instance, and it was thus not contentious that Pfizer had

substantial market power in early 2011. This conclusion flows from the fact that the market was defined (correctly in authors' opinion) as limited to atorvastatin.

As the date for a patent to expire approaches, the market power that it confers begins to diminish. This is because market power derives not just from a lack of actual competitors, it also derives from a lack of potential competitors. The trial judge, Flick J, recognized that these potential competitors begin to appear as the expiry date approaches and that, even on the day on which the patent expires, not all market power is extinguished. Leave aside for the present action by the patentee to preserve its power, the strength of its brand, its reputation and its relationship with prescribing physicians may well continue to confer some market power after expiry.

Flick J rightly noted that there is "no clear or definitive point of time at which Pfizer's market power ceased to be '*substantial*.'"[11] His Honour found that "Pfizer maintained some degree of market power up to May 2012,"[12] but concluded that from January 2012 Pfizer's market power was no longer substantial.[13] This was because Ranbaxy (a generic competitor) was able to market and supply atorvastatin as from February 19, 2012[14] (as a result of being issued a license by Pfizer as part of a settlement agreement arising out of unrelated proceedings).[15] Flick J was of the view that this "alone had the potential to significantly diminish the market power once held by Pfizer."[16] Pfizer's power was held to have diminished further because between January and May 2012 "a number of generic manufacturers had listed their impending atorvastatin products on the Australian Register of Therapeutic Goods"[17] and because major generic manufacturers were holding discussions with key customers in early 2012.[18]

On appeal, the Full Court recognized that the key issue was not whether Pfizer's power had diminished, but rather when it could no longer be regarded as substantial in early 2012. The Full Court reached a different conclusion to Flick J, noting that:

> an important indicator of substantial market power as at January and February 2012 is the fact that Pfizer was able to introduce into the atorvastatin market its own generic atorvastatin by means of the bundled offers at the time and in the manner which gave it a significant commercial advantage over its potential future competitors, even if only for a short time…By making the bundled offers which it did on or about 16 January 2012, Pfizer exploited its then existing dominant position in the atorvastatin market to establish from April 2012 a strong foothold in that market for the supply of generic atorvastatin.[19]

Given this, the Full Court concluded that "[i]n January and February 2012 Pfizer was not yet constrained in its behavior to any significant extent by the future inevitable competition"[20] resulting from the impending expiry of its patent. It remained the only possible source of supply until March 18, 2012 (when Ranbaxy started distributing a generic atorvastatin product). The Full Court did not accept, as had been accepted at trial, that future entry increased the bargaining strength of Pfizer's pharmacy customers, enabling them to game the market.[21] Further, the Full Court observed that during the relevant period, Pfizer continued to supply Lipitor at prices previously achieved which some regarded as supra-competitive prices, made possible by the significant market power Pfizer possessed during that period.[22] This finding is consistent with research undertaken by the European Commission, namely that the price the owner of a "blockbuster" patent is able to charge not impacted until the patent expires.[23]

Nevertheless, until the Australian unilateral conduct prohibition was amended in 2017, a refusal to license a "blockbuster" patent was unlikely to breach Australian competition laws. Prior to the 2017 amendments, only certain forms of conduct engaged in by a firm with substantial market power were caught, namely conduct that amounted to a "taking advantage" of market power. A firm with substantial market power "takes advantage" of such power when it engages in conduct that it would not be likely to engage in if it did not possess such power. A refusal would not involve the proscribed "taking advantage." Thus, the taking advantage test required the courts to consider the business rationale for the decision and allowed the courts to determine whether the IP owner was illegitimately seeking advantages collateral to the IP grant, such as leveraging any power the IP creates into a second market. Since the owner of an IP right without market power is objectively justified in refusing to license it, a refusal to license, even if by an IP right holder with substantial market power, would not breach competition law provided the IP right holder was not attempting to extend the IP grant.

As noted earlier, significant amendments were made to the unilateral conduct prohibition on November 6, 2017.[24] Now, firms that possess market power will breach the prohibition if they engage in conduct (of any kind) that has the purpose, or has or is likely to have the effect, of substantially lessen competition in a market in which the firm possesses substantial market power, a market in which the firm supplies, or is likely to supply, goods or services, or a market in which the firm acquires or is likely to acquire goods or services. The replacement of the "take advantage" requirement with the "competition test" extends the reach of the unilateral conduct prohibition and renders the scope of the grant, and the incentives for innovation created by the granting of IP rights, irrelevant to the question of whether or not a refusal to license involves a breach of the unilateral conduct prohibition.

Imagine the following scenario, a holder of a patent for a "blockbuster" pharmaceutical product for which there are no substitutes, does nothing more than refuse, during the patent term, to license a generic manufacturer who wishes to manufacture a generic version in competition with the patent owner. Under the "take advantage" approach, the fact that the patent owner was doing nothing more than excluding a party who wished to compete in the same market as the patent holder meant that such a refusal was unlikely to contravene competition law. Even patent holders who do not possess substantial market power often refuse to license others so that they can exploit the patent themselves. However, under the "competition test" that now applies, the court does not ask this question. Rather, it asks if the refusal has the purpose, effect or likely effect of substantially lessening competition. Arguably the refusal has this effect. In the "future with" the refusal, the patent holder maintains its monopoly. In the "future without" the market becomes a duopoly, not a monopoly. The competition test limits the extent to which intellectual property policy can be taken into account when determining liability.

