THE GUIDE TO LIFE SCIENCES

SECOND EDITION

Editors
Ingrid Vandenborre and Caroline Janssens

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Second Edition

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Publisher's Note

The intersection between life sciences innovation and antitrust oversight continues to be a busy and heavily scrutinised area. The past 12 months have seen a particular focus on big deals in the space, especially in the United States, while in Europe it is the issue of pricing – particularly negotiations with health authorities – that remains in the spotlight. As Caroline Janssens and Ingrid Vandenborre point out in their introduction, competition in the biosimilar space is a growing challenge, given that inherent features of such products can make it more difficult for healthy competition to thrive. Product denigration is another key area, with the European Commission having opened two separate investigations in the past year. Practical and timely guidance for both practitioners and enforcers trying to navigate this fast-moving environment is thus critical.

The second edition of the *Guide to Life Sciences* – published by Global Competition Review – provides this detailed analysis. It examines both the current state of law and direction of travel for those jurisdictions with the most impactful life sciences industries. The Guide draws on the expertise and experience of distinguished practitioners globally, and brings together unparalleled proficiency in the field to provide essential guidance on subjects as diverse as merger control and excessive pricing, as well as a forensic examination of the most significant and far-reaching regulations and decisions from around the world.

Introduction

Ingrid Vandenborre and Caroline Janssens[1]

Welcome to the second edition of Global Competition Review's *Guide to Life Sciences*. In the past year, we have seen continued and sustained enforcement activity by antitrust authorities around the world in the life sciences space, with regard to a wide range of practices. Price increases, denigration of rivals' products, and delayed entry of generic and biosimilar medical products continue to attract scrutiny. We have also seen continued scrutiny of large transactions in life sciences, in particular in the United States (US) and in Europe, with a focus on deals' rationale, pipeline products, and the impact of mergers on non-horizontal business relations.

The pricing of medicines, pricing negotiations with health authorities, supply practices and unfair pricing remain an enforcement priority for antitrust authorities in the European Union (EU) and the United Kingdom (UK) and are likely to remain so in the years to come, despite economists highlighting the complexities around the enforcement of exploitative abuses of companies in a dominant position through excessive pricing. There have been several investigations into the pricing of certain off-patent medicines and orphan (rare disease) drugs at both the EU and Member State levels and in the UK. Most recently, antitrust authorities have also started investigating pricing practices relating to medicines with exclusivity rights, and innovative treatments. The number of stand-alone civil lawsuits brought before national courts in the EU for alleged unfair and excessive pricing practices for off-patent medicines and follow-on damages actions has risen as well in the UK. By contrast, while we have seen a recent push from academics in the US to acknowledge high (excessive) prices of pharmaceuticals as an antitrust violation, US courts have not yet recognised these claims.

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1 Ingrid Vandenborre is a partner and Caroline Janssens is a senior professional support lawyer at Skadden, Arps, Slate, Meagher & Flom LLP.

Biosimilar competition continues to receive growing attention from competition authorities across Europe. While antitrust scrutiny may help facilitate biosimilar market entry and uptake, inherent features of biological medicines, such as high costs and longer approval times, raise fundamental challenges in increasing biosimilar competition. In recent years, we have seen antitrust investigations in the UK, and in the EU, with the Netherlands leading the way, focusing on the impact of commercial practices adopted by incumbent suppliers on biosimilar competition, with a particular interest on pricing strategies, discount schemes and contract terms with hospitals. There have also been concerns in the US regarding strategies to delay biosimilar entry, through patent disputes and alleged product denigration.

Product denigration (or disparagement) behaviours in life sciences are attracting renewed scrutiny at the EU level. While these cases used to be rare, the European Commission (EC) opened two investigations into alleged disparaging practices in the pharmaceutical sector that are still ongoing. In contrast, there has been an abundance of investigations into product denigration at the EU Member State level, especially in France, Italy and Denmark. The French cases have progressively widened the definition of 'denigration', but a recent ruling from the court of appeal of Paris in the *Avastin* case clarified the legal test and also illustrated the difficulties for the French competition authority to characterise denigration as an abuse of a dominant position.

