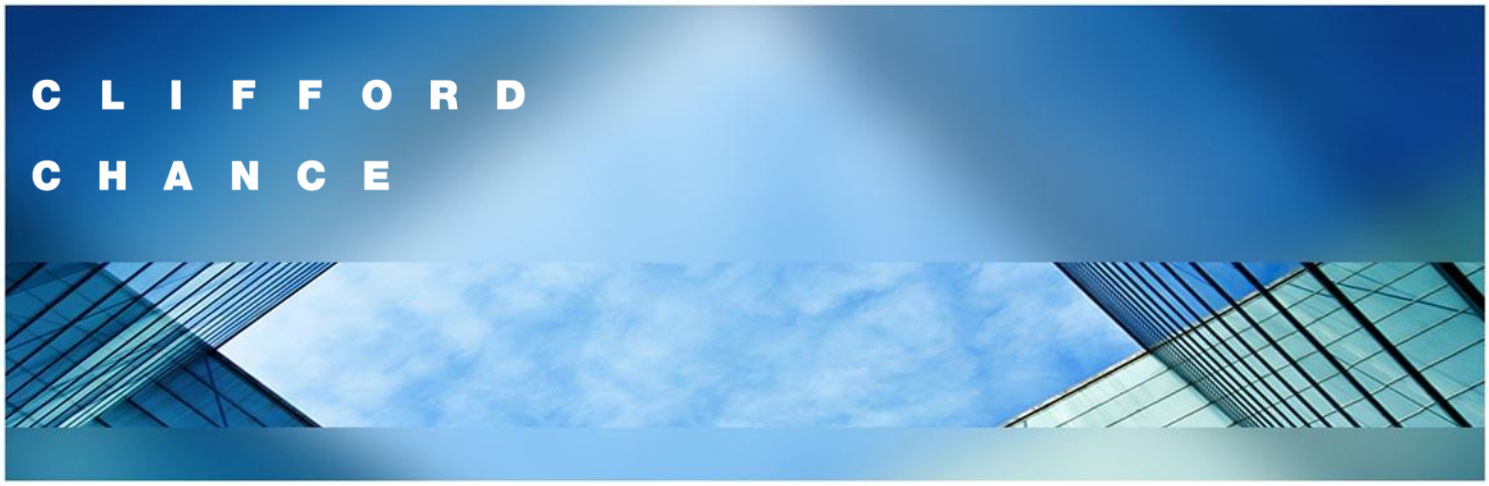

HEALTHCARE & LIFE SCIENCES – GLOBAL ANTITRUST NEWSLETTER – DECEMBER 2023

Welcome to the December 2023 edition of the Clifford Chance Global Antitrust Healthcare & Life Sciences Newsletter, providing an overview of recent antitrust developments and trends of particular relevance to companies active in the healthcare & life sciences sector.

INTRODUCTION

Welcome to our inaugural edition of the Clifford Chance Global Antitrust Healthcare & Life Sciences Newsletter. The aim of this Newsletter is to provide updates on what has been happening, and the trends we are seeing, in antitrust law in the healthcare & life sciences sector. The Newsletter covers highlights from the major competition enforcement jurisdictions.

Global antitrust regulators continue to focus on mergers in the sector. While the majority of merger control investigations continue to focus on traditional concerns, there have been instances of the UK Competition and Markets Authority (**CMA**) and the US Federal Trade Commission (**FTC**) exploring novel theories of competitive effects in sector transactions. The review of below-the-thresholds transactions continues to be a trend; in China, the regulator unprecedentedly imposed conditions on such a merger in the pharmaceutical sector, and the *Illumina / GRAIL* saga continues to rumble on in Europe and the US. At the same time, sector deals continue to be consummated after obtaining clearance – the CMA notably cleared *UnitedHealth / EMIS* unconditionally following a phase II investigation and the FTC settled with *Amgen / Horizon* allowing that transaction to proceed.

Authorities also continue to bring behavioural cases in this sector. Cases involving allegations of originators restricting generic competition continue to be in the spotlight, with active cases in Australia, the UK, and the EU. Excessive pricing also continues to be in the spotlight in Europe, with three important judgments/decisions in the Netherlands and the UK recently being published, all three of which went in favour of the regulators. And there has been no let-up on cartel cases, with criminal cartel cases being pursued in Australia in the Alkaloids

Key issues

This regular newsletter is a digest of key antitrust developments in the healthcare & life sciences sector in the following regions:

- Asia Pacific
- Europe
- Americas

If you would like to know more about the subjects covered in this publication, please refer to the list of contacts on page 13 & 14.

case, a product for which the European Commission (**EC**) also levied fines, and cartel-like cases being brought in Germany and in the US.

