THE GUIDE TO LIFE SCIENCES

Editors
Ingrid Vandenborre and Caroline Janssens

© Law Business Research 2022

The Guide to Life Sciences

Editors

Ingrid Vandenborre and Caroline Janssens

Reproduced with permission from Law Business Research Ltd
This article was first published in October 2022
For further information please contact insight@globalcompetitionreview.com

© Law Business Research 2022

Publisher
Clare Bolton

Deputy Publisher
Rosie Cresswell

Commercial Editor
Liz Rutherford-Johnson

Account Manager
Samuel Romp

Content Coordinator
Isabelle Gray

Production and Operations Director
Adam Myers

Production Editor
Katrina McKenzie

Subeditor
Martin Roach

Chief Executive Officer
Nick Brailey

Published in the United Kingdom by Law Business Research Ltd
Holborn Gate, 330 High Holborn, London, WC1V 7QT, UK
© 2022 Law Business Research Ltd
www.globalcompetitionreview.com

No photocopying: copyright licences do not apply.

The information provided in this publication is general and may not apply in a specific situation, nor does it necessarily represent the views of authors' firms or their clients. Legal advice should always be sought before taking any legal action based on the information provided. The publishers accept no responsibility for any acts or omissions contained herein. Although the information provided was accurate as at September 2022, be advised that this is a developing area.

Enquiries concerning reproduction should be sent to Law Business Research, at the address above. Enquiries concerning editorial content should be directed to the Publisher – clare.bolton@lbresearch.com

ISBN 978-1-83862-882-6

Printed in Great Britain by
Encompass Print Solutions, Derbyshire
Tel: 0844 2480 112

© Law Business Research 2022

Acknowledgements

The publisher acknowledges and thanks the following for their learned assistance throughout the preparation of this book:

Arnold & Porter Kaye Scholer LLP

Compass Lexecon

Eversheds Sutherland

Gilbert + Tobin

Goodwin Procter LLP

King & Spalding LLP

Latham & Watkins LLP

Norton Rose Fulbright LLP

Oxera Consulting LLP

Portolano Cavallo

Prager Dreifuss AG

Skadden, Arps, Slate, Meagher & Flom LLP

Stevens & Bolton LLP

Stibbe

© Law Business Research 2022

Publisher's Note

One of the unexpected side-effects of the covid-19 pandemic is how the hunt for both vaccines and treatments has pushed the life sciences industry centre stage, with debates over price controls and IP waivers making headlines around the world. While many of these concerns are global, the same is not always true of the solutions adopted by national regulators. As Ingrid Vandenborre and Caroline Janssens point out in their introduction, there has been growing regulatory attention paid to mergers in this innovative space and increasing intervention by antitrust agencies in a range of practices particular to the biopharma sector. Practical and timely guidance for both practitioners and enforcers trying to navigate this fast-moving environment is thus critical.

The first edition of *The Guide to Life Sciences* – published by Global Competition Review – provides exactly this detailed analysis. It examines both the current state of law and the 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 biosimilar competition and product denigration, as well as a forensic examination of the most significant and far-reaching regulations and decisions from around the world.

© Law Business Research 2022

Contents

© Law Business Research 2022

© Law Business Research 2022

© Law Business Research 2022

Introduction

Ingrid Vandenborre and Caroline Janssens[1]

Antitrust agencies around the world have been highly active in recent years, examining a range of practices, including alleged denigration of rivals' products, price increases, biosimilar entry, delayed entry of generic medicines, collaboration agreements and local regulatory/procurement practices. There is also growing attention to mergers, especially in dynamic, innovation-driven areas. While many of the concerns are similar in most jurisdictions, enforcers have addressed those specific to the functioning of their local markets and antitrust principles. This first edition of Global Competition Review's *Guide to Life Sciences* explores how enforcers have approached these practices and where key jurisdictions diverge or converge in their analysis.

Spending on pharmaceuticals constitutes a significant share of government spending on healthcare. This has driven increased regulatory focus on pharmaceutical pricing, including from competition authorities. While competition authorities in the European Union and the United Kingdom have historically been reluctant to intervene, the pharmaceutical sector has seen mounting regulatory interest in alleged excessive pricing practices in recent years. Even with economists highlighting the complexities and shortcomings around the enforcement of exploitative abuses of companies in a dominant position through excessive pricing, antitrust scrutiny of pharmaceutical pricing is expected to continue. By contrast, while we have seen a recent push from academics in the United States to recognise high (excessive) prices of pharmaceuticals as an antitrust violation, US courts have not yet recognised these claims.

---

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

© Law Business Research 2022

Biosimilars, and more generally biological medicines, have received growing attention from competition authorities across Europe. Recent antitrust investigations in the EU and the UK have examined how commercial practices adopted by incumbent suppliers may hinder biosimilar competition. However, the inherent features of biologicals, such as high costs and longer approval times, raise fundamental challenges in increasing biosimilar competition.

Product denigration cases in life sciences have been rare in the EU and around the world, and in most of them the denigration behaviour was combined with other infringements such as abuse of patent procedures or product hopping. There has since been an abundance of similar investigations at national level, with France leading the way, where cases have expanded the scope of the conduct to include product denigration and the provision of unsubstantiated, but not necessarily incorrect, information to consumers and other parties concerning either the company's own products or competing products.

Cooperative agreements have always played an important role in the pharmaceutical industry with companies partnering from early stage research and development through to late-stage commercialisation. The covid-19 pandemic has been an opportunity for the industry to demonstrate the benefits that expeditious and flexible cooperation can bring, and competition authorities have also recognised this. Beyond the pandemic, the pharmaceutical industry is facing increasing pressure to enhance affordable access to new medicines. In that context, cooperation agreements will remain of central importance to pharmaceutical companies, perhaps increasingly so.