Cooperative agreements play an important role in the pharmaceutical industry, with companies partnering from early-stage research and development through to late-stage commercialisation. Most licensing and commercialisation agreements that companies enter into to create efficiencies should remain within the limits of competition law. The EU and the UK each recently released updated block exemption regulations and guidelines to help competitors collaborate in ways that do not breach the rules. Both frameworks introduce stricter rules on information exchange and the EU framework also reinforces the protection of innovation competition.

With regard to merger control, clearance processes for some pharmaceutical transactions are expected to become more uncertain. This is due to many countries broadening jurisdiction over acquisitions through flexible notification requirements and new theories of harm.

All of these trends and developments are reflected in the following chapters. Italy has been a front runner in antitrust enforcement in life sciences, with landmark cases on excessive pricing and product denigration influencing the EC's decisional practice. The Italian Competition Authority is likely to continue its enforcement efforts in this area in the future. The activity of the Authority in

merger control in recent years has been limited, but this could change with the Authority's new powers to review mergers falling below the national merger control thresholds, intended to catch acquisitions of nascent, innovative, target companies. Germany and Austria increased their scrutiny of innovation-driven markets with the introduction of alternative transaction value thresholds in 2017, designed to capture high-value/low-revenue deals. To date, the life sciences sector has not raised major competition law issues in Switzerland, under neither the cartels, abuse of dominance nor merger control rules. It remains to be seen whether recent and ongoing regulatory changes, as well as mutual market access concerns with the EU, will lead to a different competitive environment in the near future.

In the UK, the Competition and Markets Authority (CMA) continues to regard the life sciences sector as an enforcement priority, both from an anti-trust and merger control angle. With regard to merger control, recent cases have illustrated the CMA's willingness to push the limits of jurisdictional rules and intervene in deals in dynamic, innovation-driven sectors where target companies have limited (or no) revenues or direct activity in the UK. Also, Brexit has created heightened risks of parallel conduct investigations and merger reviews in the EU and UK, in some cases leading to different views on theories of harms or fact patterns. When enacted, the Digital Markets, Competition and Consumers Bill introduced on 25 April 2023 may have significant impact, including on the life sciences sector, through the strengthening of the CMA's investigative powers, and new powers for the authority to review acquisition of innovative market disruptor targets under proposed new jurisdictional thresholds.

In the US, recent merger enforcement in the pharmaceutical sector continues to follow traditional principles and reasoning. However, the Federal Trade Commission (FTC) is expected to adopt more aggressive theories of harm. Recent behavioural enforcement has largely consisted of pay-for-delay litigation and continuing prosecution of price-fixing charges against generic manufacturers. However, the FTC has given strong indications that it has competitive concerns with fees and rebates paid by pharmaceutical manufacturers to pharmacy benefit managers, which is likely to lead to new fronts of enforcement.

Lastly, in Australia, there have been some important regulatory developments affecting the life sciences sector and the Australian Competition and Consumer Commission (ACCC) has taken some significant cases against companies in this sector in recent years. The ACCC has also called for significant reforms to Australia's merger control law. If enacted, these proposed reforms will be highly relevant to dealmaking in the life sciences sector.

CHAPTER 8

Australia: ACCC's Enforcement and Merger Reform Approach Could Foreshadow Increased Scrutiny

Elizabeth Avery and Susan Jones[1]

In Australia, there have been some important regulatory developments affecting the life sciences sector and the Australian Competition and Consumer Commission (ACCC) has taken some significant cases against companies in this sector in recent years. The ACCC has also called for significant reforms to Australia's merger laws. If enacted, these proposed reforms will be highly relevant to dealmaking in the life sciences sector.