ASIA PACIFIC

Australia

ACCC publishes draft guidance to improve businesses' environmental claims and AusBiotech launches world-first Practical Guide to ESG for Australian biotech and life sciences companies

As part of its 2023-24 Compliance and Enforcement Priorities, the Australian Competition and Consumer Commission's (**ACCC**) is prioritising consumer, product safety, fair trading and competition concerns in relation to environmental and sustainability claims (otherwise known as "Greenwashing"). Greenwashing has been the focus of increasing regulatory scrutiny in Australia in recent years with the ACCC recently publishing draft guidance on 14 July 2023 (**Draft Guidance**) to improve the integrity of environmental and sustainability claims. The Draft Guidance aims to address conduct identified by the ACCC's recent Greenwashing internet sweep, which found 57% of businesses reviewed were making potentially misleading environmental claims.

Relevant to healthcare and life sciences, in August 2023, AusBiotech published its Practical Guide to ESG for Australian biotech and life sciences SMEs (**Guide**),which is intended to be a practical resource for small to medium-sized Australian life sciences companies looking to begin or expand their ESG strategy and sets out an approach to communicating progress.

Inconsistency in global standards poses challenges for healthcare and life sciences businesses in managing compliance and tracking progress, particularly due to the lack of a common definition or standard in Australia for terms such as 'biodegradable', 'recyclable' and 'compostable'. The Draft Guidance and the Guide may be helpful interim resources, while standards and regulations continue to evolve in Australia and globally.

ACCC consults on Australian Clinical Lab Limited's (ACL) proposed divestiture remedy in respect of AU$1.5bn acquisition of Healius

On 20 July 2023, the ACCC published a statement of issues (SOI) outlining significant preliminary competition concerns with ACL's proposed acquisition of Healius.

The ACCC's primary concern relates to the combination of two of the top three providers of community pathology services in Australia (with Sonic being the third), which would result in the combined entity becoming the largest provider in every state and territory in which they both operate. The ACCC considered that ACL and Healius compete closely and indicated its concern that the merged entity would have the ability to increase prices and/or reduce service quality in relation to the supply of pathology services to the community, private and public hospitals, and veterinary clinics. The ACCC was also particularly concerned with the risk of coordinated conduct in the form of increased private billing for pathology services (i.e., a decrease in bulk billing) between the merged entity and Sonic, which post-transaction would control over 75% of all Approved Collection Centres (**ACC**) in

every Australian state and territory (except Tasmania, where ACL does not operate).

On 3 October 2023, ACL offered a court-enforceable undertaking to the ACCC to address the ACCC's preliminary competition concerns (**Proposed Undertaking**). The Proposed Undertaking requires ACL to divest 60 ACCs in Perth, 25 ACCs across regional Victoria, and 14 ACCs in the Northern Territory. The ACCC is currently seeking feedback from stakeholders on whether the Proposed Undertaking is capable of addressing the relevant competition concerns.

The review of this transaction is a recent example of the ACCC's approach of intensifying scrutiny of mergers in sectors of interest, including in healthcare. This increased level of scrutiny is occurring against the backdrop of legislative reforms to introduce a mandatory merger notification regime in Australia, under which an increased onus of proof would be placed on merger parties to positively satisfy that the merger is not likely to substantially lessen competition in any Australian markets. The ACCC is increasingly requiring parties to offer remedies / divestitures as a condition of approval, with the last merger that was not opposed (without remedies) being in February 2023.

Commonwealth brings its AU$325m damages claim against Sanofi over generic Plavix ban to the High Court

In a decade-long dispute, the Commonwealth has sought leave to appeal to the High Court of Australia, after the Full Federal Court dismissed its $325m damages case against Sanofi over an allegedly unjustified injunction that prevented the release of Apotex's generic clopidogrel (Plavix) in Australia.

In June 2023, the Full Federal Court upheld the primary judge's findings that Apotex would not have successfully launched and listed on the Pharmaceutical Benefits Scheme (**PBS**) in 2008 but for an injunction, therefore rejecting Commonwealth claims that the PBS listing would have resulted in significant cost savings. Notably, the Full Federal Court held that the primary judge had not erred in its decision, including by drawing an adverse inference from the fact that the Government had not called the Apotex CEO to testify on whether he would have given Apotex the green light to launch its clopidogrel products at risk.[1]

The case highlights the significant challenges the Commonwealth faces in establishing that generic or biosimilar pharmaceuticals would have been listed on the PBS but for an injunction, in particular where the generic or biosimilar supplier settles, and does not claim damages at trial. In any future damages claim, the Commonwealth is likely to put forward stronger evidence that the generic/biosimilar supplier would have launched at risk, including subpoenaing evidence from various generic/biosimilar suppliers.