With regard to merger control, clearance processes for some pharmaceutical transactions are expected to become more uncertain. This is due to several procedural developments in many countries designed to broaden jurisdiction over acquisitions by incumbents of nascent competitors that could play a significant competitive role in the market in the future ('killer acquisitions'), coupled with flexible and creative notification requirements and new theories of harm. The Multilateral Pharmaceutical Merger Task Force (a working group comprised of the US Federal Trade Commission (FTC), the Canadian Competition Bureau, the European Commission (EC) Directorate General for Competition, the UK's Competition and Markets Authority (CMA), the US Department of Justice Antitrust Division and offices of state attorneys general) can play an important role in brokering alignment in analysis between key jurisdictions.

Competition authorities in Europe, and in particular the EC, have historically been very active in antitrust enforcement and merger control review in the pharmaceutical sector. Consistent with its focus on innovation, the EC has significantly increased its scrutiny in recent years and is expected to continue

© Law Business Research 2022

doing so, including, as we have seen, by way of expanding jurisdictional scope of review. At Member State level, France has been leading the way on enforcement of product denigration, while Germany and Austria have 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.

Italy has been a pioneer 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. In contrast, the activity of the Authority in merger control in recent years has been limited.

In the Netherlands, the focus has been on price levels, with the Authority for Consumers and Markets making important contributions to the debate on excessive pricing both through case practice and working papers.

In the UK, the CMA is expected to continue to regard the life sciences sector as an enforcement priority. 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. In addition, Brexit has created heightened risks of parallel conduct investigations and merger reviews in the EU and UK.

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 US, recent merger enforcement in the pharmaceutical sector continues to follow traditional principles and reasoning. However, it is increasingly likely that the FTC's enforcement actions will reflect 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.

In Australia, the life sciences sector is not currently identified as a priority area for Australian Competition and Consumer Commission (ACCC) enforcement. However, there have been some important regulatory developments affecting the sector, such as the repeal of a safe harbour for intellectual property assignments or licensing arrangements, and the ACCC has also taken some significant cases

© Law Business Research 2022

against companies in this sector in recent years. Lastly, in Brazil, the health sector is under close scrutiny from the Brazilian antitrust authorities, and this is not expected to change in the near future.

© Law Business Research 2022

CHAPTER 15

United Kingdom: a Key Jurisdiction for Competition Law Compliance

Robert Eriksson and Gustaf Duhs[1]

Introduction

In the United Kingdom, the Competition and Markets Authority (CMA) has had a clear competition law enforcement focus on the life sciences sector in recent years, both from an antitrust and a merger control perspective. This looks set to continue, with the CMA promising to progress investigations into anticompetitive conduct in the pharmaceutical sector. Going forward, companies in the sector will therefore be well advised to carefully consider the UK as a key jurisdiction from a compliance point of view, particularly as the CMA and UK courts can now diverge from EU case law, following the UK's exit from the EU.

Regulatory developments

A significant development impacting life sciences in the UK is the introduction of the National Security and Investment Act 2021 (the NSI Act).[2] Due to concerns over the shifts in balance of both global economic and military power, the increasing competition between states and the emergence of powerful non-state actors, the UK government has considered it necessary to modernise its powers to intervene in certain transactions that could threaten the UK's national security. While the Secretary of State previously held powers to intervene on

1 Robert Eriksson is a managing associate and Gustaf Duhs is a partner at Stevens & Bolton LLP.

2 See www.legislation.gov.uk/ukpga/2021/25 (the NSI Act came into force on 4 January 2022).

© Law Business Research 2022

national security grounds in mergers subject to the regular merger control regime, these were not considered adequate to protect national security and safeguard the economy's success and the safety of citizens.

The 'national security' scope under the NSI Act is wide and could cover areas such as security of supply in life sciences (e.g., potentially, vaccines).

Under the NSI Act, acquirers must notify a transaction (including internal restructuring) pre-completion to the Investment Security Unit within the Department for Business, Energy and Industrial Strategy, if:

- the transaction increases control of the target entity to or above 25 per cent of shares or voting rights (or increases the percentage of shares/votes in the entity to more than 50 per cent or 75 per cent); or an entity acquires voting rights in the target entity that enable it to secure or prevent the passage of any class of resolution governing the target's affairs; and
- that target carries out activities in the UK or supplies goods or services to persons in the UK within one of 17 identified sectors.[3]

Among the sectors that could capture transactions within life sciences are synthetic biology, artificial intelligence and advanced robotics.

Sanctions for failure to comply with the NSI Act include the risk of transactions being void if completed prior to clearance, fines and imprisonment.

For certain transactions that fall outside the mandatory regime, there is a voluntary notification regime and 'call-in' powers. This includes acquisitions of 'qualifying assets', which can include acquisitions of intellectual property rights.[4]

---

3 These 17 sectors are: advanced materials; advanced robotics; artificial intelligence; civil nuclear; communications; computing hardware; critical suppliers to government; cryptographic authentication; data infrastructure; defence; energy; military and dual-use; quantum technologies; satellite and space technologies; suppliers to the emergency services; synthetic biology; and transport. These are all further defined in the NSI Act 2021 (Notifiable Acquisition) (Specification of Qualifying Entities) Regulations 2021.

4 Asset acquisitions will more likely be called in where the assets are linked to any of the 17 specified sectors. In fact, the first transaction to be blocked to date under the NSI Act concerned an asset acquisition relating to a licence agreement that had been voluntarily notified to the Investment Security Unit; see *Beijing Infinite Vision Technology Company Ltd (BIVTC)/ University of Manchester*, 20 July 2022, where the licence agreement in question would have enabled BIVTC to use intellectual property relating to technology that the UK Department for Business, Energy and Industrial Strategy considered had dual-use applications and could be used in military drones or missiles.