Relevant regulatory developments

Repeal of safe harbour exemption for IP licences

With effect from 13 September 2019, the Australian parliament repealed a safe harbour exemption for certain conditions in intellectual property (IP) licences in Section 51(3) of the Competition and Consumer Act 2010 (Cth) (CCA). As a result, all IP assignments or licensing arrangements are now subject to the entire CCA, including cartel prohibitions. The repealed provision provided a limited exemption for conditional licences or assignments of patents, registered designs, copyright and protected circuit layouts. However, it did not exempt conduct that contravened the prohibitions on misuse of market power or resale price maintenance.

1 Elizabeth Avery and Susan Jones are partners at Gilbert + Tobin.

Since the repeal of the IP exemption, there have been reports of the ACCC's Cartels Branch initiating investigations into restrictions in distribution agreements, IP licences and patent settlements for pharmaceuticals, but no proceedings have been commenced at this stage.

On 11 July 2023, ACCC Chair Gina Cass-Gottlieb, in a speech on the ACCC's approach to compliance and enforcement at a Law Institute of Victoria event, called for careful attention to potential anticompetitive arrangements with competitors, even in the settlement of litigation, and noted that:

> *there are sometimes situations where cartel conduct is harder to identify. We have recently seen an example where a market sharing arrangement formed part of a deed of settlement of proceedings.*[2]

This has clear implications for the settlement of IP disputes in particular. If parties to an assignment or licence of IP rights could be competitors, it is important to assess whether there are any conditions that could be viewed as cartel provisions, such as setting prices, restricting output or sales, or allocating markets (including disease areas, customers and territories). In addition to exposing the parties to cartel prosecution, conditions that contravene the CCA would also be void and unenforceable.

Ongoing covid-19 authorisations for the wholesale pharmaceutical sector

During September and October 2020, in the context of the covid-19 pandemic, the ACCC granted a number of final authorisations to allow members of various pharmaceutical industry associations, pharmaceutical wholesalers, medical oxygen suppliers and suppliers of medical equipment, respectively, to cooperate to ensure security of supply of essential medicines and related devices, pharmacy products, medical oxygen, medical equipment and related supplies in the event of shortages resulting from the pandemic. These authorisations are subject to conditions that allow the ACCC to monitor the authorised conduct. Under the CCA, the ACCC may grant authorisations to provide businesses with legal protection for conduct that might otherwise contravene the CCA but is not harmful to competition

2 www.accc.gov.au/about-us/media/speeches/the-acccs-approach-to-compliance-and-enforcement-speech-at-the-law-institute-of-victoria-breakfast-matters-event.

or likely to result in overall public benefits, or both. The ACCC also granted a number of interim authorisations in early 2020, at the beginning of the pandemic, in some cases in extremely short time frames.

On 6 September 2021, pharmaceutical wholesalers applied for reauthorisation to continue to cooperate in providing access to essential medicines and pharmacy products during the continuing covid-19 pandemic. After granting an interim authorisation on 13 September 2021 to allow the cooperation to continue while the ACCC considered the application, on 17 February 2022 the ACCC reauthorised the cooperation until 28 February 2023.

On 15 February 2023, the pharmaceutical wholesalers lodged a further application for reauthorisation to continue the cooperation but the ACCC did not make a decision to grant reauthorisation due to the short time available before expiry of its prior authorisation. The ACCC left open the possibility for the parties to lodge a fresh application, which has not yet transpired.

Indications of ACCC approach to patent settlements

On 23 March 2022, the ACCC published for comment a draft determination in which it proposed to deny an application for authorisation of a patent settlement and licence agreement between Celgene and two generic companies (Juno and Natco).[3] The authorisation application related to a proposed patent settlement and licence agreement between Celgene, Juno and Natco for Revlimid and Pomalyst, which are used in the treatment of multiple myeloma and other forms of cancer.