The decision also demonstrates that generic/biosimilar suppliers should unambiguously document their intention to launch to enable them to rely on a patentee's usual undertaking as to damages when the Court orders an injunction.

[1] An 'at risk' generic launch occurs when a manufacturer launches a generic pharmaceutical product prior to the expiry of the relevant patents for that product, without the approval of the patent holder.

Alkaloids of Australia hit with nearly AUD$2m fines over criminal cartel conduct

The ACCC's enforcement court action against Alkaloids of Australia (**Alkaloids**) has led to one of the most significant criminal cartel prosecutions in Australia since the introduction of criminal cartel laws in Australia in 2009. Australia appears to be the first of several international jurisdictions to finalise the prosecution of the relevant cartel, which involves a number of global pharmaceutical businesses. (The EC later imposed penalties, as discussed below.) The Alkaloids case is the fourth criminal cartel case brought by the ACCC that has been resolved by guilty pleas, and the first in which a guilty plea has been entered by an individual in addition to a corporate defendant.

By way of brief background, in November 2021, Alkaloids and its former export manager pleaded guilty to three cartel charges, and admitted a further seven charges of price fixing, bid rigging and market allocation offences with other overseas pharmaceutical ingredient suppliers, including in Switzerland, Brazil, and India. In November 2022, the Federal Court of Australia convicted and fined Alkaloids almost AUD$2 million for cartel arrangements over the production and supply of generic scopolamine N-butylbromide (**SNBB**). Alkaloids' former manager was sentenced to 32 months' imprisonment to be served by way of 400 hours of community service, fined AU$50,000 and disqualified from managing a company for five years.

The penalty imposed and the successful prosecution is a timely reminder that recent reforms to the CCA, which came into effect on 10 November 2022, have increased the maximum penalties for cartel (and other anti-competitive contraventions) five-fold. For corporations, the maximum civil penalty or criminal fine per cartel contravention/offence now is the greater of: (i) AUD$50 million (previously AUD$10 million); (ii) three times the total value of the benefits that have been obtained by one or more persons that are “reasonably attributable” to the conduct; or (iii) if the court cannot determine the total value of those benefits, 30% of the adjusted turnover of the corporate group during the period the contravention occurred, with a minimum period of 12 months (previously 10% of annual turnover for the 12 months preceding the contravention).

For individuals, the maximum civil penalties have increased to AUD$2.5 million per contravention. The maximum criminal sanctions remain unchanged at up to AUD$626,000, 10 years’ imprisonment, or both.

China

SAMR unprecedentedly imposes conditions on a below-threshold pharmaceutical deal

The State Administration for Market Regulation (**SAMR**) conditionally approved Simcere Pharmaceutical Co., Ltd.'s (**Simcere**) acquisition of Beijing Tobishi Pharmaceutical Co., Ltd. (**Tobishi**), marking the first ever conditional clearance of a below-threshold deal in China. Both parties voluntarily submitted the transaction to SAMR soon after the release of the amended Anti-Monopoly Law, which empowers SAMR to call in below-threshold transactions.

Simcere is the exclusive distributor of the batroxobin concentrate active pharmaceutical ingredient (**Batroxobin API**) in China as a result of an exclusive supply agreement with the sole global manufacturer of the Batroxobin API, DSM, entered into in 2019. Tobishi is active in the downstream market of Batroxobin injections that primarily treats sudden hearing loss, with a 100% market share in China. In addition to the vertical overlap, there is a potential horizontal overlap between the parties as Simcere has been developing a Batroxobin injection. SAMR was concerned that the transaction could disincentivise Simcere from its planned entrance of the Batroxobin injection market, and incentivise Simcere to engage in input foreclosure, in particular, since Simcere was penalised by SAMR in 2021 due to its refusal to deal with Tobishi on the Batroxobin API from 2019 to 2020.

