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Antitrust developments in the pharma sector – Part I

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This paper considers recent developments in competition law in Europe relative to the life sciences and pharmaceutical sector. The sector has continued to be a focus of competition law enforcement in Europe, with the UK's Competition and Markets Authority (CMA), in particular, pursuing a high number of investigations.[1]

The high level of enforcement activity has in turn given rise to a number of court judgments that have addressed arrangements between actual or potential competitors concerning market sharing and pay-for-delay, as well as exclusionary and exploitative abuse by dominant firms including the denigration of competing products and excessive pricing. Importantly, the judgments have also considered the investigative powers, processes and procedures of the competition authorities and made some important determinations in that regard.

The paper is divided into two parts. Part I considers recent developments under Article 101 of the Treaty on the Functioning of the European Union (TFEU) and Chapter I of the UK Competition Act 1998 (CA98) in relation to anti-competitive agreements and cartels, and in particular pay-for-delay and market sharing.

Part II will examine abuse of dominance under Article 102 TFEU/Chapter I CA98, and in particular excessive pricing and exploitative conduct. It will also consider the competition authorities' powers, processes and procedures.

Patent settlement agreements and "pay-for-delay"

Introduction

Pay-for-delay arrangements have traditionally arisen in the context of patent dispute settlements. While patent dispute agreements between an originator manufacturer and a generic firm can be perfectly legitimate, the courts have held that: (i) where the originator and generic firm are actual or potential competitors; and (ii) a payment (a "value transfer") is made by the originator firm, whose drug is protected by patents, to a generic firm, under the guise of a patent settlement agreement, with the sole aim to disguise an arrangement between them to delay or prevent the market entry of the generic firm,[2] this will breach Article 101/Chapter I.[3] Competition authorities have generally considered such pay-for-delay arrangements as market sharing and, accordingly, "by object" infringements, meaning that they infringe competition law by their very nature without the need to show anti-competitive effects on the relevant market.

Pay-for-delay can also arise outside the context of patent settlement agreements, with the case law on patent dispute agreements shaping the authorities' approach. However, this causes a disconnect in the application of the case law, since pay-for-delay decisions to date relate specifically to patent dispute settlements, at the point of patent expiry, giving rise to a very dynamic competitive relationship between the originator manufacturer and generics. As follows from our discussion below, the case law has no easy read-across or general application outside the context of patent settlements, not least since it will not give rise to the same competitive context. This is important for companies to bear in mind as authorities are increasingly seeking to utilise the pay-for-delay case law as a convenient tool for an increasingly interventionist approach, including with regard to general supply agreements *outside* the context of patent disputes.

We set out below some key takeaways and observations on the relevant analytical framework arising from the recent case law in this highly complex area of law.

Potential competition in the context of patent disputes

There can be no market sharing/pay-for-delay unless the parties to the arrangement are actual or potential competitors. In addressing this, two things are key: the relevant market definition; and the extent to which the generic manufacturer has in fact "real and concrete possibilities" to enter the market notwithstanding the patent situation.

Relevant market definition

The starting point of any competition law analysis is the relevant market in which the relevant party or parties operate. Clearly market definition takes into account both demand and supply-side substitutability.

From a demand-side perspective, the relevant product market definition for a medicine tends to revolve around the anatomical therapeutic classification system (ATC).[4] Another consideration is the existence of any intellectual property rights or any other proprietary rights protecting a drug. This obviously arises in relation to patents, but it also arises in relation to other types of protection rights afforded to a drug, such as an orphan drug designation, and the effect this has on, for example, dispensing practices.

A recent development in the analytical framework that has wide consequences is the extent to which the price of a drug is a useful (or indeed the only) point of reference from a product market definition perspective, in circumstances where price may not dictate the prescriber's decision as to which medicine to prescribe. Both the UK's specialist competition court of first instance, the Competition Appeals Tribunal (CAT), in its 2018 judgment in *Paroxetine* (*Paroxetine (2018)*)[5] as well as the General Court in its 2018 judgment in *Servier*,[6] say that a market concerning a prescription medicine cannot be defined on the basis of the price constraint from other prescription medicines, in circumstances where there is a lack of price sensitivity to prescription only medicines. The General Court in *Servier* also determined that all the relevant evidence should be considered, not just price constraints, in an assessment of the therapeutic substitutability of different products.

