THE GUIDE TO LIFE SCIENCES

Editors
Ingrid Vandenborre and Caroline Janssens

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Publisher's Note

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

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

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Introduction

Ingrid Vandenborre and Caroline Janssens[1]

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

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

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

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

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

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

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

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

doing so, including, as we have seen, by way of expanding jurisdictional scope of review. At Member State level, France has been leading the way on enforcement of product denigration, while Germany and Austria have increased their scrutiny of innovation-driven markets with the introduction of alternative transaction value thresholds in 2017, designed to capture high-value/low-revenue deals.

Italy has been a pioneer in antitrust enforcement in life sciences, with landmark cases on excessive pricing and product denigration influencing the EC's decisional practice. The Italian Competition Authority is likely to continue its enforcement efforts in this area in the future. In contrast, the activity of the Authority in merger control in recent years has been limited.

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

In the UK, the CMA is expected to continue to regard the life sciences sector as an enforcement priority. With regard to merger control, recent cases have illustrated the CMA's willingness to push the limits of jurisdictional rules and intervene in deals in dynamic, innovation-driven sectors where target companies have limited (or no) revenues or direct activity in the UK. In addition, Brexit has created heightened risks of parallel conduct investigations and merger reviews in the EU and UK.

To date, the life sciences sector has not raised major competition law issues in Switzerland, under neither the cartels, abuse of dominance nor merger control rules. It remains to be seen whether recent and ongoing regulatory changes, as well as mutual market access concerns with the EU, will lead to a different competitive environment in the near future.

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

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

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

CHAPTER 10

France: FCA Increases Scrutiny Over the Sector

Adrien Giraud, Eveline Van Keymeulen, Julien Morize and Jeanne Fabre[1]

France is a key jurisdiction to consider when discussing the life sciences sector. This chapter presents the main recent antitrust developments in this sector in France by examining recent regulatory developments and covid-19 measures, the French Competition Authority's (FCA) enforcement in recent mergers and antitrust cases and the likely short-term outlook for the sector.

Main recent regulatory developments

FCA involvement in the new Article 22 EUMR policy

At the 24th International Bar Association Conference of 11 September 2020, the executive vice president of the European Commission (EC) and European Commissioner for Competition, Margrethe Vestager, announced a new approach to Article 22 of the EU Merger Control Regulation (the EUMR).[2] Under this new application, the EC stated that it would start accepting referrals from national competition authorities (NCAs) even when national jurisdictional thresholds are not met, for mergers 'that are worth reviewing at the EU level'.[3] The main purpose of this was to tackle 'killer acquisitions' in which the target is typically in its infancy with sales that do not meet the EU or national thresholds. In her

1 Adrien Giraud and Eveline Van Keymeulen are partners, and Julien Morize and Jeanne Fabre are associates, at Latham & Watkins LLP.

2 Council Regulation (EC) No. 139/2004 of 20 January 2004 on the control of concentrations between undertakings.

3 Margrethe Vestager, 'The Future of EU Merger Control', 11 September 2020.

Conference speech, Commissioner Vestager mentioned the pharmaceutical sector, hinting at the fact that this new approach was likely to be implemented first in this industry.

Sure enough, the EC first implemented its new approach in February 2021 with respect to the *Illumina/Grail* transaction and invited all EU NCAs to refer the case to it under Article 22 of the EUMR. Later, in March 2021, it published a communication providing guidance on how it intends to implement its new approach to Article 22 of the EUMR.[4] On 19 April 2021, the EC accepted the referral request from France. Illumina and Grail's challenge of that decision was dismissed by the General Court on 13 July 2022.[5]

France played a key role in causing the shift in policy and has been involved from the outset.

First, since 2017, the FCA had been urging the EC to deploy Article 22 of the EUMR for the review of mergers falling beneath national thresholds.[6] Upon the adoption of the renewed version of the guidelines on the control of concentration issued on 23 July 2020, the FCA reiterated its position regarding Article 22.[7] It is thus not surprising that the FCA warmly welcomed the EC's new interpretative framework when it was announced by Commissioner Vestager.[8] Similarly, it recently welcomed the judgment handed down by the General Court on 13 July 2022.[9]

Second, the FCA was the only NCA that actually referred the *Illumina/Grail* transaction to the EC under the new interpretation of Article 22 (several other NCAs joined France's referral but failed to actually refer the case themselves).