To address the competition concerns, SAMR imposed six-year hybrid conditions requiring the parties to: (i) terminate the exclusive supply agreement between Simcere and DSM in China; (ii) divest Simcere's research and development business associated with the Batroxobin injection, and ensure the supply of the Batroxobin API to the divestiture buyer (including necessary assistance to directly connect the buyer with DSM); (iii) lower the end price of Batroxobin injections by at least 20%; (iv) ensure adequate supply of Batroxobin injections commonly used in clinical practice; and (v) if it failed to timely terminate the DSM agreement or complete the proposed divestiture (including the buyer failing to complete the research and development in time), lower the end price of Batroxobin injections by at least 50%.

EUROPE

European Union

EC takes first cartel decision in the pharmaceutical sector and in relation to an active pharmaceutical ingredient

The EC has fined pharmaceutical companies €13.4 million for participating in a cartel concerning SNBB, which was also the subject of an Australian criminal cartel case mentioned above. The EC found that the six companies involved had coordinated and agreed to fix the minimum sales price of SNBB to distributors and generic drug manufacturers, allocated quotas, and exchanged commercially sensitive information. The companies covered by the decision are Alkaloids of Australia, Alkaloids Corporation, Boehringer, C2 PHARMA, Linnea and Transo-Pharm.

Boehringer received the largest fine of €10.4 million. Three companies benefitted from fine reductions through applications under the EC's leniency programme. C2 PHARMA was not fined as it revealed the cartel to the EC. Transo-Pharm received a 50% fine reduction and Linnea a 30% fine reduction for cooperation with the EC after unannounced inspections. In addition, the EC reduced all companies' fines by 10% for acknowledging their participation in the cartel and settling under the Settlement Notice.

A seventh company, Alchem, decided not to settle and remains under investigation by the EC under the standard cartel procedure.

European General Court upholds the EC's decision that Teva and Cephalon's modafinil patent settlement agreement restricted competition

The European General Court has upheld the EC's 2020 decision, which fined Teva and Cephalon a combined €60.5 million for their patent settlement agreement relating to modafinil, which is used to treat sleep disorders.

The case centres on a 2005 agreement between the parties to settle their patent dispute over modafinil. By 2005, Cephalon's main modafinil patents had expired, and Teva was working to launch its own generic modafinil (and had started UK sales). Cephalon sued to block Teva's entry based on secondary patents that were still valid. The companies resolved the dispute through a settlement agreement, which included that Teva would be able to launch modafinil three years before the expiry of the secondary patents' expiry date (i.e., October 2012) under a license from Cephalon. Prior to that date, Teva agreed not to launch its generic modafinil or to challenge Cephalon's modafinil patents.

Concomitantly to settling their dispute on modafinil, Teva and Cephalon agreed on certain business transactions. Teva was appointed as Cephalon's exclusive distributor of modafinil in the UK for five years; and Cephalon acquired Teva's licence for its modafinil production patents, agreed to purchase modafinil API from Teva, granted Teva access to clinical and safety data to a drug unrelated to modafinil, and agreed to make payments to Teva in recognition of Cephalon's avoided costs resulting from the settlement. Ultimately, Teva did not enter under the licence because it acquired Cephalon in October 2011. This acquisition was approved by the EC, subject to the divestiture of Cephalon’s generic modafinil pipeline product and related rights.

The EC found that the settlement agreement infringed Article 101 because it delayed the entry of Teva (the most advanced potential generic modafinil player at the time) in exchange for value transfers from Cephalon. The EC concluded that, without the settlement agreement, Teva could have entered with generic modafinil earlier which could have resulted in lower prices.

The General Court upheld the EC's finding that the settlement agreement restricted competition by object and by effect. In assessing whether the agreement restricted competition by object, the General Court provided its interpretation of the test outlined by the Court of Justice in *Paroxetine*. The Court concluded that the sole purpose of the settlement agreement was to induce Teva to the non-compete and non-challenge clauses in the settlement agreement, rejecting the parties' alternative explanations. The Court further upheld the EC's conclusion that the settlement agreement and side deals were part of a single contractual framework, the net benefit of which was sufficiently large to have incentivised Teva from delaying its entry to compete against Cephalon in modafinil.

The General Court also rejected the parties' argument that the settlement agreement had pro-competitive effects, including that the agreement allowed Teva had entered earlier that it would otherwise have done. The Court viewed Teva's early entry as not being *pro-competitive* early entry, but rather *contractually* agreed entry, and only early in the sense that it took place before patent expiry. In particular, the General Court considered that the fact that the EC had decided, in its merger control review of the acquisition of Cephalon by Teva, that the license

obtained from Cephalon made Teva "*the most likely competitive constraint on Cephalon at least in the period from October 2012 to October 2015*", which led to the acquisition requiring the divestment of the generic modafinil pipeline product, did not mean that the agreement had procompetitive effects.

