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Life Sciences ...Still in the Antitrust Spotlight

Over the last few years, the UK and EU competition authorities have continued to closely scrutinise the life sciences sector, investigating numerous different anticompetitive practices – including excessive pricing, illegal information exchange and market sharing arrangements, sometimes resulting in the disqualification of directors. There has been continued scrutiny of pay for delay agreements, leading to the issue of substantial fines, as well as a focus on mergers in this sector resulting in high-profile prohibitions by the authorities and abandonments of deals by the parties. This note summarises some of the key antitrust developments in the sector under UK and EU competition law.

Excessive Pricing

As a couple of recent cases highlight, the UK's Competition & Markets Authority ("**CMA**") has stepped up its enforcement activity against pharmaceutical companies accused of breaching competition law by charging excessive prices for generic drugs.

A bitter pill to swallow? CMA gets tough on pharmaceutical companies

Hydrocortisone tablets

On 15 July 2021, the CMA announced that it had imposed fines of over £260 million on a number of companies for breaches relating to the supply of hydrocortisone tablets, used to treat adrenal insufficiency.

The CMA found that two companies, Auden Mckenzie (Pharma Division) ("**Auden**") and Actavis UK (now known as Accord-UK ("**Accord**")) charged the NHS excessively high prices for hydrocortisone tablets for almost a decade. During this time, prices for the drug rose by over 10,000% (i.e. an increase from 70p per 10mg pack in April 2008 to £88 by March 2016). Auden sold hydrocortisone tablets between 2008 and 2015, at which point Actavis UK took over the business.

Further, in order to protect its position as the sole provider of 10mg and 20mg hydrocortisone tablets in the UK, and thus be able to maintain price increases, Auden paid potential competitors AMCo (now known as Advanz Pharma) and Waymade £21 million and £1.8 million respectively not to enter the market between 2011 and 2015. When Actavis UK took over sales of hydrocortisone tablets in 2015, it continued to pay AMCo.

Accord (as well as its parent companies and former parent company Allergan for their respective ownership periods) has been fined £155 million for excessive and unfair pricing. In addition, Accord (and Allergan) has been fined a further £66 million for its market-sharing agreements with Waymade and AMCo. Advanz Pharma (and its former parent Cinven) and Waymade have been fined £43 million and £2.5 million respectively for their participation in the market-sharing agreements. Waymade's small fine reflects the fact that it was only party to the agreement in respect of 10mg hydrocortisone tablets, and even then only for a short period before it sold its 10mg business to Cinven and AMCo took its place.

It is yet to be seen whether the NHS will bring damages claims against any of the companies for their conduct. Auden, Accord and the other companies involved continue to dispute the fines handed down to them, however, submitting an appeal to the UK's Competition Appeal Tribunal ("**CAT**") on 6 October 2021. Auden and Accord contend that the CMA was incorrect in its market definition, in its assessments of dominance and abuse, and in its finding of a 'by object' infringement. They have therefore suggested the fine should be revoked, or substantially reduced.

Phenytoin sodium capsules

Subsequently, on 5 August 2021, the CMA issued a Statement of Objections ("**SO**") against pharmaceutical companies Pfizer and Flynn, provisionally finding that they had breached competition law by charging excessive prices for

phenytoin capsules, used to treat epilepsy. The CMA alleges that the companies exploited a loophole by de-branding the drug, meaning that it was no longer subject to price regulation in the way that branded drugs are.

For over four years, Pfizer's prices for the drug were between 780% and 1,600% higher than previously. Pfizer then supplied the drug to Flynn, which sold it at prices between 2,300% and 2,600% higher than previously. Between 2012 and 2013 the price of 100mg packs of phenytoin rose from £2.83 to £67.50. The prices charged in the UK were also many times higher than Pfizer's prices for the same drug in every other European country where it sold capsules.