© Law Business Research 2022

Covid-19 response

During the early stages of the covid-19 pandemic, the CMA warned pharmaceutical suppliers not to abuse the situation[5] but also issued guidance, stating it would not take enforcement action where temporary, necessary measures were taken to coordinate activities to ensure supply of essential products affected by the crisis.[6]

A more indirect impact from the pandemic has been the increased levels of companies' staff working from home. The government has therefore proposed to give the CMA powers to 'seize and sift' evidence when it carries out dawn raids at domestic premises under warrant and to strengthen the CMA's powers to obtain information stored remotely.

Main merger control matters

CMA jurisdiction and 'killer acquisitions'

Currently, the CMA has merger control jurisdiction over a transaction if two enterprises cease to be distinct and either:

- the target's UK turnover is at least £70 million; or
- the transaction creates or strengthens a UK share of supply of 25 per cent or more in the UK or part of it (the share-of-supply test (SOST)).

If there is a realistic prospect of a merger giving rise to a substantial lessening of competition within any market in the UK, the CMA has a duty to refer the transaction for an in-depth Phase 2 investigation. The CMA's merger control enforcement has arguably become more interventionist, with the share of Phase 2 referrals of total decisions increasing from around 12 per cent in 2013–2018 to over 21 per cent in 2018–2022.[7]

Notification in the UK is voluntary and no penalties can be imposed for not pre-notifying, even where the jurisdictional thresholds are met. However, the CMA is vigilant about identifying un-notified mergers for investigation.

---

5 Competition and Markets Authority (CMA) open letter to the pharmaceutical and food and drink industries, 20 March 2020.

6 This coordination had to be in the public interest, benefit consumers and deal with critical issues arising from covid-19 (see the 'CMA approach to business cooperation in response to coronavirus (covid-19)', 25 March 2020); this temporary guidance was withdrawn on 24 June 2022. Due to the covid-19 impact on businesses, the government also implemented orders to exclude the application of the UK Competition Act 1998 in relation to certain types of cooperation (e.g., in the health services sectors) but the Health Services Order was revoked with effect from 29 July 2021.

7 Up to 31 July 2022.

© Law Business Research 2022

Following Brexit, the CMA can now also separately investigate mergers that have been notified to the European Commission (EC) under the EU Merger Regulation, a recent example of which is the *AstraZeneca/Alexion* case.[8]

Under the SOST, the CMA can consider a very broad or narrow scope to take jurisdiction. However, to date, the CMA has found it challenging to tackle 'killer acquisitions'[9] due to the current jurisdictional thresholds, as the SOST requires overlaps of supply. Pending legislative changes (see below), the CMA has applied the SOST expansively, arguing that it was intended to enable the CMA to intervene in any transactions that may be expected to raise competition concerns within the UK.

For example, in *Roche/Spark*, the parties argued that the CMA did not have jurisdiction, as the turnover test was not met and Spark did not generate any turnover in the UK in the year preceding the transaction.[10] However, the CMA considered that firms compete well before products are fully commercialised[11] and considered that Spark's UK activities overlapped with Roche's, given the following:

- Spark was currently developing two gene therapy products that could constitute a competitive constraint on certain Roche products;
- Spark had already engaged in marketing in the UK through UK-based employees; and
- Spark intended to have UK patients participating in clinical trials at UK sites.

---

8 *AstraZeneca plc/Alexion Pharmaceuticals, Inc.* (ME/6926/21), 14 July 2021. The merger was cleared by the CMA and by the European Commission (EC) on 5 July 2021 (Case M.10165, *AstraZeneca/Alexion Pharmaceuticals*).

9 'Killer acquisitions' are transactions in which an incumbent acquires an innovative target firm (often a start-up or nascent firm) to remove a competitive threat (e.g., by discontinuing its research and development projects) and in a merger control context, the theory of harm will generally be around the loss of potential competition from the target business.

10 *Roche Holdings/Spark Therapeutics* (ME/6831/19), 16 December 2019.

11 id., paragraphs 82–83: 'Markets can be characterised by a variety of different business models and . . . the ways in which firms interact (with each other and other market participants) to win business over time can vary significantly. In practice, this means that competitive interactions between firms may not be reduced to overlaps in directly-marketed products or services (as they may in more traditional markets) but can result from overlaps involving pipeline products or services. In the present case, the available evidence shows that significant competition exists between firms well before their products are fully commercialised (i.e., a firm with a currently-marketed product will alter its commercial strategy to compete against a product that is still in clinical development and vice versa).'

© Law Business Research 2022

As the parties' combined share of supply exceeded 25 per cent, based on full-time equivalent employees engaged in research and development activity relating to the treatments in question, the SOST was considered to be triggered.

The government has recently proposed to amend the jurisdictional thresholds,[12] whereby the CMA would have jurisdiction if:

1 the UK turnover of the target exceeds £100 million;
2 the merger creates or enhances a 25 per cent share of supply or purchases in the UK (or a substantial part of it) and each party's UK turnover exceeds £10 million; or
3 the acquirer has:
    - an existing share of supply of goods or services of 33 per cent in the UK or a substantial part of the UK; and
    - a UK turnover of £350 million.

The changes to the current thresholds are, therefore:

- increasing the UK turnover threshold from £70 million to £100 million (point (1));
- introducing a new 'small merger safe harbour' under the SOST (point (2)); and
- introducing a new tier of thresholds (point (3)).