The Court also rejected the parties' challenges to the EC's finding that the agreement restricted competition by effect, that the agreement did not fulfil the conditions for exemption under Article 101(3), and to the EC's approach to calculating the fines.

EC orders Illumina to divest GRAIL and fines both companies for gun-jumping

In the latest chapter in the *Illumina / GRAIL* saga, in October 2023 the EC ordered Illumina to unwind its acquisition of GRAIL, which develops blood-based cancer tests based on genomic sequencing and data science tools. Illumina has twelve months to divest GRAIL, with the possibility of a three-month extension, and is allowed to explore different sale structures. Illumina will be permitted to retain a stake in GRAIL of up to 14.5% and to re-establish its previous royalty arrangement with GRAIL. The EC also imposed transitional measures requiring Illumina to hold GRAIL separate and to maintain its viability until the divestiture takes place, replacing the interim measures which the EC ordered previously.

Illumina maintains that the EC does not have jurisdiction over the deal. Its appeal of the European General Court's judgment upholding the EC's decision to accept jurisdiction following a referral under Article 22 of the EU Merger Regulation is pending before the Court of Justice. If Illumina were to win that challenge, the basis for the EC's divestiture order would fall away.

Also in this case, in July 2023 the EC fined Illumina for gun-jumping by closing its acquisition of GRAIL in August 2021 while the EC's merger control investigation was ongoing. The EC rejected Illumina's arguments that it had not jumped the regulatory gun, including because it held GRAIL as a separate and independent unit. The EC imposed the maximum possible fine on Illumina of 10% of its worldwide group turnover (a fine of €432 million) and fined GRAIL a symbolic €1000 for playing an active role in the infringement. This is the first time that the EC has fined a target company for gun-jumping. Illumina has appealed the EC's gun-jumping decision to the General Court.

Illumina also has appeals pending before the General Court of the EC's decisions to block its acquisition of GRAIL and to impose interim measures. In the US, Illumina has appealed to the Fifth Circuit after the FTC Commissioners overruled the initial administrative law judge decision, which found for Illumina. Both the FTC and Illumina provided briefs to the Fifth Circuit explaining that the EU order has no impact on the US appeal.

Unannounced inspections are on the rise, including in the healthcare and life sciences sector

The EC and national competition authorities have carried out various unannounced inspections as part of investigations into suspected anticompetitive practices, including an inspection at the premises of a cardiovascular device

company (Edwards Lifesciences) in September in the context of an alleged abuse of a dominant position.

Competition authorities have been active in unannounced inspections in recent months after these were largely suspended during the Covid-19 pandemic. The EC has indicated that the volume of documents it is obtaining during dawn raids is increasing as more data and documents are stored on the cloud. Authorities are also stating that they are more likely than previously to use powers to inspect private premises due to employees working remotely and storing data and documents at home.

Germany

German medical-aids association ends joint surcharges after antitrust intervention

According to an official statement by the German Federal Cartel Office (**FCO**), the working group of German medical aids providers (referred to as ARGE) will no longer impose joint surcharges on healthcare insurers that exceed the permissible level of cooperation between providers of medical aids. This is as a result of an FCO investigation that resulted in the dissolution of ARGE.

Under German law, providers of medical aids, such as medical supply stores, orthopaedic technicians, and others, are allowed to form national associations to collectively negotiate with healthcare insurers regarding the provision of medical aids to patients. This exemption from antitrust law is guaranteed under German social law and is aimed at ensuring the effective provision of medical aids throughout Germany.

Under this exemption, the German Association for Orthopaedic-Technology, EGROH, CURA-SAN, rehaVital, Reha-Service-Ring, and Saitätshaus Aktuellf formed ARGE, which represented around 80% of the relevant medical supply stores, acted as a quasi-monopolist in collective those negotiations.

Beginning no later than September 2021, ARGE members demanded – in many cases successfully – uniform price increases from healthcare insurers for their products and services under existing supply contracts. The ARGE members justified these with the cost-related effects of the Covid-19 pandemic (e.g., increased freight, supply, and raw material costs).

The FCO rejected ARGE's justification, as the price increases were demanded for practically all products and services offered, without any objective differentiation. While cooperation is legally possible in the medical aids sector, the law does not allow for a situation where all relevant medical aid providers coordinate their conduct to such an extent that effective competition comes to a complete standstill. The FCO therefore assumed that ARGE's conduct constitutes both a violation of the ban on cartels, and an abuse of the dominant position on the market.