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4 European Commission, 'Commission Guidance on the application of the referral mechanism set out in Article 22 of the Merger Regulation to certain categories of cases', 26 March 2021.

5 General Court of Justice, Case T-227/21, *Illumina v. Commission*, 13 July 2022.

6 In line with this position, the French Competition Authority (FCA) took the view in January 2020 that *Continental Can v. Commission* (C-6/72) did not apply to concentrations falling beneath the jurisdictional thresholds (Decision 20-D-01 of 16 January 2020), arguing that the very existence of rules on the control of concentrations excluded any prosecution on the ground of an abuse of dominance pursuant to Article 102 of the Treaty on the Functioning of the European Union. The FCA's position regarding *Continental Can* was recently referred to the Court of Justice of the European Union (CJEU) (Paris Court of Appeal, 1 July 2021, No. RG 20/04300). The case is registered before the CJEU under No. C-449/21.

7 FCA, 'Guidelines on the control of concentration', 23 July 2020, paragraph 340.

8 FCA, Press release, 15 September 2020.

9 FCA, Press release, 13 July 2022.

It is therefore to be expected that the FCA will actively consider using its prerogative under the new approach to Article 22, particularly with respect to the life sciences, pharmaceutical and healthcare sectors.

FCA calls for increased competition in the medical biology sector

In an opinion dated 4 April 2019, the FCA showed its willingness to support the strengthening of competition in the medical biology sector.[10]

The FCA advocated for a change in the prudential regulation governing the ownership of medical biology laboratories, which limits capital ownership by non-practising biologists to a maximum of 25 per cent.[11] The removal of this regulatory barrier would stimulate the development of medical biology supplies and, consequently, improve the overall quality of the services provided to end customers. To this end, the FCA suggested either opening capital ownership to private investors, or at the very least, raising the threshold to 50 per cent.[12]

The FCA also criticised the prudential rules prohibiting merger and acquisition (M&A) transactions that result in an investor controlling more than 33 per cent of the supply of medical biology tests in a given health territory.[13] It also challenged the rules empowering the director of a regional health agency to block transactions that result in a laboratory controlling more than 25 per cent of the supply of medical biology tests in a given health territory.[14] The FCA recommended that these rules be removed or reformed as they would hinder external growth in the sector.[15]

Similarly, on 9 June 2021, the EC sent France a letter of formal notice under Article 258 of the Treaty on the Functioning of the European Union (TFEU) (the infringement procedure), requesting it to bring its legislation in the field of veterinary services in line with the 2006 Services Directive.[16] In particular, the EC requires France to increase the maximum capital that private investors can hold in veterinary clinics from 25 per cent to at least 50 per cent.

10 FCA, Opinion No. 19-A-08, 4 April 2019.
11 Article R-6223-64 of the French Public Health Code.
12 FCA, Opinion No. 19-A-08, 4 April 2019, paragraph 1398.
13 Article L-6223-4 of the French Public Health Code.
14 Article L-6222-3 of the French Public Health Code.
15 FCA, Opinion No. 19-A-08, 4 April 2019, paragraphs 1408–1412.
16 Directive 2006/123/EC of the European Parliament and of the Council of 12 December 2006 on services in the internal market. The infringement procedure is open under No. INF_21_2743.

FCA calls for more flexibility in the pharmacy sector

The FCA is also in favour of liberalising the pharmacy sector and recommended some changes – in the same opinion dated 4 April 2019[17] – to ensure competitiveness with other EU Member States.

The rules governing pharmacy ownership are, at present, very restrictive. The FCA suggested several alternative scenarios, envisaging an increase in the number of minority and majority shareholdings by pharmacists, and even including opening up capital ownership to minority or majority outside investors (i.e., non-pharmacists).