The CMA's SO is the latest round in a long-running fight between the CMA and the companies. Pfizer and Flynn were originally fined £84.2 million and £5.2 million respectively by the CMA in 2016 for the same conduct, but the companies appealed this decision to the CAT and in 2018 the CAT held that the CMA had not correctly applied the legal test to prove that Pfizer and Flynn's behaviour amounted to an abuse of their dominant market position, remitting this to the CMA for reinvestigation. The CMA and Flynn then appealed this decision to the Court of Appeal, which in 2020 dismissed Flynn's appeal and upheld part of the CMA's appeal in relation to calculations used to determine whether or not prices charged were excessive. However, the Court of Appeal ruled that other elements of the abuse finding should still be remitted to the CMA for reconsideration.

It is this remittal that has now led to the CMA's latest SO. Both Pfizer and Flynn will have an opportunity to respond formally to the CMA's SO before it issues its final decision.

Market Sharing and Illegal Information Sharing

CMA issues £3.4 million in fines and secures director disqualification over the supply of antidepressant

Resulting from a long-running investigation opened in October 2017, the CMA announced on 4 March 2020 that it had issued two separate infringement decisions against four pharmaceutical companies amounting to over £3.4 million, as well as a payment of £1 million to the National Health Service ("**NHS**") and the disqualification of a director.[1]

The first infringement decision, which related to market sharing, found that King Pharmaceuticals Ltd ("**King**") and Auden shared between them the supply of nortriptyline to a large pharmaceutical wholesaler. The two companies engaged in the concerned action of agreeing between themselves to supply 25mg and 10mg of the anti-depressant tablets respectively between September 2014 and May 2015. Consequently, the CMA has fined King £75,573. Accord-UK Ltd, which has since taken over Auden's nortriptyline business, was fined £1,882,238. The CMA has also secured that King and Accord-UK Ltd will make a £1 million payment to the NHS in conjunction with the aforementioned fines.

The second of the two investigations related to illegal information sharing between King, Lexon (UK) Ltd ("**Lexon**") and Alissa Healthcare Research Ltd ("**Alissa**"). The CMA found that the three companies were colluding between 2015 and 2017, at a time when the cost of nortriptyline was falling, by exchanging information as to the price and volume at which the King and Lexon were selling the drug at and Alissa's plans to enter the market. King and Alissa were fined £75,573 and £174,912 respectively, having admitted in September 2019 to an illegal information exchange. King's and Alissa's fines were reduced to reflect their cooperation and admission of breaking the law. Lexon, however, did not admit breaching competition law and, as a result, received a much higher fine of £1,220,383.

In addition, a director at King, Dr Philip Hallwood, who was involved in the conduct of the former's illegal activity through a separate consultancy firm of which he was sole director, has signed a legally binding undertaking which prevents him from taking on a leadership or management role at any company for a period of seven years.

The CMA has had the pharmaceutical sector firmly on its radar in recent times. It has recently taken

[1] See Over £3m in fines and £1m for NHS in CMA pharma probe - GOV.UK (www.gov.uk)

competition law enforcement action in relation to the supply of liothyronine tablets and fludrocortisone. It also has a number of other competition cases ongoing in the pharmaceutical sector, including in respect of the supply of prochlorperazine, and has recently closed its investigation into the supply of the antibiotic Nitrofurantoin.[2]

Misuse of Patent Procedures

European Commission investigates Teva for potential misuse of patent procedures

On 4 March 2021, the Commission announced that it was opening a formal abuse of dominance probe relating to the potential misuse of patent procedures and exclusionary disparagement of competing products in the pharmaceutical industry by Israeli company Teva Pharmaceuticals ("**Teva**"). Teva is suspected of unlawfully delaying the entry of medicines competing with its multiple sclerosis drug, Copaxone, through patent litigation. If proven, Teva's behaviour may amount to an abuse of a dominant position in a rare Commission investigation which serves as a caution to companies to ensure that their intellectual property strategies do not amount to breaches of the competition rules.

Teva is a global leader in the pharmaceutical industry which specialises in the development, production and marketing of generic drugs and speciality pharmaceuticals. The Commission began investigating the pharmaceutical company in October 2019 undertaking raids at Teva's subsidiaries in the EEA and carrying out inspections at the company's Brussels premises. The Commission is now looking to determine whether Teva had:

i. Abused its dominance by repeatedly filing and withdrawing divisional patent applications[3] relating to Copaxone, the company's best-selling drug; and

ii. Used a marketing campaign to discourage healthcare professionals from using its competitors' products containing 'glatiramer acetate' (the active ingredient in its competing Copaxone product).