So then, how does Australian competition law allow for the consideration of intellectual property policy, and the need to preserve incentives to innovate? In recognition that there may be circumstances in which conduct that would lessen competition may confer a benefit on society, Australia's competition laws allow parties to seek exemption from such laws. On the same day that the unilateral conduct prohibition was amended, two important changes were made to the regime that allows the ACCC to grant exemptions. First, for the first time, it became possible for a party or parties proposing to engage in prohibited conduct to seek authorisation (exemption) from the unilateral conduct prohibition. Second, the ACCC was

given the power to issue class exemptions with respect to particular forms of conduct. Where a class exemption is granted, this removes the need for individual businesses to apply for authorisation in order to lawfully engage in the conduct specified in the class exemption.

As former ACCC Commissioner Jill Walker has explained the exemption regime provides "a framework for trading off the benefits of overcoming market failure with the costs to competition, that is, looking at overall efficiency outcomes of conduct."[25] Under both the authorisation and the class exemption regimes, the question is whether in relation to the conduct in question, public benefits likely to be generated by the conduct under consideration outweigh the public detriments the conduct is likely to cause.[26] The preservation of the incentives to innovate created by IP grants could thus be framed as public benefits, to be offset against any lessening of competition that flows from a refusal to license.

Should a class exemption of sufficient breadth and clarity relating to refusals to license IP be issued by the ACCC, this would overcome concerns that incentives to innovate could be dampened by the possibility that a refusal to license IP would amount to a breach of competition laws. However, there is nothing to suggest that the ACCC has plans to issue a class exemption in relation to refusals to license IP rights.[27] While the option remains for an IP right holder to apply for authorisation, it is important to note that the ACCC has been criticized for "lack of transparency and accountability, for uncertainty in the way it applies the law, and for a commercially unrealistic application of the law"[28] when determining authorisation applications. The authorisation process can also be inflexible. Exemption is only provided to the precise form of conduct specified in the authorisation application. The applicant would need to be specific about the circumstances in which it will refuse to license, and to avoid being held liable for a constructive refusal to deal on the basis that the offer to license was subject to unreasonable conditions, the authorisation application would need to detail such conditions. If the IP right holder replace a condition that has been authorised with a slightly different provision, it will be necessary to apply to vary the authorisation in order for the new condition to be exempt. This is so even where the authorised condition is likely to generate the same level of public benefits and public detriments as the new condition.

[*] Respectively, Senior Lecturer, Melbourne Law School (University of Melbourne); Senior Lecturer, Economics Department (University of Melbourne).

[1] [2018] FCAFC 78 (*Pfizer appeal*).

[2] *Australian Competition and Consumer Commission v Pfizer Australia Pty Ltd* [2015] FCA 113, [3]. (*Pfizer trial*).

[3] *Pfizer appeal* (n 1), [10]. \

[4] *Pfizer trial* (n 2), [110].

[5] *Ibid*. [6], [180].

[6] Apotex Australia Pty Ltd, for example, started planning the development of its generic product five years before the atorvastatin patent was due to expire. *Pfizer trial* (n 2), [124].

[7] For a discussion of the impugned conduct, see Arlen Duke & Rhonda L. Smith, "Protecting Profits Post-Patent Expiry: ACCC v Pfizer," Patents and Competition Law (2019) 30(1) *Australian Intellectual Property Journal* 26.

[8] *Pfizer appeal* (n 1), [78].

[9] M. Howard Morse, "Product Market Definition in the Pharmaceutical Industry," (2003) 71 *Antitrust Law Journal* 663, 674 (see fn 191 for a list of U.S. cases that have accepted this argument).

[10] Patricia M. Danzon, "Competition and Antitrust Issues in the Pharmaceutical Industry," (Final Report, July 2014), 5. Available at: https://faculty.wharton.upenn.edu/wp-content/uploads/2017/06/Competition-and-Antitrust-Issues-in-the-Pharmaceutical-IndustryFinal7.2.14.pdf, 5.

[11] *Pfizer trial* (n 2), [287].

[12] *Ibid*. [286].

[13] *Ibid*. [285]-[286].

[14] *Ibid*. [289].

[15] *Ibid*. [5], [157].

[16] *Ibid*. [289].

[17] *Ibid*. [290]. In fact, some registrations had been made as early as late 2009/early 2010.

[18] *Ibid*.

[19] *Pfizer appeal* (n 1), [353].

[20] *Ibid*. [354].

[21] *Ibid*. [358].

[22] *Ibid*. [349].

[23] European Commission, *Pharmaceutical Sector Inquiry* (Final Report, July 2009) (EC 2009 Report), 78 (figure 21). Available at http://ec.europa.eu/competition/sectors/pharmaceuticals/inquiry/staff_working_paper_part1.pdf.

[24] See *Competition and Consumer Amendment (Misuse of Market Power) Act 2017* (Cth).

[25] Jill Walker, "Developments in Competition Law," (presented at RBB Economics Australian Conference, Sydney, 8 June 2011), 25.

[26] For a discussion of the exemption regimes see: Arlen Duke, *Corones' Competition Law in Australia* (Lawbook Co, 7th ed, 2019), Ch 15.

[27] In fact, almost three years after the ACCC was given the power to issue class exemptions, there are still no class exemptions in place.

[28] Christine Parker & Vibeke Lehmann Nielsen, "What Do Australian Businesses Really Think of the ACCC, and Does it Matter?" (2007) 35(2) Federal Law Review 187, 217. See also Trade Practices Act Review Committee, Review of the Competition Provisions on the Trade Practices Act (Final Report, April 16, 2003) 49.