In terms of the online sale of medicines, the Falsified Medicines Directive[18] currently requires EU Member States to allow the online sale of medicines subject to optional prescriptions, while reserving the possibility to set certain conditions applicable to these online sales, provided that they are necessary and proportionate to the objective of safeguarding public health. However, the French legal framework transposing the Directive is one of the strictest among EU Member States, and the FCA considers that it prevents the development of competitive national operators able to effectively compete with foreign players. The FCA further highlights that this could, 'in the long term, lead French patients to turn away from national operators in favour of foreign sites'.[19]

In that respect, the Council of State (France's highest administrative court) shut the door that the Paris Court of Appeals had opened to allow purely technical intermediaries to intervene in the online medicines sale process. However, the Paris Court of Appeals referred preliminary questions to the Court of Justice of the European Union (CJEU), which may provide clarity on this point in due course.[20] Depending on the responses provided by the CJEU, some platforms allowing the sale of over-the-counter medicines through authorised pharmacy websites, which were deemed compliant (until recently), may now be held illegal. If platforms were to be considered as an illegal intermediary, the French legal framework could suffer from another restriction in comparison with other EU Member States.

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17 FCA, Opinion No. 19-A-08, 4 April 2019.

18 Directive 2011/62/EU of the European Parliament and of the Council of 8 June 2011 amending Directive 2001/83/EC on the Community code relating to medicinal products for human use, as regards the prevention of the entry into the legal supply chain of falsified medicinal products.

19 FCA, Opinion No. 19-A-08, 4 April 2019, paragraph 289.

20 Paris Court of Appeals, 17 September 2021, No. RG 21/00416. The case is registered before the CJEU under No. C-606/21 (*Doctipharma*).

The FCA has suggested a number of recommendations to alleviate regulatory barriers, such as: allowing the use of storage facilities even further away from pharmacies; providing an exception allowing consortia of pharmacists to be entrusted with the design and maintenance of their members' websites to increase their profitability; and softening the prohibition related to entrusting the design and technical maintenance of the website to a company producing or marketing health products.

In terms of pharmacy monopolies, in France the sale of medicines to patients is characterised by a dual monopoly: one regarding pharmacies (known as the pharmacy monopoly)[21] and the other regarding pharmacists (known as the pharmaceutical monopoly).[22] As a consequence, only a pharmacist can dispense medicines to patients and is required to do so in a pharmacy. Despite several attempts to liberalise this framework, the key principles have changed very little over time. The FCA also recommended authorising the dispensing of certain health products currently subject to the pharmacy monopoly outside pharmacies. However, this flexibility could only apply to a limited number of products and would exclude prescription-only medicines. This would include optional prescription medicines and some other health products, such as in vitro diagnostic medical devices, medicinal plants listed in the pharmacopoeia and essential oils.

The lobbying exercised by French pharmacists' unions is extremely important in France. Any changes proposed or made to the pharmacy profession are intensely scrutinised by the unions, which are – generally – against any liberalisation of the professional monopolies (e.g., opening pharmacy ownership to persons outside the profession).

FCA covid-19 measures

The outbreak of covid-19 brought slight but noticeable changes in terms of both procedure and substantive assessment.

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21 The pharmacy monopoly was first affirmed in France by a royal order of 25 April 1777. It was then reinforced by French Law No. 3890 of 11 September 1941.

22 Pharmacists have a monopoly on the retail sale of medicines, whether these medicines are subject to compulsory medical prescription or optional medical prescription. The monopoly also applies to the sale of other products listed in Article L4211-1 of the French Public Health Code, namely items to treat wounds and all articles presented as conforming to the pharmacopoeia, as well as generators, kits and precursors. Pharmacists are also the only ones allowed to retail medicinal plants listed in the pharmacopoeia (except in cases of derogation), essential oils (the list of which is set by decree), infant milk (intended for young children and with certain characteristics) and in vitro diagnostic medical devices (except for pregnancy or ovulation tests and HIV self-tests) intended for use by the public.

Merger filing was digitised as of March 2020. Initially conceived as a temporary measure in the context of the covid-19 lockdown (causing the FCA's merger registry to shut down), dematerialisation was established permanently in June 2021. Companies can now rely on an online platform called 'Hermès' to make all relevant submissions. Dematerialisation has been integrated in the French Commercial Code itself by codification in Article R430-2.23.