If adopted, the new third threshold could enable the CMA to investigate transactions without overlaps, increasing its ability to review killer acquisitions and mergers between non-competitors (e.g., between companies operating at different levels of the supply chain (vertical transactions)), which often fall outside the CMA's jurisdiction under the current thresholds. While this has been considered particularly relevant in tech acquisitions, the new threshold could also capture life sciences acquisitions (including of small companies) with no overlap.

The proposal also introduces a new 'small merger safe harbour' under the SOST, which would allow mergers where the acquirer and target each has a UK turnover of less than £10 million, irrespective of market shares. This could prove particularly relevant for mergers between small and medium-sized enterprises and start-ups in more narrowly defined 'niche' markets within life sciences.

12 See www.gov.uk/government/consultations/reforming-competition-and-consumer-policy.

© Law Business Research 2022

Overlaps and substantive assessment

Similar to the EC, the CMA applies the Anatomical Therapeutic Chemical classification (ATC),[13] for defining the product scope of relevant pharmaceutical markets. The CMA considers ATC3 as a starting point for overlap analysis, as ATC3 groups together pharmaceuticals based on therapeutic indications, but typically also assesses overlaps at molecule level and pipeline product stages where a product launch appears likely within a reasonable time frame.[14]

Potential future competition can also be considered in competitive assessments. In *Illumina/PacBio*, a merger between DNA sequencing system suppliers, the CMA found that PacBio had potential to become the closest alternative supplier to Illumina, particularly after the release of a new instrument that would increase PacBio's competitive constraint on Illumina. Due to the parties being

13 As developed by the European Pharmaceutical Market Research Association.

14 The CMA is more likely to consider it an overlap the more advanced stage the pipeline product is at (if products are at an early stage in development and entry is highly speculative or a product has failed stability tests, it is less likely to consider it an overlap). Conversely, the CMA is more likely to consider it an overlap if: a party has already taken steps towards commercialisation; internal documents demonstrate intentions to commercialise products in the UK; or relatively advanced pipeline products in practice are operating as a constraint on existing suppliers; see *Roche Holdings/Spark Therapeutics* (ME/6831/19), 16 December 2019; and *Actavis UK/Auden Mckenzie* (ME/6513/15), 21 May 2015. Market definitions for veterinary pharmaceuticals are similarly assessed on a narrow basis, based on use and treatment (e.g., in the CMA's decision in *Dechra Pharmaceuticals/Osurnia business of Elanco Animal Health* (Case ME/6878/20), 9 June 2020, the CMA assessed overlaps for the supply of first-line antibiotic otitis treatments in the UK and the supply of prescription non-antibiotic otitis treatments in the UK, as well as assessing pipeline overlaps). Note that, as life sciences markets can be defined narrowly, the total value of the UK market may also be low as a result, in which case the *de minimis* exception could be applied. Under the *de minimis* exception, where the total UK market value is below £5 million, the CMA will generally not consider an in-depth Phase 2 investigation to be justified unless a clear-cut undertaking in lieu of reference is available. Where the value is between £5 million and £15 million, the CMA will consider whether the expected customer harm resulting from the merger is materially greater than the average public cost of a Phase 2 reference. The application of this exception is rare but has been applied in some life science mergers; see, e.g., the *Integra LifeSciences/Codman neurosurgery* case where the estimated total size in aggregate of the four relevant markets concerned was approximately £6.6 million (*Integra LifeSciences Holdings/Codman neurosurgery business* (ME/6682/17), 6 July 2017); and the *GLO Dutch Bidco/Mallinckrodt Nuclear Medicine* case, where the size of the relevant market in the UK was approximately £4.6 million (*GLO Dutch Bidco/Mallinckrodt Nuclear Medicine/Mallinckrodt Netherlands Holdings* (ME/6689/17), 26 June 2017).

© Law Business Research 2022

close competitors, the limited available alternatives for customers and the uncertainty about new market entry, the merger was referred for a Phase 2 investigation and ultimately abandoned.[15]

Main infringement proceedings

The CMA has enforced competition law actively in life sciences sectors, particularly in relation to pharmaceuticals, with 10 cases since 2017. Fines imposed have been at record levels and directors have been disqualified under the Company Directors Disqualification Act 1986.

Many CMA cases have concerned 'niche generics'[16] and the type of conduct challenged has often concerned forms of market sharing or exploitation through excessive pricing. Examples include:

- suppliers entering profit sharing arrangements to encourage would-be competitors to stay out of a market;
- agreeing with competitors to share downstream supply to a wholesale level customer;
- exchanging commercially sensitive information; and
- withdrawing supply of a product to force patients to switch to more expensive treatments.

Cartels/anticompetitive agreements

The CMA has issued the following decisions in recent years.

Prochlorperazine

The CMA decided that Alliance Pharma (AP) had infringed competition law by effectively paying two would-be competitors (Lexon and Medreich) not to compete in the supply of prochlorperazine.[17] The CMA found that the arrangements had resulted in prices rising by 700 per cent over a four-year period. Having learned that it was about to face competition from Lexon and Medreich, which had taken steps to launch and had obtained licences to supply prochlorperazine,

15 *Illumina/Pacific Biosciences of California* (ME/6795/18), 18 June 2019.

16 While prices normally fall when generics enter a market, for some generics this does not happen due to market features (e.g., high barriers to entry or low volumes can result in markets being too small to attract further entry). These products have been referred to as 'niche generics', where the market ends up being concentrated and sometimes results in significant price increases, thus attracting CMA scrutiny.

17 Case 50511-2, *Prochlorperazine*, 3 February 2022.

© Law Business Research 2022

AP appointed Focus Pharma as a distributor of its own prochlorperazine and agreed a profit-sharing arrangement relating to AP's product in return for Lexon and Medreich agreeing not to compete.