The Commission's probe arose from concerns that:

- Following the expiration of Teva's basic patent for glatiramer acetate in 2015, Teva artificially extended the market exclusivity of Copaxone by strategically filing and withdrawing divisional patent applications;
- Teva's generics competitors who wished to enter the market would be obliged to file a new legal challenge each time the company filed a new divisional patent. Teva could withdraw the divisional patent in question and file a new application, meaning the generics competitor would need to recommence their legal challenge each time;
- The effect of Teva filing numerous divisional patent applications was multiplying the barriers to enter the market for its generics competitors, given that there would be several patents all deriving from the original 'parent' patent; and
- Teva's marketing campaign (aimed at healthcare institutions and professionals) created a "false perception" of health risks associated with its competitor's alternatives to Copaxone (despite public health authorities having approved their use). The Commission has informed Teva and other Member State competition authorities that it has opened proceedings. However, there is no further detail on the timetable of the investigation at this stage. Teva is cooperating with the Commission's probe, but the company opposes the accusations that it used abusive or anti-competitive practices in relation to Copaxone.

EU Competition Commissioner Margrethe Vestager stated that preserving competition in the market for drugs aimed at aiding multiple sclerosis patients is "paramount". Vestager emphasised that the "most important message" the Commission has for pharmaceutical companies is to "play by the book,

[2] Read more on these two cases here: Prochlorperazine and Nitrofurantoin.

[3] Divisional patent applications contain matter from a previously filed application (known as the 'parent' application). Multiple divisional patents can derive from the parent application, and further divisional patents can then derive from each of the previous divisional patents. This results in a large group of connected patents, often with overlapping inventions. This means that a competitor wishing to enter the market could be faced with the barrier of numerous patents that their product could be capable of infringing.

and we will make sure they are faced with fair competition".

This is not the first time Teva has been investigated for anti-competitive behaviour. In November 2020 the Commission investigated and subsequently fined the company €30.5 million after finding that it had agreed to delay the entry of a cheaper generic narcolepsy medicine in return for commercial side-agreements and cash payments from its rival Cephalon (which owned the branded version of the medicine).

In 2005, the Commission also fined AstraZeneca €60 million for misuse of the patent system, having determined that AstraZeneca had misled patent offices to extend its patent for its stomach ulcer drug Losec (once the world's bestselling medicine) by changing the drug from capsule to tablet form to renew the patent.

Pay for Delay

"Pay for delay" agreements highlight the tension between patent and competition laws

Over the last few years, clarity has been given to the legality of "pay for delay" arrangements under EU competition laws by the European Court of Justice ("**ECJ**") in two separate cases, both of which have been welcomed by the European Commission ("**Commission**") and the CMA. The ECJ first gave a landmark ruling in January 2020 concerning the Paroxetine case,[4] and the ruling was then followed in an opinion given in the Lundbeck case on 4 June 2020. Both cases have confirmed that "pay for delay" agreements may contravene the EU's competition laws.

"Pay for delay" agreements involve one pharmaceutical company which has developed a new medicine (the "**Originator**") agreeing to pay another pharmaceutical company which has developed (or is in the process of developing) an equivalent product to delay the launch of such product. These agreements are typically entered into once an Originator's patent in a new medicine has expired, which no longer affords them any legal recourse to prevent a competitor from launching a generic version of the medicine on the market. Clearly, Originators wish to avoid having to compete with generic manufacturers for as long as possible, as the availability of equivalent products to their own on the market inevitably lowers the price they can sell for and reduces their market share. As such, "pay for delay" agreements enable incumbent pharmaceutical companies to maximise their profits whilst rival pharmaceutical companies are provided with either a lump sum or a share in the former's profits (or both) as consideration for not entering the market.