The major economic setback caused by the covid-19 crisis has prompted all NCAs (including the FCA) to adapt antitrust enforcement. The European Competition Network issued a joint statement in which all NCAs expressed their willingness not to actively enforce Article 101 of the TFEU (or its national equivalents) against companies that would cooperate to avoid a supply shortage provided that the measures were temporary and strictly necessary to restore the balance between supply and demand.[24]

To provide legal certainty on this temporary framework, NCAs provided informal advice on the compliance of certain practices with antitrust rules to avoid infringement proceedings. These mechanisms are reminiscent of the long-standing comfort letters of Regulation 17/1962 under which companies were required to notify the EC of any cooperation agreement before implementation.

In this context, the FCA assisted a professional organisation of opticians, which sought informal advice on the extent to which it could intervene alongside its members to help them renegotiate their commercial rents with lessors. This led the FCA to confirm that the proposed initiative did not appear to infringe antitrust law.[25]

Main recent merger developments

The first ever application of the new Article 22 policy

As mentioned above, the FCA was the first NCA to refer a case to the EC under the new approach to Article 22 of the EUMR. On 19 February 2020, it was invited by the EC to refer the *Illumina/Grail* transaction and it obliged a few days later, by way of a decision adopted by its president on 9 March 2020.

The FCA argued that the transaction threatened to significantly affect competition in France.

23 FCA, Press release, 8 June 2021.

24 European Competition Network, 'Joint statement by the European Competition Network (ECN) on application of competition law during the Corona crisis', 23 March 2020.

25 FCA, Press release, 22 April 2020.

Illumina and Grail challenged the referral and filed an application for interim relief before the Council of State.

On 1 April 2021, the Council of State rejected the interim relief request, taking the view that it had no jurisdiction to review the legality of the FCA's referral request.[26] The Council of State considered that the referral request was only a preparatory measure and could not be severed from the EC decision to actually accept the referral, which is, according to the Council of State, the only decision that can be challenged.

It is not surprising that this first application of the new policy on Article 22 came from France, given the FCA's involvement in this policy change.[27] Looking forward, more referrals are likely to come, especially in the industries characterised by a high pace of innovation, and in particular the life sciences sector, which is specifically mentioned in the FCA press release following the 13 July 2022 judgment of the General Court.

The growth of concentrations within the French medical biology sector

In recent years, the French medical biology sector has gradually consolidated around three major groups (Biogroup, Inovie and Cerba), which have all made numerous acquisitions.

The FCA's substantive assessment of mergers in the sector may have facilitated consolidation. Its analysis is steady and predictable, which increases legal certainty as companies may know well in advance whether a potential transaction will require divestments and how many sites will need to be divested.

In fact, the FCA's analysis is almost mechanical. When the combined market share of the parties to a transaction does not exceed 50 per cent in terms of the number of sites within a given department, it is unlikely that competition concerns will be raised and the concentration should not require divestitures. On the contrary, when the combined market share exceeds this threshold, competition concerns will, in principle, be identified and divestitures will most likely be necessary if the parties want their case to be cleared in Phase I.

The number of sites to be divested is also predictable. Where one of the parties involved has a market share exceeding 40 per cent in a given department prior to the transaction, the FCA is likely to require the divestment of all the

26 Council of State, *Illumina v. French Competition Authority*, No. 450878, 1 April 2021. The case on the merit was still pending at the time of writing.

27 FCA, Press release, 15 September 2020.

additional laboratories brought by the transaction.[28] On the contrary, where all parties involved have a market share below 40 per cent in a given department prior to the transaction, the FCA will likely be satisfied with the divestiture of only some of the additional laboratories brought by the transaction to bring the combined market share below the 50 per cent threshold.[29]

The reason why the FCA's assessment seems to promote the creation of strong groups with significant market shares at department level (up to 50 per cent) may be twofold. First, the FCA has shown its willingness to promote transactions in the sector to increase competition (see above). Second, price competition is very limited in this sector as the vast majority of medical biology tests are regulated according to the Nomenclature of Medical Biology Acts (NABM), a list of reimbursed medical biology tests. Competition between laboratories is therefore essentially based on factors independent of price, such as geographical proximity and quality of services (opening hours, delays in reporting tests, range of analyses offered, quality of patient reception, relationship between the biologist and the patient, etc.).