The CMA fined the firms (AP, Lexon, Medreich and Focus) over £35 million in total. The decision has been appealed to the Competition Appeal Tribunal (CAT).

On 2 September 2022, the CMA also announced that it is issuing proceedings in the High Court to seek competition director disqualification orders against seven directors of the four companies.

Fludrocortisone

The CMA found Aspen Pharma had paid its competitors Amilco and Tiofarma to stay out of the market, leaving Aspen as the sole supplier for fludrocortisone, a corticosteroid, thereby breaching competition law.[18]

The case was settled with fines totalling approximately £2.3 million. The CMA also secured a director disqualification undertaking from a director of Amilco not to act as a director of any UK company for five years.

Aspen also agreed to pay an £8 million *ex gratia* payment to the National Health Service (NHS), to seek to mitigate the risks of a damages claim from the Department of Health. The payment falls outside the formal CMA settlement process and does not preclude the Department of Health from seeking further damages from the businesses involved in the infringement. However, the payments would be offset against any further damages award and would therefore be expected to reduce the risk of damages actions being lodged. This payment was the first of its kind in the UK.

Nortriptyline

The CMA found that King Pharmaceuticals and Auden Mckenzie, two suppliers of the anti-depressant nortriptyline, had engaged in 'brand equalising' (i.e., agreeing to supply a customer at wholesale level at a low price to dissuade it from bringing in parallel imports).[19] The suppliers also agreed to share downstream supply to that customer and fixed the prices of supply, thereby breaching competition law. The CMA characterised this as market sharing, although the 'sharing' was

18 Case 50455, *Fludrocortisone acetate 0.1mg tablets*, 9 July 2020.

19 Case 50507.2, *Nortriptyline*, 4 March 2020.

© Law Business Research 2022

limited to dividing supply to one customer with its agreement. The companies also exchanged commercially sensitive information (e.g., on market entry intentions) with each other and with another competitor, Alissa Healthcare Research.

The CMA fined the firms over £3.4 million in total and secured director disqualification undertakings.[20]

Accord-UK (previously Auden Mckenzie/Actavis UK) also agreed to make a £1 million *ex gratia* payment to the NHS.

Hydrocortisone

The CMA found that Accord-UK (previously Auden Mckenzie/Actavis UK) had effectively paid two would-be competitors, AMCo (now Advanz Pharma) and Waymade, to stay out of the market, thereby breaching competition law.[21] Under the alleged conduct, payments were concealed by an arrangement whereby Auden 'sold' hydrocortisone packs to Waymade at discounts of 87 per cent to 97 per cent and then immediately 'bought back' these at market prices, without the product leaving Auden's warehouse.

The CMA fined Accord-UK (and Allergan as the former parent) approximately £66 million, Waymade £2.5 million (for their part in the collusion) and Advanz and the private equity house Cinven (which had exercised decisive influence over the infringing entity for a certain period) a total of approximately £43 million.

The decision has been appealed to the CAT.

Spire

Outside the area of pharmaceuticals, the CMA has also demonstrated that it is willing to investigate cases and impose fines where individual healthcare consultants engage in cartels. In *Spire*, the CMA found that a hospital of the Spire Healthcare Group had instigated and facilitated a price-fixing arrangement with seven consultant ophthalmologists.[22] Under a settlement, the parties all admitted they agreed to fix fees for initial private consultations for self-pay patients and

20 A King director (disqualified for seven years), an Auden Mckenzie director (disqualified for five years) and an Alissa director (disqualified for two years). The Alissa director was later granted leave to act under strict conditions, partly due to the covid-19 pandemic and the fact that Alissa was effectively a one-man company. Following Lexon's failed appeal to the Competition Appeal Tribunal (CAT), a Lexon director failed in challenging a director disqualification order before the High Court and was disqualified for four years.

21 Case 50277, *Hydrocortisone*, 15 July 2021.

22 Case 50782-1, *Privately funded ophthalmology services*, 1 July 2020.

© Law Business Research 2022

the fines totalled more than £1.2 million, with the consultants being subject to individual fines of up to £3,900.

Pay-for-delay settlements

Pay-for-delay settlements are agreements between originator pharmaceutical companies and generics manufacturers in which the generics manufacturer agrees to delay market entry of its generic in return for payment from the originator. The CMA's approach to the legality of pay-for-delay settlements is similar to the EC's.

As regards the view on potential competition in pharmaceutical markets, the CMA considers that if there are 'real concrete possibilities' for a generic supplier to enter the market and compete with the originator, they are at least potential competitors. The issue of what constitutes a 'potential competitor' in pay-for-delay cases was considered in the CMA's *Paroxetine* case and, on appeal, the CAT referred this question to the Court of Justice of the EU (CJEU) in light of the then ongoing *Lundbeck* case.[23] In its judgment,[24] the CJEU concluded that a generic manufacturer preparing to enter the market is a potential competitor of the originator where:

- the generic manufacturer has a firm intention and inherent ability to enter the market. This will be the case if, when the agreement was concluded, it had taken sufficient preparatory steps to enable it to enter the market concerned within such a period of time as would impose competitive pressure on the originator. These preparatory steps might include:
  - obtaining the necessary marketing authorisation (MA) and an adequate stock of generic medicine;
  - legal steps undertaken to challenge the originator's patents; or
  - marketing initiatives to market its product; and
- there are no insurmountable barriers to market entry. While this is for the national court to assess, the CJEU found that the existence of a patent, which protects the manufacturing process of an active ingredient in the public domain, cannot of itself lead to a conclusion that there is an insurmountable barrier to entry, as:
  - the uncertainty as to the validity of patents covering medicines is a fundamental characteristic of the pharmaceutical sector;
  - the presumption of validity of an originator's patent does not amount to a presumption that a generic version is illegal;