Thus, the FCO initiated a cartel administrative procedure in March 2022 and, in January 2023, sent a statement of objections to the ARGE members. Subsequently, the parties dissolved ARGE. The affected contracts have since been terminated or nullified, and the parties have committed to refraining from the behaviour at issue in the future. The commitments presented by the parties were

accepted by the FCO, and made legally binding, leading to the conclusion of the proceedings.

Netherlands

Leadiant's €19.6 million fine reduced to €17 million: ACM revises decision on market abuse claims

In July 2021, the Dutch Authority for Consumers and Markets (**ACM**) imposed a fine of €19.6 million on the pharmaceutical company Leadiant. The ACM ruled that Leadiant abused its dominant position in the Netherlands by charging an excessive price for its drug, CDCA-Leadiant, during the period from June 2017 to December 2019. Leadiant filed an administrative objection against this decision, with the aim of having the fine completely waived. According to Leadiant, the ACM *inter alia* made errors in its description of the market dynamics and the products sold by Leadiant. Leadiant also contested the ACM's market definition, asserting that it neither held nor abused a dominant position on such market.

The ACM largely dismissed these objections in its decision on objection dated 22 June 2023. It rejected Leadiant's claim of a collective boycott by health insurers, which the company said had prevented it from negotiating the price. The ACM also dismissed Leadiant's argument that the predecessors of CDCA-Leadiant were incorrectly classified as the same product, leading to an unfair price comparison. The ACM maintained that the drugs, due to their high similarity and the use of the same active ingredient, should be considered as the same product. This stance leaves Leadiant's price of €14,000 – a stark contrast to the €46 price tag of the same drug in 2009 – unexplained; it could only be that this was as the result of an abuse of a dominant position.

However, the ACM found Leadiant's objection to market definition to be well-founded. The ACM noted that the pharmaceutically compounded CDCA, as offered in the Netherlands from April 2018 to July 2018, belongs to the same relevant product market. In this four-month period, a majority of CTX patients in the Netherlands first switched from the drug CDCA-Leadiant to the magisterial preparation and then, after the Amsterdam UMC stopped the deliveries of this pharmacy preparation, back to the CDCA-Leadiant. During this period, Leadiant could therefore not demand the high price for CDCA-Leadiant without consequence and, as a result, temporarily did not have a dominant position on the relevant market.

Given the shorter period of the infringement, the ACM reduced the fine to €17 million. The ACM dismissed any further objections regarding the criteria for determining the abuse and the excessive nature of Leadiant's pricing, as well as several procedural objections.

United Kingdom

UK Competition Appeal Tribunal (Tribunal) hands down judgments in two excessive pricing cases in the pharmaceutical sector

The Tribunal published two judgments on appeals against decisions by the CMA relating to excessive pricing in the pharmaceutical sector. The first judgment related to the CMA's decision that found that Advanz charged excessive and unfair pricing for liothyronine tablets. The Tribunal upheld the CMA's findings,

dismissing the appellants' arguments, including that the prices were not unfair when compared to the prices charged for liothyronine tablets under conditions of competition five years after multiple competitors entered the market. However, the Tribunal found that the penalties imposed by the CMA were too high, and the Tribunal reduced the penalties from c. £101m to £84.2m, with one appellant's fine being reduced from £51.9m to £37.1m.

The second judgment related to the CMA's decision that found that certain companies charged excessive and unfair prices for hydrocortisone tablets. As with the previous case, the Tribunal upheld the CMA's findings. However, in doing so, the Tribunal made significant criticisms of the CMA's approach to market definition and also put forward a new test for the test for unfair and excessive pricing. In particular, for market definition, the Tribunal examined the market from the perspective of a hypothetical customer with the combined perspective of an end consumer, a pharmacist, and a prescribing doctor. The Tribunal also set out three categories of cases where prices may exceed costs; the first being where there is relative inefficiency amongst sellers, and the efficient seller is able to sell above its costs. The second is where the seller created additional value through the prevision of distinctive value. The third is where the seller obtains additional profits without adding value to customers. The Tribunal found that prices in cases 1 and 2 could be justified. However, case 3 prices tend to be excessive and unfair; the Tribunal found that the prices charged in this case were case 3 prices, and were excessive and unfair.

Continued focus by the CMA on mergers in the healthcare sector

The CMA has recently investigated three healthcare merger cases: *Cochlear / Oticon Medical, Bestway / Lexon and Asurex*, and *UnitedHealth / EMIS*. The cases suggest that the CMA is looking to act with some predictability and proportionality; the theories of harm examined are not novel. While remedies were required in the two cases that reached decisions, none of the cases resulted in total prohibitions; *UnitedHealth / EMIS* was cleared unconditionally.