From a geographical perspective, while there may be regulatory restrictions suggesting a national geographical market, the market may be wider including on the basis of parallel imports.

The generic entrant's "real and concrete possibilities" to enter the market notwithstanding the patent situation

The relevant analytical framework was considered recently by the European Court of Justice (CJEU) in *GSK*[7] and *Lundbeck*,[8] and the CAT in its 2021 supplementary judgment in *Paroxetine* (*Paroxetine (2021)*),[9] as well as the European courts and the European Commission (Commission) in *Perindopril (Servier)*[10] and *Fentanyl*.[11]

As the CJEU held in *GSK* and *Lundbeck*, and the CAT was keen to underscore in *Paroxetine (2021)*, the question whether a generic firm has real and concrete possibilities to enter such that it can be regarded as a potential competitor to the originator manufacturer will turn on whether two conditions are satisfied:

- First, whether the generic firm has a "firm intention and inherent ability" to enter the market notwithstanding the patent situation, which will be satisfied where the generic has taken "sufficient preparatory steps" to enter the market within such a period of time as would impose a "competitive pressure" on the originator. Such steps might include, for example, obtaining an MA, having an adequate stock of the generic drug, taking legal steps to challenge the originator's patents and making marketing efforts to market its product; and
- Second, where such entry does not face "insurmountable barriers" to entry. The CJEU explained that the existence of a patent protecting the manufacturing process of an active ingredient that is in the public domain is not an insurmountable barrier, while the generic firm's readiness to challenge the validity of that patent and to take the risk of being subject to infringement proceedings by the patent holder upon entering the market suggest that it can be characterised as a "potential competitor". In this regard, it is irrelevant whether there is uncertainty as to the validity of the patents covering medicines, since this is a fundamental characteristic of the pharmaceutical sector. As the CJEU noted, the "at risk" launch of a generic medicine, and the consequent patent court proceedings, commonly take place in the period before or immediately after the market entry of the generic medicine and, in fact, in the pharmaceutical sector, potential competition may be exerted before the expiry of a patent protecting an originator medicine, since the generic manufacturers want to be ready to enter the market as soon as that patent expires.

It follows that, where a generic firm has taken sufficient preparatory steps to enter the market, it runs the risk of being considered a "potential competitor" to the originator manufacturer, *despite* the existence of a potentially valid patent protecting the originator's medicine and *regardless* of any actual or potential court proceedings. The CJEU said that, in fact, the more genuine the patent dispute between the parties (particularly where it is the subject of patent dispute proceedings), the more likely it is that the generic firm will be considered a potential competitor to the originator. In this context, the CJEU also said that the greater the value transfer, the stronger the indication that the generic firm is a potential competitor. This is worth bearing in mind, since, entering into a patent settlement agreement in these circumstances, may give rise to pay-for-delay concerns.

However, the CJEU also said in *GSK* and *Lundbeck* that the authority cannot "exclusively or principally" rely on subjective factors, such as the perception by the manufacturer of the risk that the generic manufacturer presents to its commercial interests, in order to establish the existence of potential competition. The existence of potential competition must be assessed in the light of objective factors, taking into account the structure of the market and the economic and legal context within which the parties operate.

The "misleading" features of the settlement agreements

The one single feature that all of the relevant cases share is the misleading nature of the arrangements in place.

For example, in *Paroxetine (2018)*, GSK, the originator, made what it described as "marketing allowance" payments to the two generic firms and a "promotional allowance" to the distributor, but the CAT concluded that these sums were not related to any such activities, and that designating the payments in this manner was "misleading".