23 Case AT.39226, *Lundbeck*, 19 June 2013.

24 Case C-307/18, *Generics (UK) Ltd and Others v. CMA*, 30 January 2020.

© Law Business Research 2022

- 'at risk' launches of generics and consequent court proceedings commonly take place in the period before or immediately after a generic market entry;
- to obtain an MA for a generic, there is no requirement to prove that the marketing does not infringe any originator's patents; and
- in the pharmaceutical sector, potential competition may be exerted before the expiry of a compound patent protecting an originator, as generic manufacturers want to be ready to enter the market as soon as that patent expires.[25]

The definition of a 'potential competitor' in pay-for-delay cases is therefore likely to continue to follow that established on an EU level, despite the UK's exit from the EU.[26] In its *Paroxetine* decision, the CMA took a similar view to the EC's in considering that patent challenges in themselves were part of the competitive process.[27]

'By object' infringement

Another crucial issue in recent pay-for-delay cases has been whether these agreements give rise to an infringement 'by object'. In the UK, the definition of 'by object' restrictions closely mirror that of the European Courts (e.g., in the *Paroxetine* case, the CAT referred to the *Cartes Bancaires* case and stated that

25 id., paragraph 51; and *Paroxetine* [2021] CAT 9, 10 May 2021, paragraphs 16, 74.

26 For example, the CMA's definition in this regard is very similar to that of the CJEU's; see Case CE-9531/11, *Paroxetine*, 12 February 2016, Annex D (in particular, paragraphs D43–D47).

27 ibid.; see, for example, paragraph 1.10: 'It is particularly important to prevent patentees (the incumbents) and challengers from entering into anti-competitive settlement agreements in the pharmaceutical sector. That is because patent challenges, often by companies manufacturing generic versions of drugs, are an important means by which the validity of a "legal monopoly" in an important economic area can be tested. As such, patent challenges in this field can in themselves be viewed as an important aspect of the competitive process'. A similar approach was taken by the EC in *Lundbeck*, upheld by the European courts: 'Patent litigation, which is very common when new generic products become available through expiry of exclusivity on originator medicines, is in fact an expression of the independent efforts of generic undertakings to enter the market and therefore a form of competition in the pharmaceutical sector. Likewise, patent litigation is also an expression of competition from the side of the originator undertaking, which in this way is trying to defend its market position against generic competition. In the pharmaceutical sector, patent challenges are an *essential part of the competitive process* between generic companies seeking market entry for compounds that are no longer patent-protected and originator companies that invoke process patents or other process patents against such market entry' (emphasis added) (see EC decision AT.39226, 19 June 2013, paragraphs 625–626).

© Law Business Research 2022

there needs to be an appreciable effect on trade for an infringement to have been properly demonstrated). For there to be a restriction by object, that assessment 'focusses on determining the potential effect of the agreement, having regard to its nature and its context, rather than on establishing on the facts what are, or were, its likely effects . . . that potential must be realistic and not fanciful and it must be clear that the potential effects would materially harm competition'.[28]

In considering what constitutes by object restrictions in pay-for-delay cases, the CAT included questions on this in its referral to the CJEU in *Paroxetine*. In its judgment[29] the CJEU held that a settlement agreement between potential competitors, whereby a manufacturer of generic medicines undertakes not to enter the market or challenge a patent in return for transfers of value, has the object of restricting competition if the net gain from the value transfers can have no other explanation than the commercial interest of the parties not to engage in competition on the merits unless the settlement agreement has proven pro-competitive effects capable of giving rise to a reasonable doubt that it causes a sufficient degree of harm to competition.

The CMA is thus likely to regard a patent litigation settlement as a by object breach if:

- there is a delay to generic entry (e.g., any agreed entry after patent expiry will almost certainly be regarded as a delay); and
- there is any significant value transfer to the generic supplier,[30] particularly if the originator's patent appears to be weak.[31] Any payments by the originator to the generic supplier beyond litigation costs or anticipated damages[32] are likely to be seen as a payment to stay out of the market.

---

28 See *Paroxetine* [2018] CAT 4, 8 March 2018, paragraph 170; see Case C-67/13P, *Groupement des Cartes Bancaires v Commission*, 11 September 2014, paragraphs 52–58.

29 Case C-307/18, *Generics (UK) Ltd and Others v. CMA*, 30 January 2020.

30 For example, higher payments calculated on basis of the generic supplier's forecast profits or turnover, post-launch.

31 See Case T-460/13, *Ranbaxy v. Commission* (*Lundbeck*), 8 September 2016, paragraph 242: 'reverse payments, were not always problematic from a competition law perspective, provided that such payments were linked to the strength of the patent concerned, as perceived by each of the parties, and were not accompanied by restrictions intended to delay the market entry of generics.' See, also, the EC's *Lundbeck* decision, in which the EC noted that Lundbeck's internal documents considered they had a 60 per cent chance of failing in a patent invalidity action and that was seen as significant uncertainty that they replaced with certainty by concluding the agreements.

32 For example, when an originator first obtained an interim injunction against the generic but later feared to lose the main case and settled, the generic supplier could claim damages for lost sales whilst having been prevented from marketing its product.

© Law Business Research 2022

Abuse of dominance

Excessive pricing

Recent CMA cases regarding abuse of dominance in the life sciences sector have mainly concerned excessive pricing. The definition of excessive pricing as an abuse of dominance under competition law remains largely that outlined in the *United Brands* case[33] (i.e., the price bore 'no reasonable relation to the economic value of the product', which is assessed through a two-limb test of demonstrating that the difference between the cost incurred and the price charged was excessive (excessiveness limb) and the price was unfair either in itself or when compared to competing products (unfairness limb)).