"Pay for delay" agreements have been on the radar of competition authorities for many years, given the belief that they generally contradict both the prohibition on anti-competitive agreements and abuse of dominance. In 2009, the Commission published an inquiry report into the pharmaceutical sector in which the effect of "pay for delay" agreements featured prominently.[5]

The ECJ's ruling in January 2020 came about as a result of a reference from the CAT. The CAT had been hearing an appeal on the CMA's ruling in Paroxetine[6] in which fines of £44.99 million were imposed on GlaxoSmithKline plc ("**GSK**"), Generics (UK) Limited and others in relation to "pay for delay" agreements over the anti-depressant drug paroxetine.[7] The CMA found that the arrangement delayed the arrival of equivalent drugs to paroxetine on the UK market, which had the effect of artificially raising the price consumers faced for the drug. On hearing the appeal, the CAT referred a number of questions to the ECJ including: (i) whether generic manufacturers of medicines can be considered potential competitors; and (ii) whether the agreements constituted a restriction of competition by object and effect.

The ECJ found that "pay for delay" agreements would violate the prohibition on anticompetitive agreements "by effect" if there was a real and concrete possibility that a generic manufacturer would enter the market. This test will be satisfied so long as a generic manufacturer had the intention and

[4] Case C-307/18 Generics (UK) and others v CMA (Paroxetine).
[5] The European Commission. Pharmaceutical Sector Inquiry – Final Report. Published on 8 July 2009. Available at: https://ec.europa.eu/competition/sectors/pharmaceuticals/inquiry/staff_working_paper_part1.pdf

[6] Case CE-9531/11 – Paroxetine. The Competition and Markets Authority. Published on 12 February 2016. Available at: https://assets.publishing.service.gov.uk/media/57aaf65be5274a0f6c000054/ce9531-11-paroxetine-decision.pdf
[7] GSK marketed the paroxetine drug under the brand name "Seroxat".

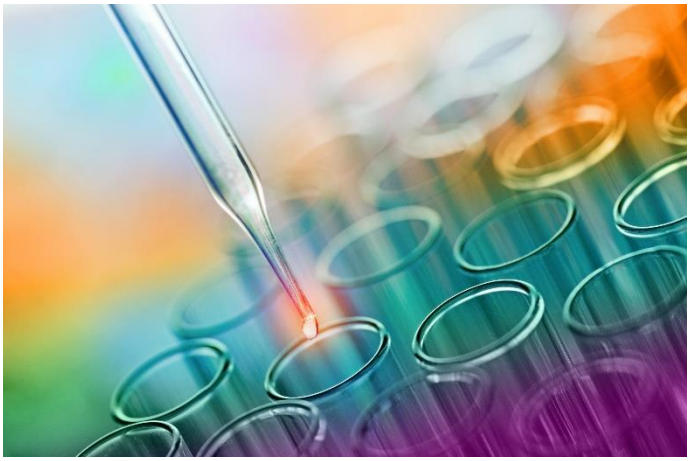
the wherewithal to enter the market with an equivalent product. The ECJ stopped short, however, of finding that "pay for delay" agreements should automatically be considered to constitute a restriction of competition "by object" (i.e. that they constitute a restriction of competition in and of themselves). Such a ruling would have significant implications, as infringements of competition by object do not require the usual burden of proof for regulators, as an infringement arises by default merely by entering into such agreements. A determination of whether "pay for delay" agreements constitute infringements of competition "by object" will need to be decided on the facts of each case.[8] Furthermore, the ECJ determined that "pay for delay" agreements could also amount to an abuse of dominance but that, again, this would need to be informed by the specific facts of each given case.

Separately, Advocate General Juliane Kokott – who gave the opinion in the CAT's reference from Paroxetine which underpinned the ECJ's ruling – also gave an additional opinion on 4 June 2020 in relation to the appeal made by Lundbeck Limited and H. Lundbeck A/S (together, "**Lundbeck**") over the €94 million fine imposed on it by the Commission over "pay for delay" agreements it entered into over the production of a medicine known as citalopram. In this opinion, too, Kokott reiterated the position of "pay for delay" agreements she had advanced in the Paroxetine reference and ruled that Lundbeck's appeal should be dismissed on the grounds that the agreements constituted a breach of the prohibition on anticompetitive agreement.

These rulings represent a cautionary tale to pharmaceutical companies contemplating entering into "pay for delay" agreements. Though it is prudent to take all steps necessary to protect patents, these rulings and opinions from the ECJ make it clear that companies should not go so far as to create barriers to entry and prevent generic products being available on the market. It is likely that the CMA – in the present COVID era when it is more important than ever for medicines to be widely available on the market for as competitive a price as possible – will take an even tougher approach in this area in the future.