Similarly, in *Fentanyl*, the agreement included a provision requiring the recipient of the payment to conduct promotional activities in return. However, the Commission found that the manufacturer carried out only limited promotion activities, of limited usefulness, further to the first agreement, and no activities whatsoever further to a subsequent agreement.

A settlement agreement involving a value transfer will not always be a "by object" restriction

In general, a market sharing arrangement will be perceived as a "by object" infringement. However, in *GSK*, the CJEU ruled that an agreement to settle a patent dispute could not automatically be considered a restriction by object, even where the agreement entails a value transfer from the incumbent to the generic manufacturer. In fact, a value transfer may be justified and be "appropriate and strictly necessary" having regard to the legitimate objectives of the parties to the agreement. The CJEU said that in the context of patent dispute settlements: "a characterisation as a 'restriction by object' must be adopted when it is plain from the analysis of the settlement agreement concerned that the transfers of value provided for by [the originator] cannot have any explanation other than the commercial interest of both the holder of the patent and the party allegedly infringing the patent not to engage in competition on the merits."

It follows that for a settlement agreement involving a value transfer to be a restriction of competition by object, it must be "designed with the sole aim of disguising a market sharing agreement or a market-exclusion agreement". The authority must establish that the sole aim to disguise the true nature of the anti-competitive arrangement is "plain from the analysis" of the surrounding facts, and that the alleged value transfer can only be explained by the commercial interest of both parties to avoid competition on the merits. For example, a value transfer in a patent dispute settlement agreement would be assessed in the context of the following:

- First, all the transfers of value that have been made between the parties, whether pecuniary or non-pecuniary, direct or indirect;
- Second, an assessment of whether the "net gain" arising from the transfer of value by the originator to the generic company may be justified by the existence of any "quid pro quo" or waivers by the generic company "that are proven and legitimate"; and, if it's not,
- Third, the extent to which the net gain is sufficiently large that the generic company refrains from entering the market.

Importantly, however, a value transfer without more is not sufficient for it to classify as a by object restriction. Context is vitally important, since the value transfer may be appropriate and strictly necessary having regard to the legitimate objectives of the parties to the agreement.

If it can be shown that the patent settlement agreement has pro-competitive effects, they must be taken into account, and the agreement must be considered under a "by effect" analysis.

A settlement agreement involving a value transfer may give rise to a "by effect" restriction

Where an agreement is not a by object infringement, it is important to consider whether the arrangement restricts competition by effect. This requires an assessment of what the competitive landscape would have been in the so-called "counterfactual", ie in the absence of the impugned arrangement. As the CAT repeated in *Paroxetine (2021)*, the restrictive effects must be sufficiently appreciable; and competition must be assessed within the actual context in which it would occur in the absence of the disputed agreement.

Other recent UK developments pursuant to Chapter I

In March 2020, the CMA issued an infringement decision relating to market sharing and a second infringement decision relating to information exchanges in relation to the supply of Nortriptyline tablets in the UK,[12] and in July 2020, the CMA issued an infringement decision relating to a market exclusion agreement in relation to the supply of Fludrocortisone in the UK.[13] In an unusual move, in both cases, the CMA secured payments by some of the infringing parties to the UK's National Health Service (NHS) in consideration for damages the NHS was said to have suffered as a result of the infringements, thereby avoiding the NHS having to launch court proceedings for damages.

In addition, the CMA secured legally binding disqualification undertakings[14] from several of the relevant companies' directors.[15]

In July 2021, the CMA issued an infringement decision relating to market sharing in relation to the supply of Hydrocortisone tablets in the UK.[16] The CMA found that Auden Mckenzie/Actavis UK abused its dominance by charging excessive prices for its Hydrocortisone tablets. The CMA also found that Auden/Actavis, to protect its dominant position as sole provider of the tablets and enable it to continue to increase prices, "paid off" potential competitors AMCo (now Advanz Pharma) and Waymade to stay out of the market. The infringement decision has been appealed to the CAT by all the parties.

What next?

We continue to see significant levels of enforcement from the CMA in the life sciences and pharmaceuticals sector which show no signs of abating in the months and years ahead.