In *Hydrocortisone*, the CMA found that Auden Mckenzie/Actavis UK (later acquired by Accord-UK) had charged the NHS excessive prices for hydrocortisone tablets by increasing prices by over 10,000 per cent compared to the original branded version, thereby breaching competition law, and imposed a record fine of £155 million on Accord-UK.

In *Phenytoin*, the CMA applied the 'Cost+' method to determine 'excessiveness' and compared the price to a Cost+ maximum of 6 per cent of 'reasonable return', which is the Pharmaceutical Price Regulation Scheme target rate return on sales. The CMA recognised that a return on sales of 6 per cent would not necessarily be a reasonable rate of return for a Cost+ assessment for other generic products and could be greater.

The use of Cost+ was challenged on appeal and the CAT found that the CMA had been too strict in restricting the excessiveness limb to Cost+ and excluding other methodologies. The CMA appealed to the Court of Appeal and won on the ground of the existence of a duty to use a hypothetical benchmark price (as the CAT indicated), with the Court of Appeal stating that while there needs to be 'a' benchmark against which to measure excess or fairness, that choice of benchmark is for the CMA to choose. However, if the CMA chooses one method (e.g., Cost+) and the defendant relies upon other well-reasoned methods and evidence, the CMA must then fairly evaluate it and cannot easily dismiss it.

Applying a narrow Cost+ as a method in future cases therefore remains a possibility, but these judgments suggest the CMA could be challenged when it does. Following the Court of Appeal's judgment, the CMA decided to reinvestigate matters on abuse that had been remitted to it by the CAT, and issued a new infringement decision on 21 July 2022.[34] As in its original decision, the CMA

33 Case C-27/76, *United Brands*, 14 February 1978.

34 A public version of the decision is not yet available.

© Law Business Research 2022

found that the firms de-branded the drug, meaning it was no longer subject to price regulation and that Pfizer charged prices 780 per cent to 1,600 per cent higher than previously and supplied the drug to Flynn, which then sold it on to wholesalers and pharmacies at a price up to 2,600 per cent higher than previously charged by Pfizer. According to the CMA, this led to the NHS's annual costs for phenytoin increasing from £2 million to approximately £50 million in a year. The CMA has fined Pfizer £63.3 million (previously £84.2 million) and Flynn approximately £6.7 million (previously £5.2 million). Pfizer and Flynn have confirmed they will appeal the decision.

In its *Hydrocortisone* decision of July 2021, which followed the remittals to the CMA of the *Phenytoin* case, the CMA continued its approach of a narrow Cost+ reasonable rate of return. It used the return on capital employed as its primary measure of the rate of return (as opposed to a return on sales measure, as applied in *Phenytoin*), concluding that a return of between 5 per cent and 15 per cent was reasonable.[35] The CMA put the Cost+ for 10mg tablets at between £2.70 and £4.45 per pack and for 20mg, between £2.91 and £5.20 per pack. However, in assessing whether the prices were excessive, the CMA stated that it had decided to exercise its 'discretion to determine its administrative priorities', not prioritising investigating prices below £20 per pack.

The CMA considered that its calculation of Cost+ was a 'generous measure' and maintained that prices above Cost+, but below £20 per pack, could still be excessive and unfair. However, it limited itself to finding that prices were excessive and unfair when they exceeded £20 per pack, stressing that this meant the lowest price at which prices were found to be excessive and unfair (£20) still exceeded the upper bound of Cost+ 'by 285%' (or around £15). Presumably this was to seek to reduce the risks of a successful appeal to its decision. Nevertheless, the *Hydrocortisone* decision has been appealed to the CAT.[36]

In parallel with *Hydrocortisone*, the CMA also pursued an abuse of dominance case against Advanz Pharma for excessive pricing in relation to liothyronine, at the time a niche generic, and found that Advanz had charged excessive and unfair prices.[37] Advanz was considered to have increased prices by 1,110 per cent

35 The exact figure is redacted due to confidentiality.

36 The hearing is listed for the week commencing 21 November 2022.

37 Case 50395, *Liothyronine tablets*, 29 July 2021.

© Law Business Research 2022

from £20 in 2009 to £248 in 2017 and the CMA imposed fines totalling over £100 million, including on two private equity firms that previously owned the businesses now forming part of Advanz.[38]

Rebates

In recent cases, the CMA has not concluded that any loyalty rebates infringed UK competition law. In *Remicade*, the CMA closed an investigation in which MSD's discount scheme with the NHS was thought to have been aimed at foreclosing biosimilars.[39] However, the scheme was found to have been unlikely to limit competition in practice.[40]

In another case closure decision, the CMA also provided some guidance, confirming that its approach as regards loyalty rebates as an abuse is largely similar to the EC's, as outlined in its Article 102 enforcement priorities guidance.[41] The CMA stated that even where rebates are not conditional on the customer obtaining most of its requirements from a dominant company, rebates or discounts may be capable of restricting competition by having a loyalty-inducing or fidelity-building effect.[42] These schemes may raise competition concerns due to their potential to limit competing firms' ability to operate in the market.

Product hopping/evergreening

In the UK, the CMA's position as regards 'product hopping' (or 'evergreening') is that it can constitute an abuse of dominance. For example, in *Reckitt Benckiser*, the CMA held that the firm had infringed competition law by replacing its original product with a new version after the original patent had expired, but prior to

38 HgCapital (fined £8.6 million) and Cinven (fined £51.9 million).

39 By linking the level of discount offered on Remicade to the total amount of the drug purchased, the scheme – when coupled with caution in the National Health Service (NHS) over moving away from tried and tested drugs – was designed to dissuade the NHS from trialling biosimilars, regardless of potential savings.