In *Cochlear / Oticon Medical*, the acquirer, Cochlear, is active in the manufacture and supply of hearing devices, including bone conduction solutions (**BCS**). The seller was active in developing, manufacturing, and supplying hearing implants, including BCS, through Oticon Medical, the Target. The CMA's found that, for the supply of BCSs, the merger was a '3-to-2' and that it would be expected to lead to a reduction in choice, quality, and innovation, and increased prices. In doing so, the CMA took a narrow approach to defining the market, excluding other hearing solutions from the frame of reference. The CMA also relied on a potential competition theory of harm to find that the parties would become closer competitors in the Active BCS segment. The CMA therefore prohibited the acquisition of the BCS business, but allowed the remainder of the transaction to proceed.

Bestway / Lexon and Asurex was primarily a pharmacy case. In this case, the CMA engaged in a familiar local area analysis, and kept reasonably faithful to its approach and findings in the 2016 case of *Celesio / Sainsburys*. This included limiting its analysis to retail pharmacies and using the catchment areas adopted in *Celesio / Sainsburys* (ranging from 1.4 miles to 3.6 miles). The CMA filtered the resulting local areas to identify areas where, broadly speaking, the parties had a

combined 30% or 35% share of supply, with an increment of 5% from the merger. The CMA applied a decision rule that provisionally found issues in the identified areas – 12 local areas arose. To remedy this, Bestway has undertaken to sell seven of its own pharmacies to pre-approved purchasers.

In *UnitedHealth / EMIS*, EMIS, the Target, is active in IT healthcare solutions, including primary care electronic patient record (**EPR**) systems via its EMIS Web brand. EMIS Web allows GPs to manage appointment bookings, conduct patient consultations, and update, store, and share patient records. At the GP level, the acquirer, UnitedHealth, offers medicines optimisation (**MO**) software via ScriptSwitch (i.e. software to ensure prescriptions are effective and cheap to the NHS) and population health management services (which use data analytics to improve health outcomes). There was only one other company, First Databank (**FDB**), that provided such MO software. Both ScriptSwitch and FDB's MO software integrates with the primary care EPR systems so that they can provide GP users with prescribing recommendations. Following a full, in depth phase II review, the CMA found that the merger would not lead to the parties limiting competitors' access to EMIS Web's systems, since any foreclosure strategy would not be profitable and would also be in part prevented by the NHS's rules and standards.

For further information on these cases, please see our dedicated briefing here.

AMERICAS

United States

FTC Sues Private Equity Firm for Alleged Anticompetitive Consolidation in Anaesthesiology Practices

In *FTC v. U.S. Anesthesia Partners, Inc.*, the FTC filed suit against Anesthesia Partners (**USAP**) and Welsh, Carson, Anderson & Stowe (**WCAS**) in the Southern District of Texas for allegedly executing an anticompetitive strategy to monopolize anesthesiology practices in Texas. The FTC claims that USAP and WCAS engaged in a three-prong scheme to control the market by rolling up anesthesia practices, entering price-setting arrangements with other anesthesia practices, and allocating the market with another provider, all of which led to higher prices for in-hospital delivered anesthesia services. This is the first major case brought under Section 5 of the FTC Act, under which the agency can pursue enforcement against activities that tend to bring about anticompetitive harms, "*but individually may not have violated the antitrust laws.*"[2] The challenge also directly implicates draft Merger Guideline 9, which states that the DOJ and FTC will scrutinize serial acquisitions in the same industry that may lead to market concentration.

For further information on this case, please see our dedicated briefing here.

Louisiana Hospital Merger is Exempt from FTC Review pursuant to the State's Certificate of Public Advantage

In an order granting summary judgment to two hospital systems, Judge Lance M. Africk of the U.S. District Court for the Eastern District of Louisiana held that the parties in a hospital merger did not need to report their $150 million transaction to

[2] https://www.ftc.gov/system/files/ftc_gov/pdf/P221202Section5PolicyStatement.pdf at 12.

the FTC under the Hart-Scott Rodino Act because state statutory approval (referred to as a Certificate of Public Advantage or **COPA**) exempts the deal from federal antitrust law.[3] While the immediate effects of the summary judgment are local in scope, the matter is a broader win for state action doctrine, which shields from federal antitrust laws activity that is regulated and actively supervised by the state. For states with enacted healthcare COPA statutes, this victory may provide a blueprint for exempting future healthcare-related transactions from FTC and DOJ scrutiny.