Although there is now a general framework for considering pay-for-delay, the cases very much depend on their own facts. In this regard, the CMA's recent decision in relation to Hydrocortisone tablets, raises a number of novel issues.

While pay-for-delay arrangements have traditionally arisen in the context of patent dispute settlements, the *Hydrocortisone* case bears no relevance to that context. This means that the court will need to consider the extent to which the pay-for-delay case law is applicable to cases that do not concern patent settlement agreements, and the extent to which they can be said to give rise to an "object" infringement.

Furthermore, Auden's 10mg Hydrocortisone tablets are licensed to treat adrenal insufficiency in adults and children (often described as "full indication"). As a result of the operation of Orphan Drug regulations, Auden effectively had exclusivity to supply full indication 10mg Hydrocortisone tablets, while all subsequent applicants for a marketing authorisation (MA) were permitted a "reduced indication" MA for the treatment of adrenal insufficiency in children only. This gives rise to questions regarding market definition in the pharmaceutical sector, including in the context of medicines licensed for different indications, the regulatory prohibitions on holding such medicines out as substitutable, and issues arising out of the Orphan Drug regime and the regulatory prohibitions on pharmacists dispensing medicines off-label.

The case also gives rise to a consideration of the meaning of a consensus (meeting of minds) for a finding of an "agreement" for the purposes of Chapter I, as well as whether competition law requires a non-dominant firm to bring a product to market, and then in the absence of demand.

These considerations mean that the scope for further legal developments in this highly complex area of law remains.

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Disclaimer

The authors have been acting in relation to several of the recent CMA antitrust investigations in the pharmaceutical/life sciences sector, including both investigations that were subsequently closed by the CMA as well as four ongoing investigations, namely:

- *Mercury Pharmaceuticals Ltd and Others v Competition and Markets Authority* (1422/1/12/21) in relation to Case 50395 – *Liothyronine*: the CMA was investigating alleged excessive and unfair pricing with respect to Liothyronine tablets under Chapter II/Article 102. In the course of its investigation, the CMA issued a Statement of Objections, a Supplementary Statement of Objections, and, in a rare move, a Further Supplementary Statement of Objections. On 29 July 2021, the CMA issued an infringement decision, which was appealed to the CAT on 14 October 2021 in *Mercury Pharmaceuticals Ltd and Others v Competition and Markets Authority*. The authors act for Mercury (now owned by Advanz Pharma).
- *Advanz Pharma Corp Ltd v Competition and Markets Authority* (1411/1/12/21) in relation to Case 50277 – *Hydrocortisone tablets*: the CMA was investigating alleged anti-competitive agreements and abusive conduct with respect to Hydrocortisone tablets under Chapters I and II and Articles 101 and 102. The authors are acting with regard to the CMA claims under Chapter I/Article 101. In the course of its investigation, the CMA issued a Statement of Objections and, after bringing together its three separate investigations into Hydrocortisone tablets, a Supplementary Statement of Objections. The CMA's procedural approach was without precedent. On 15 July 2021, the CMA issued an infringement decision, which was appealed to the CAT on 15 September 2021 in *Advanz Pharma Corp Ltd v Competition and Markets Authority*. The authors act for Advanz Pharma.
- Case 50511-2 – *Prochlorperazine*: the CMA has been investigating alleged anti-competitive agreements and/or concerted practices in relation to the supply of Prochlorperazine tablets in the UK under Chapter I/Article 101. The CMA has issued a Statement of Objections. On 21 January 2021, the CMA decided to close on administrative priorities grounds its investigation into two elements of its complaint. The CMA is continuing its investigation with regard to a third element relating to an alleged overarching agreement between the parties.
- Case 50511-1 – *Nitrofurantoin*: the CMA had been investigating alleged anti-competitive agreements and/or concerted practices in relation to the supply of Nitrofurantoin capsules in the UK under Chapter I/Article 101. The CMA also investigated the alleged disclosure of sensitive pricing information with the aim of reducing competition between the parties. The CMA had issued a Statement of Objections in July 2019. The CMA announced on 8 October 2021 that it closed its investigation on administrative priority grounds.