While there are numerous ACCC authorisations relating to agreements to supply or distribute pharmaceutical products that contain restrictions that could give rise to exclusive dealing, this is the first draft determination by the ACCC regarding an application for authorisation relating to a patent settlement. This authorisation application follows the repeal of the IP exemption in Section 51(3) (discussed above), which may have previously been relied upon by parties assessing such agreements.

When considering whether to grant an authorisation, the ACCC exercises its discretion as to whether the relevant public benefit test is satisfied (outweighing the detriment arising from a lessening of competition), and here the ACCC proposes to deny the application as it considers that the agreement is likely to

3 ACCC, Application for authorisation, AA1000592-1, lodged by Juno Pharmaceuticals Pty Ltd, Natco Pharma Ltd, Celgene Corporation and Celgene Pty Ltd (27 May 2022), available at www.accc.gov.au/public-registers/authorisations-and-notifications-registers/authorisations-register/juno-pharmaceuticals-pty-ltd-ors.

result in anticompetitive effects but is not satisfied it will give rise to the claimed public benefits that would outweigh the detriment.[4] The entry date provisions appear to be the focus of the ACCC's views that the agreement is likely to result in public detriment.

In describing the likely public detriment in the draft determination, the ACCC set out factors that might foreshadow how it could apply the CCA to patent settlements in the future, outside of the context of an authorisation determination. The ACCC indicates that an entry date might reduce the competitive constraint posed by the threat of generic entry by providing an originator with greater control and certainty of the timing of generic entry and might deter other generic entrants by conferring a first mover advantage on one generic entrant.

Patent settlements that provide for an entry date within the exclusionary scope of a valid and in-force patent and without any value transfer from the originator to the generic have typically not been the focus of enforcement action in Europe and the US. If enforcement risk arises solely from an agreed entry date in patent settlements, this makes settlements that involve any term with a potential for early entry problematic and could mean that parties might be forced to litigate their patent disputes to the end as settlements may be unable to be reached on commercially acceptable terms.

On 27 May 2022, the ACCC extended the statutory deadline for its final determination, with the agreement of the applicants, until 29 July 2022. On 29 July 2022, Celgene, Juno and Natco withdrew their application for authorisation without explanation.

Main merger control developments

In April 2023, the ACCC Chair Gina Cass-Gottlieb called for reforms to Australia's merger laws to protect competition in Australia.[5] Ms Cass-Gottlieb said that Australia's merger laws are no longer fit for purpose and risk allowing potentially anticompetitive mergers to proceed.

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4 The Australian Competition and Consumer Commission (ACCC) does not rule out the possibility that it might grant authorisation of a patent settlement in the future if the parties are able to provide convincing evidence of a net public benefit.

5 ACCC, The role of the ACCC and competition in a transitioning economy address to the National Press Club 2023 (12 April 2023), available at https://www.accc.gov.au/about-us/media/speeches/the-role-of-the-accc-and-competition-in-a-transitioning-economy-address-to-the-national-press-club-2023.

The proposed reforms include introducing a mandatory and suspensory notification system requiring parties to notify the ACCC upon reaching certain thresholds (that could be based on global or domestic turnover of parties or transaction consideration), as well as the ability to call in mergers of concern below those thresholds. Ms Cass-Gottlieb also proposed changes to the substantive merger test, including an update to the factors considered when assessing whether a merger is anticompetitive (such as the loss of potential competition).

The reform proposals are not finalised and will require legislative change. The ACCC has provided a paper to the Treasury on its proposals. The Treasurer and the Assistant Minister for Competition, Charities and Treasury jointly announced on 23 August 2023 that the government has established a Competition Taskforce, supported by an expert panel that includes former ACCC Chair, Rod Sims, to undertake a review of competition policy, which includes consideration of the ACCC's proposals for merger reform.