Commission continued to show intolerance over "pay for delay" agreements with a €60.5 million fine

On 26 November 2020, the Commission fined Cephalon, Inc. ("**Cephalon**") and Teva Pharmaceutical Industries Ltd ("**Teva**") €30 million and €30.5 million respectively in relation to "pay for delay" agreements over the drug modafinil, a medicine used in the treatment of sleep disorders such as narcolepsy. Cephalon (who marketed the drug under the brand name "**Provigil**") entered into the agreement with Teva in 2005 whereby it agreed with the latter not to launch a generic version of the drug on the EEA market in exchange for a package of commercial side-deals and some cash payments. At the time, Teva held its own patents relating to modafinil's production process and was ready to launch its own generic version – indeed, it had already launched the product in the UK at a 50% discount price to Cephalon's own brand.



The Commission's fine stems from a long running investigation originating from Teva's acquisition of Cephalon in 2011 in a deal that was in fact reviewed and approved by the Commission. As part of its approval decision at the time, the Commission required Cephalon's "Provigil" drug to be divested given the identified overlap with Teva's own generic version of the drug. Helpfully, the merger approval decision, in addition to tipping off the Commission about the existence of the "pay for delay" agreement, also crystallised the period of infringement. Once Teva and Cephalon became (in effect) a single entity, this rendered a key term of the two companies' "pay for delay" agreement null and void, which had set out that Teva would be permitted to commence selling its generic version of modafinil in 2012 in exchange for royalty payments to Cephalon. As such, the merger between the two parties made it clear that the years of 2005 to 2011 constituted the period in which the EEA market was deprived of lower prices for the drug.

[8] The ECJ noted that a "pay for delay" agreement would only be an infringement of competition "by object" if there was no other explanation for the agreement "other than the commercial interest of both the holder of the patent and [the generic manufacturer] not to engage in competition". In other words, if they cannot be justified on any other grounds.

More broadly, the Commission confirmed in this case that consideration provided vis-à-vis "pay for delay" agreements need not be limited to lump sum payments. Rather, the various commercial side deals provided by Cephalon – which included a distribution agreement, the purchase of raw materials and the granting of access to clinical data – were sufficient to constitute an effective "value transfer". This will be an important precedent in future for pharmaceutical companies who may attempt to circumvent the rules in this area by providing alternative forms of consideration to competitors in exchange for their delayed entry into a given market. It is worth noting that the Commission has now issued fines in four separate investigations over "pay for delay" agreements. In addition to the fines issued against Teva and Cephalon over the modafinil drug, the Commission has also fined:

- The French pharmaceutical company Servier and five other generic manufacturers €427.7 million in 2014 over the blood pressure medicine perindopril;
- Johnson & Johnson and Novartis €16 million in 2013 over the painkiller fentanyl; and
- The Danish company Lundbeck and other generic producers €93 million in 2014 over the antidepressant drug citalopram.

Both Teva and Cephalon have since appealed the Commission's decision to the General Court, requesting in their action of 5 February 2021 that the Commission's decision is annulled entirely or that the fine is substantially reduced. In particular, the parties have claimed that the Commission was mistaken in its characterisation of the agreement as a restriction of competition by object and effect, and in its application of Article 101(3) TFEU. The Commission is yet to publish a response to the appeal, although if the ECJ's treatment of the appeal by Lundbeck against their fine is anything to go by, when all appeals were dismissed, Teva and Cephalon's chances of success seem slim.

CAT reduces fines imposed by the CMA on drug makers and annuls fine against GSK for abuse of dominance, despite upholding pay-for-delay decision

As mentioned above, the ECJ ruled on a number of questions which had been referred to it by the CAT regarding an appeal brought by GSK, Generics UK and Alpharma to the CAT in relation to the CMA's fine of £44.99 million imposed against the companies in relation to pay-for-delay agreements. On 10 May 2021 the CAT published its decision upholding the ECJ's decision (which confirmed that competition can exist between the holder of a pharmaceutical patent and generic drug makers that are in a patent dispute) and supporting the CMA's 2016 infringement decision against GSK, Generics UK and Alpharma. However, the CAT reduced the fines imposed by the CMA by £27.1 million due to the uncertainty of the law at the time and the novelty of the case. In addition, in a significant win for GSK, the CAT completely annulled the CMA's fine on GSK for abuse of dominance. The case is a relatively rare example of a well strategized appeal with a clearly successful outcome for the appealing parties.