Endnotes

1. This is unlikely to change in the light of the commitment made by the CMA in its Annual Plan for 2021/2022, "to ensure that the NHS does not pay significantly more than it should for essential medicines and treatments, and that consumers who depend upon these drugs and treatments do not lose out".
2. We will refer to both pay-for-delay and market exclusion arrangements as pay-for-delay agreements for ease of reference.

3. Where the originator manufacturer engaging in pay-for-delay is dominant on the relevant market, this may also be considered as exclusionary unilateral conduct and give rise to an abuse of dominance under Article 102/ Chapter II.
4. The ATC is devised by the EphMRA and maintained by EphMRA and IMS. Generally, the relevant product market definition tends to focus on ATC3, the level at which products are grouped by therapeutic indication, and/or ATC4, at the level of the molecule (ie active ingredient) or group of molecules that are considered interchangeable from a therapeutic perspective – although this is very much dependent on the specific circumstances relating to a specific drug.
5. CAT in *Paroxetine*, 8 March 2018, https://www.catribunal.org.uk/sites/default/files/1.1251-1255_Paroxetine_Judgment_CAT_4_080318.pdf.
6. General Court in *Servier*, 12 December 2018, https://curia.europa.eu/juris/liste.jsf?num=T-691/14&language=EN.
7. Preliminary ruling by the CJEU in *GSK*, 30 January 2020, further to a refence from the English courts in *Paroxetine (2018)*,https://curia.europa.eu/juris/document/document.jsf?text=&docid=222887&pageIndex=0&doclang=en&mode=req&dir=&occ=first&part=1.
8. CJEU in *Lundbeck*, 25 March 2021, upholding the judgment of the General Court, https://curia.europa.eu/juris/liste.jsf?num=C-591/16.
9. CAT's supplementary judgment in *Paroxetine (2021)*, 10 May 2021, https://www.catribunal.org.uk/sites/default/files/2021-05/1251-1255_Paroxetine_Judgment_CAT9_100521.pdf.
10. Commission Decision in *Perindopril (Servier)*, 9 July 2014, https://ec.europa.eu/competition/antitrust/cases/dec_docs/39612/39612_12422_3.pdf.
11. Commission Decision in *Fentanyl*, 10 December 2013, https://ec.europa.eu/competition/antitrust/cases/dec_docs/39685/39685_1976_7.pdf.
12. Case 50507.2 – *Nortriptyline*, https://assets.publishing.service.gov.uk/media/5f115b4dd3bf7f5baab7a5e4/Market_Sharing_Decision.pdf. All the parties in this case admitted to the relevant infringements and reached a settlement with the CMA (thereby paying reduced fines), with the exception of Lexon in relation to the information exchange agreement. On 11 May 2020, Lexon filed an appeal with the CAT against the CMA's second infringement decision. On 25 February 2021, the CAT upheld the CMA's infringement decision against Lexon and dismissed Lexon's appeal, https://www.catribunal.org.uk/sites/default/files/2021-02/1344_Lexon_JUDGMENT_250221.pdf.
13. Case 50455 – *Fludrocortisone*. All the parties in this case admitted to the relevant infringements and reached a settlement with the CMA, paying reduced fines as a result, https://assets.publishing.service.gov.uk/media/5f746219e90e0740c86c7611/50455_Non-confidential_Public_Decision_.pdf.
14. As we described above, the UK competition authorities have the power to seek CDOs pursuant to which directors of companies found to have participated in a Cartel Offence may be disqualified from serving as a director for up to 15 years.
15. High Court proceedings initiated by the CMA in August 2020 seeking the disqualification of a director of Lexon are ongoing following the CAT's decision in February 2021 to uphold the CMA's infringement decision against Lexon.
16. Case 50277 – *Hydrocortisone tablets*, https://www.gov.uk/government/news/cma-finds-drug-companies-overcharged-nhs.

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