However, a very recent decision (April 2022) demonstrates that the FCA does carefully review transactions in the sector. The FCA considered that the acquisition of sole control of Bio Pôle Antilles by Inovie, combined with the concomitant project to acquire a non-controlling minority stake in the capital of the company Synergibio, was likely to harm competition. Synergibio is the only competitor of Bio Pôle Antilles in Guadeloupe and Saint-Martin (French overseas territories). The FCA considered that this would: (1) lead to an increase in the price of medical biology tests that are not regulated or a decrease in quality, or both; (2) allow Inovie to obtain information about its main competitor; and (3) block any possibility of entry by another competing private group into the market for routine medical biology examinations in Guadeloupe and Saint-Martin, with Inovie having a stake in the only two private laboratories present in these territories. Consequently, to obtain approval for the acquisition of Bio Pôle Antilles, Inovie committed to abandon its plan to acquire a non-controlling minority stake in the capital of Synergibio for a period of 10 years.[30]

28 See, e.g., FCA, Decision 20-DCC-90 of 17 July 2020.

29 See, e.g., FCA, Decision 20-DCC-92 of 24 July 2020.

30 FCA, Decision 22-DCC-35 of 27 April 2022.

Main infringement developments

In recent years, the FCA has sanctioned companies active in the life sciences sector for both abuse of dominance[31] and anticompetitive agreements.[32] These recent cases offer some useful insights into the French antitrust landscape.

Abuse of dominance and patents

The expiry of a patent may be challenging for its owner as the market opens up to competition. However, patent owners are not exempt from the prohibition of abuse of dominance, neither during the validity of the patent,nor *a fortiori* at its expiry. The FCA has emphasised the responsibility of patent holders not to exclude competing laboratories capable of conceiving a generic or alternative version.

Novartis/Roche/Genentech (September 2020) – Disparagement and abuse of collective dominant position

On 9 September 2020, Novartis, Roche and Genentech were found to have jointly disparaged the drug Avastin to maximise the sales of Lucentis, a competitive medical product that was approximately 30 times cheaper (approximately €30 to €40 for an injection of Avastin versus €1,161 for an injection of Lucentis).[33]

The FCA considered that the three laboratories had to be examined as forming a 'single collective entity' within the meaning of competition law because of their cross-holdings and contractual ties.

Genentech was exclusively controlled by Roche, and Novartis held a non-controlling minority shareholding in Roche (6.2 per cent of the issued share capital and 33.33 per cent of the voting rights). Both drugs were produced by Genentech; Avastin was commercialised by Roche while Lucentis was commercialised by Novartis. The use of Avastin rather than Lucentis would entail a significant loss of income for each of the three laboratories: (1) for Novartis, which earned income from sales of Lucentis; (2) for Genentech, which earned licensing revenue on sales of Lucentis; and (3) for Roche, as the sole shareholder of Genentech.

31 Under Article 102 of the TFEU and Article L420-2 of the French Commercial Code.

32 Under Article 101 of the TFEU and Article L420-1 of the French Commercial Code.

33 FCA, Decision 20-D-11 of 9 September 2020.

Ultimately, the FCA found the companies to have committed two infringements:

- the FCA found that Novartis led a global communication campaign that tended to discredit the use of Avastin in favour of Lucentis while both drugs allowed for the treatment of age-related macular degeneration, a disease affecting central vision. These actions notably consisted of misleading advertising and communication among physicians, pharmacists, opinion leaders, associations and the general public. The Novartis group was subject to a fine of €293,950,750; and
- the FCA found that Novartis, Roche and Genentech made an undue and unlawful intervention before the former French public health authority (the French Agency for the Safety of Health Products (AFSSAPS), which is now the ANSM) to delay the authorisation to administer Avastin in place of Lucentis to protect their monopoly power for longer. The Novartis group was fined €131,197,500, whereas Roche and Genentech were fined a joint and several amount of €59,748,726.