40 Case 50236, *Remicade*, 14 March 2019.

41 Communication from the Commission, 'Guidance on the Commission's enforcement priorities in applying Article [102] of the [Treaty on the Functioning of the EU] to abusive exclusionary conduct by dominant undertakings', OJ 2009 C45/7.

42 Case CE/9855-14, *Suspected breach of competition law in relation to the pharmaceutical sector*, 26 June 2015. When considering such rebates or discounts, the CMA is likely to consider 'all the circumstances, particularly the criteria and rules governing the grant of the rebate, and to investigate whether, in providing an advantage not based on any economic service justifying it, the rebates tend to remove or restrict the buyer's freedom to choose his sources of supply, to bar competitors from access to the market . . . or to strengthen the dominant position by distorting competition' (see Case T-203/01, *Michelin II*, paragraph 60).

© Law Business Research 2022

generic names for the original product being published. The conduct meant that prescriptions could only be issued for the new branded product, and the CMA considered it would have been irrational to withdraw the original product had it not been for the benefits of delaying generic competition.[43]

Similarly, in *Priadel*, the CMA took an initial view that Essential Pharma had planned to withdraw supply in the UK of Priadel, a bipolar medication, which would have meant patients had to switch to more expensive similar treatments and then impose higher prices for supply of medication in that product's class.[44] It should be noted that this case concerned a strategy that had not yet been implemented, and there was no CMA infringement decision. Instead, the case was resolved through commitments whereby Priadel would continue to be supplied on terms agreed with the Department of Health, meaning Priadel could not be withdrawn to obtain any allegedly unjustified price increase.

Outlook

The CMA will likely continue to regard life sciences sectors as an enforcement priority. In its Annual Plan 2022/23, it stated that it will continue to progress 'investigations into anticompetitive conduct in the pharmaceutical sector, with a view to ensuring that the NHS, and ultimately the taxpayer, does not pay more than they should for essential medicines and treatments'.[45] In that respect, the CAT's *Hydrocortisone* judgment will be eagerly awaited in determining what 'more than they should' might entail.

It is also possible that the CMA's enforcement could increase as a result of the UK's departure from the EU, as the CMA is now able to investigate cases in parallel with or subsequent to EC investigations. In that context, it is worth noting that the government has proposed to amend the Competition Act 1998 so that it can apply to concerted practices or agreements implemented outside

---

43 Case CE/8931/08, *Reckitt Benckiser/Gaviscon*, 12 April 2011 (case resolved through an early resolution agreement). In the UK, where a branded medicine's patent has expired and a 'generic name' has been assigned to it, doctors can use prescribing software to search for the brand and provide patients with an 'open' prescription that lists its generic name. Pharmacies that receive these prescriptions can then choose whether to dispense the relevant brand or equivalent cheaper generic medicines. Pharmacies that receive prescriptions for a branded product, as opposed to the generic name, must dispense that branded product, as it is patent protected with no generic equivalents.

44 Case 50951, *Decision to accept commitments offered by Essential Pharma in relation to the supply of Priadel*, 18 December 2020. The CMA also noted that switching bipolar medication can be difficult for patients and cause health issues.

45 CMA Annual Plan 2022/23, CMA155 (CMA/2022/01), 24 March 2022, paragraph 2.21.

© Law Business Research 2022

the UK if they have an effect within the UK. Further anticipated Brexit-related legislative changes that will have an impact in life sciences sectors include the UK's new public subsidy regime, replacing EU State aid rules as regards the UK, and changes to the UK's public procurement laws. It will also be interesting to see how the UK's new laws in relation to the internal market (effectively replicating EU measures at a national level to ensure no unlawful discrimination between Member States) will develop.

In parallel with the new EU Vertical Block Exemption Regulation (VBER)[46] being adopted, the UK has adopted its own vertical block exemption, contained in the Competition Act 1998 (Vertical Agreements Block Exemption) Order 2022 (VABEO). This came into force on 1 June 2022, replacing the previous block exemption. While the UK and EU approaches are currently largely similar, they may well diverge further over time. As with the new VBER, among the key changes in the VABEO are more guidance on what constitutes 'active' and 'passive' sales, particularly in the context of online sales, and some increased flexibility to allow certain restrictions on distributors in relation to online sales. In a life sciences context, these types of changes may prove to be more relevant for non-prescription pharmaceuticals and healthcare products.

46 Commission Regulation (EU) 2022/720 of 10 May 2022 on the application of Article 101(3) of the Treaty on the Functioning of the European Union to categories of vertical agreements and concerted practices.

© Law Business Research 2022

The covid-19 pandemic – and the amount of public money that governments are spending on healthcare – has thrust the life sciences industry into the international spotlight, with debates over price controls and IP waivers making headlines around the world. While many of these concerns are global, the same is not always true of the solutions adopted by national regulators. The first edition of *The Guide to Life Sciences* – edited by Ingrid Vandenborre and Caroline Janssens – provides practical and timely guidance for both practitioners and enforcers trying to navigate this high-stakes environment. The Guide draws on the wisdom and expertise of distinguished practitioners globally to provide essential guidance on subjects as diverse as biosimilar competition and product denigration, as well as a forensic examination of the most significant and far-reaching regulations and decisions from around the world.

Visit globalcompetitionreview.com
Follow @GCR_alerts on Twitter
Find us on LinkedIn

ISBN 978-1-83862-882-6

© Law Business Research 2022