In the context of the proposed merger reforms, the ACCC has been more assertive in requiring that parties meet its expectations in relation to the time and information provided for the ACCC to make its independent assessment. This more assertive approach was demonstrated by the ACCC's application for an interim injunction restraining the acquisition of Adora Fertility by Virtus Health, which was granted by the Federal Court in October 2021.[6]

In the ACCC's recent reviews of two significant mergers in life sciences – Elanco's acquisition of Bayer Animal Health and Mylan's merger with Upjohn to create Viatris[7] – brands have played an important role. The ACCC considered generics and private labels as unlikely to exercise a sufficient constraint due to customer loyalty to the brands of the merged entities, arising from: trust in the safety and efficacy of products; supply on a portfolio basis; and internal documents supporting the strength of the brand and reinforcing concerns that the brand might hinder successful new entry. These factors also influenced the

6 *ACCC v. IVF Finance Pty Limited* (No. 2) [2021] FCA 1295.

7 ACCC, Elanco Animal Health Incorporated, proposed acquisition of Bayer Aktiengesellschaft's animal health business (11 November 2020), available at www.accc.gov.au/public-registers/mergers-registers/public-informal-merger-reviews/elanco-animal-health-incorporated-bayer-aktiengesellschaft%E2%80%99s-animal-health-business; ACCC, Mylan N.V., proposed combination with Pfizer's Upjohn Inc. division (4 December 2020), available at www.accc.gov.au/public-registers/mergers-registers/public-informal-merger-reviews/mylan-nv-and-upjohn-inc-proposed-merger.

ACCC's review of divestiture purchasers with preference given to purchasers with customer relationships and experience in supplying branded products in Australia, in addition to an ability to transfer the manufacturing process.

Main infringement proceedings

Cartels are an enduring priority for the ACCC, and the most significant successful criminal cartel prosecution by the ACCC to date involved international cartel conduct in the pharmaceutical industry.

ACCC v. Alkaloids of Australia – criminal cartel prosecution

On 1 December 2020, the Commonwealth Director of Public Prosecutions filed criminal charges against Alkaloids of Australia Pty Ltd (AOA) and its former export manager, Christopher Kenneth Joyce, for cartel conduct relating to the supply of active pharmaceutical ingredient scopolamine N-butylbromide (SNBB) in contravention of the CCA, following a criminal investigation by the ACCC.[8]

SNBB is manufactured from the alkaloid scopolamine that is extracted from Duboisia plants, which are native to Australia. AOA is a supplier of SNBB and the only manufacturer in Australia.

AOA and Mr Joyce were both originally charged with 33 criminal cartel offences spanning a period of almost 10 years from 2009, relating to allegations that AOA and other international suppliers of SNBB made and gave effect to arrangements to fix prices, restrict supply, allocate markets and customers and rig bids for the supply of SNBB to manufacturers of generic antispasmodic medications.

The original charges were restructured and, over October and November 2021, AOA and Mr Joyce both pleaded guilty to three charges and also admitted guilt in respect of a further seven offences. The three cartel offences to which AOA and Mr Joyce pleaded guilty related to conduct involving:

- fixing a minimum price for the supply of SNBB at between US$1,500 and US$5,000 per kilogram;

8 *R v. Alkaloids of Australia Pty Limited*, Case No. 2020/00347778, and *R v. Christopher Kenneth Joyce*, Case No. 2020/00347777 (Downing Centre Local Court, Sydney, NSW). Section 45AD of the Competition and Consumer Act 2010 (Cth) (CCA) sets out the requirements for a cartel provision; Section 45AF makes it a criminal offence to enter into a contract, arrangement or understanding that contains a cartel provision; and Section 45AG makes it a criminal offence to give effect to a cartel provision.

- agreeing to acquire the entire supply of Duboisia leaves from a particular grower (who was also required to commit to not grow or produce Duboisia on certain property); and
- attempting to fix the price of SNBB so that it was inversely tiered based on the quantity to be supplied, with a minimum price of no lower than US$1,500 per kilogram.