FTC Accepts a Major Behavioural Remedy in Amgen/Horizon

On September 1, 2023, after filing for a preliminary injunction in federal court to block the transaction but before the case proceeded to a hearing before a federal judge, the FTC announced a settlement with Amgen Inc. over its $27.8 billion acquisition of Horizon Therapeutics. Under the proposed order, Amgen is prohibited from bundling the two acquired products (Tepezza and Krystexxa) with any other product, using any rebate or contract term that may exclude or disadvantage products that would compete with Tepezza and Krystexxa, and must seek prior approval for future acquisitions in the markets for thyroid eye disease or chronic refractory gout treatments for a 15-year term. This is the current administration's first major behavioural remedy in the pharmaceutical sector.

The FTC's challenge to the December 2022 deal confounded the antitrust community over its novel use of portfolio leverage and cross-market bundles for a matter where there were serious questions as to whether the FTC's bundling theory was even viable given the nature of the products and customer bases at issue.

[3] https://www.law360.com/competition/articles/1726538/court-finds-la-hospital-merger-exempt-from-ftc-review

CLIFFORD
CHANCE

CONTACTS

APAC

Yong Bai
Partner, Beijing

T +86 10 6535 2286
E yong.bai
@cliffordchance.com

Elizabeth Richmond
Partner, Sydney

T +61 2 9947 8011
E elizabeth.richmond
@cliffordchance.com

Mark Grime
Counsel, Sydney

T +61 2 8922 8072
E mark.grime
@cliffordchance.com

Zibo Liu
Counsel, Beijing

T +86 10 6535 4925
E zibo.liu
@cliffordchance.com

Angel Fu
Senior Associate, Sydney

T +61 2 8922 8089
E angel.fu
@cliffordchance.com

Damian Bachor
Associate, Sydney

T +61 2 8922 8079
E damian.bachor
@cliffordchance.com

Michael Yan
Associate, Beijing

T +86 10 6535 2243
E michael.yan
@cliffordchance.com

Dayu Man
Foreign Legal Counsel,
Hong Kong

T +852 2826 3467
E dayu.man
@cliffordchance.com

EUROPE

Sue Hinchliffe
Partner, London

T +44 207006 1378
E sue.hinchliffe
@cliffordchance.com

Dr. Dimitri Slobodenjuk
Partner, Düsseldorf

T +49 211 4355 5315
E dimitri.slobodenjuk
@cliffordchance.com

Torsten Syrbe
Partner, Düsseldorf

T +49 211 4355 5120
E torsten.syrbe
@cliffordchance.com

David Tayar
Partner, Paris

T +33 1 4405 5422
E david.tayar
@cliffordchance.com

Luke Tolaini
Partner, London

T +44 207006 4666
E luke.tolaini
@cliffordchance.com

Katharine Missenden
Counsel, Brussels

T +32 2 533 5913
E katharine.missenden
@cliffordchance.com

Dr. Ulrich A. Pfeffer
Counsel, Düsseldorf

T +49 211 4355 5455
E ulrich.pfeffer
@cliffordchance.com

Caroline Scholke
Counsel, Düsseldorf

T +49 211 4355 5311
E caroline.scholke
@cliffordchance.com

Anne Filzmoser
Senior Associate,
Düsseldorf

T +49 211 4355 5308
E anne.filzmoser
@cliffordchance.com

Ben Jasper
Senior Associate,
London

T +44 207006 8092
E ben.jasper
@cliffordchance.com

Jurre Jurriëns
Senior Associate,
Amsterdam

T +31 20 711 9536
E jurre.jurriens
@cliffordchance.com

Nissim Massarano
Senior Associate,
London

T +44 207006 2244
E nissim.massarano
@cliffordchance.com

Sara Ortoli
Avocat, Paris

T +33 1 4405 5130
E sara.ortoli
@cliffordchance.com

AMERICAS

William Lavery
Partner, Washington DC

T +1 202 912 5018
E william.lavery
@cliffordchance.com

Peter Mucchetti
Partner, Washington DC

T +1 202 912 5053
E peter.mucchetti
@cliffordchance.com

Leigh Oliver
Partner, Washington DC

T +1 202 912 5933
E leigh.oliver
@cliffordchance.com

Danielle Morello
Associate, Washington DC

T +1 202 912 5088
E danielle.morello
@cliffordchance.com

Elyssa Wenzel
Associate, Washington DC

T +1 202 912 5975
E elyssa.wenzel
@cliffordchance.com