Janssen-Cilag (2017–2022) – FCA jurisdiction to evaluate conduct before another regulatory body

In another case of disparagement, the FCA fined the laboratory Janssen-Cilag and its parent company, Johnson & Johnson, for having delayed the arrival on the market of a generic version of Durogesic (an opioid analgesic prescribed for the treatment of severe pain) and then for blocking the development of this generic.[34]

Janssen-Cilag was sanctioned for having repeatedly and unjustifiably approached the AFSSAPS (now the ANSM), with the aim of convincing the health authority to refuse the grant of generic status to medicinal products competing with Durogesic. In addition, Janssen-Cilag was found to have implemented a major campaign falsely disparaging the generic versions of Durogesic among healthcare professionals (including doctors and pharmacists), using misleading language to create doubts concerning the effectiveness and safety of these generic medicinal products.

While the decision is another application of the well-established principle whereby dominant firms must not deter the launch on the market of a generic upon expiry of a patent, it is also the object of a very recent interesting development.

34 FCA, Decision 17-D-25 of 20 December 2017.

On 1 June 2022, the Court of Cassation (France's highest civil court) ruled on the appeal brought by Janssen-Cilag and Johnson & Johnson. Of the many grounds of challenge, the appellants argued that competition proceedings and the procedure for issuing a marketing authorisation before the AFSSAPS were distinct in nature. Consequently, the FCA had no jurisdiction to assess the arguments put forward by Janssen-Cilag before the health regulator and could not legally take into account the intervention to establish its willingness to disparage its rivals.

The Court of Cassation rejected these arguments, pointing out that the FCA does not need to conduct any scientific evaluation to apply the relevant rules of competition law. In particular, the Court of Cassation recalled that the FCA may investigate any practice likely to constitute an infringement of competition rules, whether or not the sector of activity concerned is regulated. In addition, when a sector of activity is regulated, the FCA has the duty to assess the practices in light of the legal framework in which they take place.[35]

Anticompetitive agreements

The FCA's recent decisions sanctioning anticompetitive agreements offer interesting takeaways for companies active within the life sciences sector.[36]

Luxottica/LVMH/Chanel/Logo (2021) – Retail price maintenance and online sales restrictions

In July 2021, the FCA sanctioned Luxottica, LVMH, Chanel and Logo for a total amount of €125,804,000 for having limited the freedom of opticians to set prices and for prohibiting selling their products online.[37] The FCA found that Luxottica, Logo and LVMH imposed retail prices on optician retailers and that Chanel, Luxottica and LVMH banned opticians from selling their sunglasses and glasses frames online.

35 French Court of Cassation, Decision No. 19-20.999 of 1 June 2022.

36 The FCA also sanctioned anticompetitive agreements in two other cases of less significance: in Decision 22-D-04 of 2 February 2022, the FCA found that local ambulance companies had formed an economic interest group to respond to the call for tenders launched by hospital centres to renew their ambulance transport contracts, which was neither technically nor economically justified. Only one company was fined €32,600 as the others accepted the settlement proposed by the Directorate General for Competition Policy, Consumer Affairs and Fraud Control; and in Decision 20-D-17 of 12 November 2020, the FCA imposed fines of €4 million on professional organisations of dental surgeons for boycotting dental care networks recommended by complementary health insurance schemes.

37 FCA, Decision 21-D-20, 22 July 2021.

The developments relating to the ban on online sales are interesting insofar as Chanel notably argued that it was justified and necessary to protect the health and comfort of consumers given that optical products are medical devices.

However, the FCA recalled the *Pierre Fabre* and *Coty Germany* European case law pursuant to which absolute prohibitions of online sales are anticompetitive by object and necessarily go beyond what is necessary for the attainment of the objective pursued.[38]

The FCA considered that less restrictive measures could have been put in place for the sale of glasses frames. In particular, the FCA noted that some opticians were able to implement online sales procedures to ensure that glasses frames were properly fitted to customers, with the physical intervention of an optician where necessary.[39]

BioMérieux/Guyane Service Médical (2019) – Exclusive import agreements in French overseas territories

The prohibition of exclusive import agreements in the French overseas territories is a peculiarity of the French antitrust framework. Since its enforcement in March 2013, the Lurel Law has prohibited concerted practices or agreements whose object or effect is to grant exclusive import rights in the French overseas territories. This provision has been codified into Article L420-2-1 of the French Commercial Code and aims to address the specific problems of these territories, in particular their insularity, remoteness, narrow markets and high barriers to entry.