On 29 November 2022, AOA was convicted in the Federal Court of Australia and fined A$1,987,500. Mr Joyce was also convicted and received an aggregate sentence of 32 months' imprisonment to be served by way of an intensive correction order as well as being ordered to perform 400 hours of community service, fined A$50,000 and has been disqualified from managing corporations for five years.

The Federal Court described the conduct as 'deliberate, systematic, coordinated and covert'.[9] Due to the early guilty pleas entered by the defendants, the court applied a 25 per cent discount. Nevertheless, the imprisonment sentence received by Mr Joyce is the longest imposed on an individual for criminal conduct in Australia to date.

ACCC v. Cryosite Limited – gun-jumping as cartel conduct

In 2019, the first penalty for gun-jumping conduct in Australia was imposed in a case involving two companies supplying services for the collection and storage of cord blood and tissue (CBT), Cryosite Limited and Cell Care Australia Pty Ltd. On 13 February 2019, the Federal Court of Australia ordered Cryosite to pay A$1.05 million in civil penalties for entering into an asset sale agreement that contained a cartel provision and giving effect to that cartel provision in violation of the CCA.[10]

Cryosite had agreed to sell assets used in its CBT banking services to Cell Care, and the ACCC raised concerns about cartel conduct during its public merger review of the deal. The sale agreement contained a clause that required Cryosite to refer all customer sales enquiries regarding its CBT banking business to Cell Care in the period between signing and completion. Cryosite admitted that this clause was designed to restrict or limit the supply of CBT banking services by Cryosite and to allocate potential customers to Cell Care. Cryosite also admitted that it

9 See *Commonwealth Director of Public Prosecutions v. Alkaloids of Australia Pty Ltd* [2022] FCA 1424 [215].

10 See *ACCC v. Cryosite Limited* [2019] FCA 116.

gave effect to the cartel provision by ceasing to supply CBT banking services to new customers from the time of the signing of the deal and that it had set up and implemented a system to refer enquiries from potential customers to Cell Care following the signing of the deal. This resulted in Cryosite ceasing to compete with Cell Care even though the proposed sale had not been completed.

This case illustrates how important it is for parties involved in a proposed merger to ensure that the planning of the integration of their business ahead of completion and prior to obtaining clearance from the ACCC does not give rise to gun-jumping in violation of the prohibitions against cartel conduct in Part IV of the CCA.

ACCC v. Pfizer Australia Pty Ltd – life cycle management strategies

An older matter concerning the Australian pharmaceutical sector that retains importance is the ACCC's case against Pfizer Australia Pty Ltd, alleging exclusive dealing and misuse of market power in relation to the supply of atorvastatin to pharmacies in violation of the CCA.[11] The case focused on life cycle management (LCM) strategies employed by Pfizer to address the patent expiry for its blockbuster cholesterol-lowering medicine, Lipitor (atorvastatin). The strategies involved the introduction of a direct-to-pharmacy distribution model, establishing an accrual funds scheme with pharmacies, making bundled product offers to pharmacies and offering discounts on the condition pharmacies would not supply generic atorvastatin. The ACCC's case focused on the language used to express the objective of the LCM strategies within Pfizer's internal documents.

On 25 February 2015, the Federal Court of Australia dismissed the ACCC's case.[12] Although the Court determined that Pfizer had substantial market power prior to patent expiry and that it took advantage of that market power by implementing the LCM strategies, the Court did not find that Pfizer had a substantial purpose of deterring or preventing competitors from competing. Instead, the Court found that the substantial purpose of Pfizer's LCM strategies was to ensure that it remained competitive and that the language in Pfizer's documents needed to be understood in this context. It also found that Pfizer had not engaged in exclusive dealing conduct. The ACCC appealed.