In this instance, GSK held the patent for the active ingredient in the antidepressant tablet paroxetine, and the pay-for-delay agreements dated back to early 2000 when GSK brought patent infringement proceedings against generic drug makers IVAX Pharmaceuticals, Generics UK and Alpharma. GSK subsequently reached settlements with those drug makers enforced between 2001 – 2004 under which it agreed to pay the pharmaceutical companies not to enter the UK paroxetine market with their own products. As a result, the companies delayed the launch of equivalent drugs to paroxetine on the UK market, thereby artificially increasing the price of the drugs for consumers.

In 2016, the CMA found that GSK had abused its dominant position in the market for paroxetine, and also fined GSK, Generics UK and Alpharma for entering into the pay-for-delay agreements. Subsequently, the companies appealed against the CMA's infringement decision to the CAT.

On 10 May 2021, the CAT issued its judgment on the remaining issues it was to determine.

i. <u>Reduction in Pay-For-Delay Fines</u>

Noting the criteria set out by the ECJ, the CAT rejected the appellants' argument that Generics UK and Alpharma were not potential competitors to GSK in the UK market for the supply of paroxetine. In particular, the CAT found that Generics UK did not dispute it had both the ability and firm intention to enter the market had it not been restrained by GSK; and the CAT rejected Alpharma's arguments that it did not have a 'firm intention' to enter.

Additionally, the CAT also noted that the ECJ ruled that a settlement agreement where a generic challenger had agreed to abandon entry to the market and not to challenge the patent could constitute a 'by-object restriction' of competition rules. In other words, one of the most serious breaches of the competition rules and each agreement in this case was, 'in principle' such a restriction by object.

Importantly, however, the CAT considered that the CMA's determination of the penalties was 'flawed' for

the following reasons and as a result, reduced those penalties:

- At the time of the pay-for-delay agreements, there had been no finding that agreements of this kind infringed EU or UK competition laws (noting that their consideration was also uncertain in the US);
- There was no suggestion that any of the parties entered into further agreements of this kind since the opening of the investigation; and
- The CMA had 'failed' to 'reflect sufficiently' the effect of the 'very substantial passage of time' between the infringing arrangements (early 2000s) and the start of the CMA's investigation (2011), which did not involve the companies until 2013. As well, the CMA observed that the appellants no longer had access to many of the relevant documents and that their witnesses' recollections were also affected, all of which impacted their defence.

ii. Annulment of GSK's Abuse of Dominance Fine

In response to the CMA's finding of abuse of dominance against GSK, GSK had argued on appeal that it could not reasonably have been aware in the early 2000s that it held a dominant position in the market. However, the CAT found that GSK should have known that paroxetine was a distinct product market in which it had substantial market power

The annulment of GSK's fine for abuse of dominance was instead founded on a combination of factors, notably including the novelty of the case. Specifically, given that when GSK entered into the pay-for-delay agreements there was no precedent case to suggest these would be considered anticompetitive. Emphasising that 'each case is different and an assessment of novelty excusing a fine is very dependent on the particular facts', the CAT determined that in the particular circumstances of this case, no penalty should be imposed on GSK for abuse of dominance.

iii. Outcome

In its judgment the CAT reduced GSK's fine from £37.6 million to £22 million, whilst Generics UK's fine was reduced from £5.8 million to £3.8 million and Alpharma's from £1.5 million to £1 million. The CAT also dismissed GSK's fine for abuse of dominance entirely.

The CMA stated the judgment sends a strong message that agreements between pharmaceutical companies aimed at delaying generic entry are unlawful and 'won't be tolerated'. However, the CMA is disappointed with the CAT's reduction of the parties' penalties and intends to carefully consider the judgment and next steps.