In May 2019, BioMérieux was found to have concluded such an exclusivity in the import of instruments and reagents of medical biology products to Guyana with a local company, Guyane Medical Services.[40] The FCA imposed fines of €150,000 on Guyane Medical Services and €75,000 on BioMérieux.

An interesting takeaway from the decision is that the FCA only sanctioned the *de jure* exclusivity in place between 2013 and 2016 but did not sanction the *de facto* exclusivity as of 2016.

From 2013 to 2016, the FCA found that there was a *de jure* exclusivity between BioMérieux and Guyane Medical Services because an exclusivity clause was included in the distribution agreement. As a result, laboratories from Guyana

38 Court of Justice, C-439/09, *Pierre Fabre v. Commission*, 13 October 2011 and C-230/16, *Coty Germany GmbH v. Parfümerie Akzente GmbH*, 6 December 2017.

39 FCA, Decision 21-D-20, 22 July 2021, paragraphs 856–876.

40 FCA, Decision 19-D-11 of 29 May 2019.

had to procure BioMérieux products from Guyane Medical Services. The FCA relied on the mere existence of the exclusivity clause in the distribution agreement to conclude that the Lurel Law had been violated.

As of 2016, there was only a *de facto* exclusivity between BioMérieux and Guyane Medical Services. Although the exclusivity clause was removed from the distribution agreement, Guyana Medical Services remained, in practice, the only distributor of BioMérieux products in Guyana. However, the FCA ultimately found that the *de facto* exclusivity was only due to the specific nature of the medical biology products, and in particular due to their conditions of transport and storage (they required the use of special refrigerators). Because of these practical constraints, no new distributors sought to distribute BioMérieux products in Guyana. As a result, no infringement was characterised after 2016.

Outlook

In terms of merger control in the life sciences industry, one can expect an increased activity of the FCA with respect to potential Article 22 EUMR referrals. The new policy of the EC, supported by the FCA, has recently been validated by the General Court (although an appeal has been announced). This will not necessarily mean that the FCA will refer many cases to the EC under that provision (a couple per year, at most), but the FCA will closely monitor any life sciences consolidation movement to determine whether it should make use of this new tool. Parties to these transactions need to take this into account in many different ways: assessing the feasibility of transactions, determining the likely timing, determining the strategy with respect to the FCA, etc. These questions will arise in every transaction below the merger control thresholds in France, but with particular relevance within the life sciences space.

The outcome of the EC's infringement procedure could lead France to increase the percentage of capital that third parties may hold in veterinary clinics. As is the case for medical biology clinics, such a reform could boost M&A transactions in the sector.

The M&A market has recovered from the covid-19 pandemic to pre-pandemic levels and the healthcare and biotech sector has not been left behind. Interest in multiple segments of the life sciences sector, such as nursing homes and home care providers, medical biology labs, clinics (e.g., veterinary and radiology), biotechnology and innovative therapies, remains strong. Healthcare services, speciality care platforms, telehealth and health technologies – which have bloomed during the pandemic – are also attracting investors that still have a high level of funds available. The market has strong foundations, and investors are looking to diversify their investments.

The strategic shift towards innovative digital business models is likely to motivate the dynamics of M&A. Life sciences companies are looking to optimise their portfolios for growth through transactions that give them access to new therapies, technologies, techniques and medical devices, or towards companies engaged in providing services to this sector.[41] In recent times, the deals in the life sciences sector have been subject to increased scrutiny from competent authorities of compliance with foreign direct investment regulations.

41 Deloitte, 'Life science & healthcare, M&A research 2022, Executive Summary', March 2022, www2.deloitte.com/content/dam/Deloitte/nl/Documents/life-sciences-health-care/deloitte-nl-lshc-m-a-research-eng-2022.pdf.

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

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