11 Section 46 of the CCA prohibits the misuse of market power; Section 47 of the CCA prohibits exclusive dealing.

12 See *ACCC v. Pfizer Australia Pty Ltd* [2015] FCA 113.

On 25 May 2018, the Full Court of the Federal Court of Australia rejected the ACCC's appeal, finding that Pfizer had not misused its substantial market power for an anticompetitive purpose and had not engaged in exclusive dealing conduct when it devised and implemented a strategy with the purpose of protecting its business by reducing the financial impact of patent expiry for Lipitor.[13] The High Court of Australia refused the ACCC's application for special leave to appeal this decision on 19 October 2018.

After the ACCC had initiated its case against Pfizer, changes to strengthen the misuse of market power prohibition were introduced, which: removed the requirement that a firm had taken advantage of its market power; added an effects test; and focused the prohibition on conduct that is likely to substantially lessen competition and on conduct that has that purpose.[14] Given that the Court had previously found that the substantial purpose of Pfizer's LCM strategy was to ensure it remained competitive, even if the ACCC could have taken its case under the new market power prohibition, it would have still faced difficulties in proving that the substantial purpose of Pfizer's conduct was to substantially lessen competition instead of ensuring it remained competitive. The ACCC might have also encountered difficulties in proving that the likely effect of Pfizer's conduct was to substantially lessen competition considering the evidence Pfizer had presented that generics did compete and respond to Pfizer's strategy by offering increased discounts.[15]

Growing private litigation for misuse of market power

Since the changes to the misuse of market power prohibition, the ACCC has only brought one case to trial under the amended provision. However, a series of private actions have been brought before the competent courts, including one in the life sciences sector.

On 16 July 2021, Merck Sharpe & Dohme (Australia) Pty Ltd launched private litigation against Bristol-Myers Squibb Australia Pty Limited (BMS), claiming that BMS had misused its substantial market power in relation to the supply of immunotherapy to patients with Stage III and Stage IV melanoma.[16] Merck alleged that BMS's Opdivo melanoma continuation programme (Opdivo MCP), which offered Opdivo free of charge when used in combination with

13 See *ACCC v. Pfizer Australia Pty Ltd* [2018] FCAFC 78.

14 Competition and Consumer Amendment (Misuse of Market Power) Act 2017.

15 See *ACCC v. Pfizer Australia Pty Ltd* [2015] FCA 113 [342].

16 *Merck Sharp & Dohme (Australia) Pty Ltd v. Bristol-Myers Squibb Australia Pty Limited*, Federal Court of Australia, New South Wales Registry, NSD708/2021.

Yervoy only to those patients who had received Opdivo at an earlier stage in their treatment, had the effect of eliminating or substantially lessening competition from Merck's competing immunotherapy, Keytruda. It was also alleged that doctors would be reluctant to prescribe Keytruda, rather than Opdivo, if it restricted their patients' access to the Opdivo MCP. While the proceedings have since been dismissed by consent (on 8 February 2022) on account of BMS agreeing to open up its subsidised treatment programme to patients who have been treated with drugs manufactured by its competitors, Merck's application provides an indication of the types of claims that parties might bring under the new test, such as alleging a competitor has leveraged power in one market for the purpose or effect of substantially lessening competition in another market.

Outlook

Since her appointment as chair of the ACCC in March 2022, Ms Cass-Gottlieb has indicated a strong focus on conduct that might result in widespread harm to Australian consumers. With the rising cost of living in Australia, we would expect that the ACCC will look closely at any conduct that could result in a reduction of Australian consumers' access to cost-effective treatments or contribute to price escalation pressures regarding these treatments.

The life sciences industry – and the inherent tension between protecting innovation and a healthy competition space – continues to command attention from regulators. Edited by Ingrid Vandenborre and Caroline Janssens, the second edition of the *Guide to Life Sciences* provides practical and timely guidance for both practitioners and enforcers trying to navigate this high-stakes, fast-moving environment. The Guide draws on the wisdom and expertise of distinguished practitioners from around the globe to provide essential guidance on subjects as diverse as biosimilar competition and product denigration, as well as a forensic examination of the world's most significant and far-reaching regulations and decisions.

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