Merger Control

Tensions emerge in European Commission Illumina/Grail merger investigation

In March 2021, the Commission published new guidance on the application of the referral mechanism set out in Article 22 of the EU merger regulation ("**EUMR**") allowing for mergers falling below national merger thresholds of EU Member States to be referred to the Commission. To be referred transactions must affect trade between Member States and threaten to significantly affect competition within the territory of the Member State or States making the request. This change is very significant as it means that any transaction that may potentially raise a competition issue could end up being reviewed by the Commission, no matter how small the target, and even after the deal has closed.

The first case to be reviewed under this new policy was the proposed acquisition by Illumina, a US-based pharmaceutical company, of Grail, a US start-up that has developed multi-cancer early detection tests. Grail has not yet launched any products and has no EU turnover. However, on 19 February 2021, the Commission invited Member State competition authorities to request a referral. On 9 March 2021, the French Competition Authority did so, and this was subsequently supported by the competition authorities in Belgium, Greece, the Netherlands, Iceland and Norway. On 20 April 2021, the Commission announced that it had accepted the referral requests. Illumina has since appealed this acceptance decision to the General Court (having previously unsuccessfully appealed the French Competition Authority's referral in the French courts). The appeal has been fast-tracked by the General Court but is yet to be heard. In the meantime, Illumina has filed the transaction with the Commission.

In the latest exchange of blows between Illumina and the Commission, on 20 September 2021, the Commission announced that it had sent an SO to Illumina and Grail, setting out interim measures that it intended to adopt following the parties' alleged breach of the Commission's standstill obligation while it reviews the acquisition. Illumina had closed the acquisition on 18 August 2021, prior to obtaining EU approval, noting that it would keep the two companies separate whilst the Commission's review was ongoing. Two days later, the Commission announced that it was opening an investigation into whether Illumina's action constituted unlawful gun-jumping.

The SO preliminarily concludes that the closure of the deal did constitute a breach of the standstill obligation and that interim measures are necessary in order to restore or maintain effective competition. Commission Executive Vice-President Margrethe Vestager publicly noted that this was the first time that companies had openly implemented a deal during an in-depth investigation by the Commission, and this will also be the first time that the Commission has adopted such measures in a deal that is still being investigated. The Commission has noted that the measures go beyond Illumina's proposal to hold Grail separate from itself, although Illumina has stated that the Commission's measures are in fact based on its own proposals.

The parties will have the opportunity to respond to the Commission's SO both orally and in writing. After this, the Commission may make the interim measures binding, in which case the parties would be legally obliged to comply with them. Failure to do so could result in substantial fines.

The maximum potential fine faced by Illumina for gun-jumping is reportedly almost the same as the break fee that it could have faced if it had not completed the acquisition when it did. These separate, commercial pressures suggest that Illumina may have considered that it was caught between a rock and a hard place when it took the decision to close prior to obtaining EU merger approval.

The underlying merger review is currently suspended due to delays by the parties in providing information required by the Commission. Meanwhile, the General Court is due to hear Illumina's jurisdictional challenge to the Commission's investigation later this year.

The Commission's action in this case illustrates its zero-tolerance approach to gun-jumping. This approach has been seen in other merger cases, notably the Altice/Portugal Telecom merger where, in 2018, Altice received a record €124.5 million gun-jumping fine. Following an appeal by Altice to the General Court, on 22 September 2021 this fine was reduced slightly to €118.3 million in light of the court's finding that Altice took steps to inform the Commission about the transaction before signing the purchase agreement and filing the notification. However, the revised fine remains the highest gun-jumping incident on the Commission's books to date.

Johnson & Johnson / Takeda merger abandoned after European Commission's Phase II threat

On 25 March 2020, the Commission opened a Phase II in-depth investigation into Johnson & Johnson’s proposed acquisition of Tachosil (owned by Takeda). The Commission was concerned that the deal may reduce potential competition and innovation in the supply of dual haemostatic patches.

Tachosil is a leading producer of such patches which are used for the most problematic bleeding control and tissue sealing during surgery. Johnson & Johnson is one of Europe’s leading manufacturers of haemostats which is a surgical tool that prevents blood flow.

During Phase I, the Commission found that there was a distinct market for dual haemostatic patches that was dominated by Tachosil in Europe. The market was also characterised by high barriers to entry and expansion due to high development costs, strong brand loyalty among surgeons and Tachosil’s established position and clinical track-record.

The Commission was concerned that the deal would remove Johnson & Johnson as the best placed entrant in an already concentrated market – although Johnson & Johnson does not sell dual haemostatic patches in the EU. Absent the deal it could enter with existing products not available in the EU market or with new dual patches that it could develop. There were also concerns that the deal may reinforce Johnson & Johnson’s leading market position and hinder rival expansion, leading to reduced choice for surgeons and patients and higher prices for health services or a slow development of alternative solutions to manage difficult bleeding scenarios.

Johnson & Johnson did not submit commitments to address the Commission’s concerns in Phase I. The Commission indicated it would then carry out its Phase II investigation and had until 10 August 2020 to issue a decision. However, in April 2020, Johnson & Johnson decided to abandon the deal citing regulatory issues as the main reason.

Although perhaps now slightly out of date in taking place some 18 months ago, Johnson & Johnson's abandonment of their merger remains relevant as a key indicator of a broader trend in merger control enforcement, and particularly that relating to the life sciences sector. In 2020, one third of the abandoned deals were in this sector, despite making up less than 10% of mergers and acquisitions worldwide. Antitrust authorities across Europe, and especially in the UK, have since continued to frustrate or block deals, becoming increasingly interventionist in the process. This was also apparent during the Commission's review of Elanco Animal Health Inc's acquisition of Bayer AG's animal health division, which was only allowed to proceed subject to several divestments of both parties' products and pipelines.

Consumer Protection

CMA investigates PCR test providers amid consumer complaints

On the consumer protection side meanwhile, the CMA is currently investigating concerns about customers being treated unfairly in the PCR testing market. On 25 August 2021, it sent an open letter to PCR COVID-19 test providers warning that several existing practices in the sector could breach consumer protection law. More specifically, the CMA raised concerns about misleading price-related advertising, failures to deliver tests or provide results within stated timeframes and refusals to provide refunds where tests where not provided. As part of this, the CMA announced in September 2021 that it had launched formal investigations into two private providers of PCR tests – Expert Medicals[9] and Dante Labs[10] ("Dante") – and warned a further 19 test providers to improve their pricing information or risk further action. In particular, the CMA is investigating concerns raised directly and from customers to Citizens Advice that Dante might be treating customers unfairly by not delivering PCR tests and/or results on time, and/or failing to either respond to complaints or provide proper customer service. Indeed, the Government ran a consultation until 1 October on a request by the CMA for enhanced powers, including fines, in order to address these complaints, the outcome of which is expected in early 2022.

Final Thoughts

For those who expected the COVID-19 pandemic would lead to a lessening of scrutiny of the life sciences sector by competition authorities, sadly, have been mistaken. The past 18 months has not seen any let up in the increasingly hard-line approach to merger control and anti-competitive practices. Unfair pricing practices and 'pay-for-delay' arrangements, in particular, have been high on the competition authorities' watchlists as the regulatory bodies look to protect the interests of both consumers and those companies looking to break into the market. Notwithstanding a not wholly unexpected drop in mergers at the outbreak of the pandemic – perhaps in part due to the rise in permitted cooperation between entities to face the challenges of COVID-19 – merger control enforcement has nonetheless remained strict. Outside the life sciences sector, the CMA has, perhaps above all others, re-affirmed its status as one of the most aggressive competition authorities, prohibiting or prompting the abandonment of a record nine mergers last year. Now part of a global partnership with its competition law counterparts in the EU, US and Canada seeking to tackle pharmaceutical mergers, it will be interesting to see the extent to which the CMA's interventionist tendencies are adopted by its new partners. As the life sciences sector continues to remain a key focus of antitrust interventions, companies should remain cautious about and focussed on their compliance with competition law in the face of competition authorities who are increasingly willing to exercise their new-found assertiveness.

[9] See https://www.gov.uk/government/news/cma-launches-next-wave-of-action-in-pcr-testing-market.

[10] See https://www.gov.uk/government/news/cma-continues-action-in-the-pcr-testing-market

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