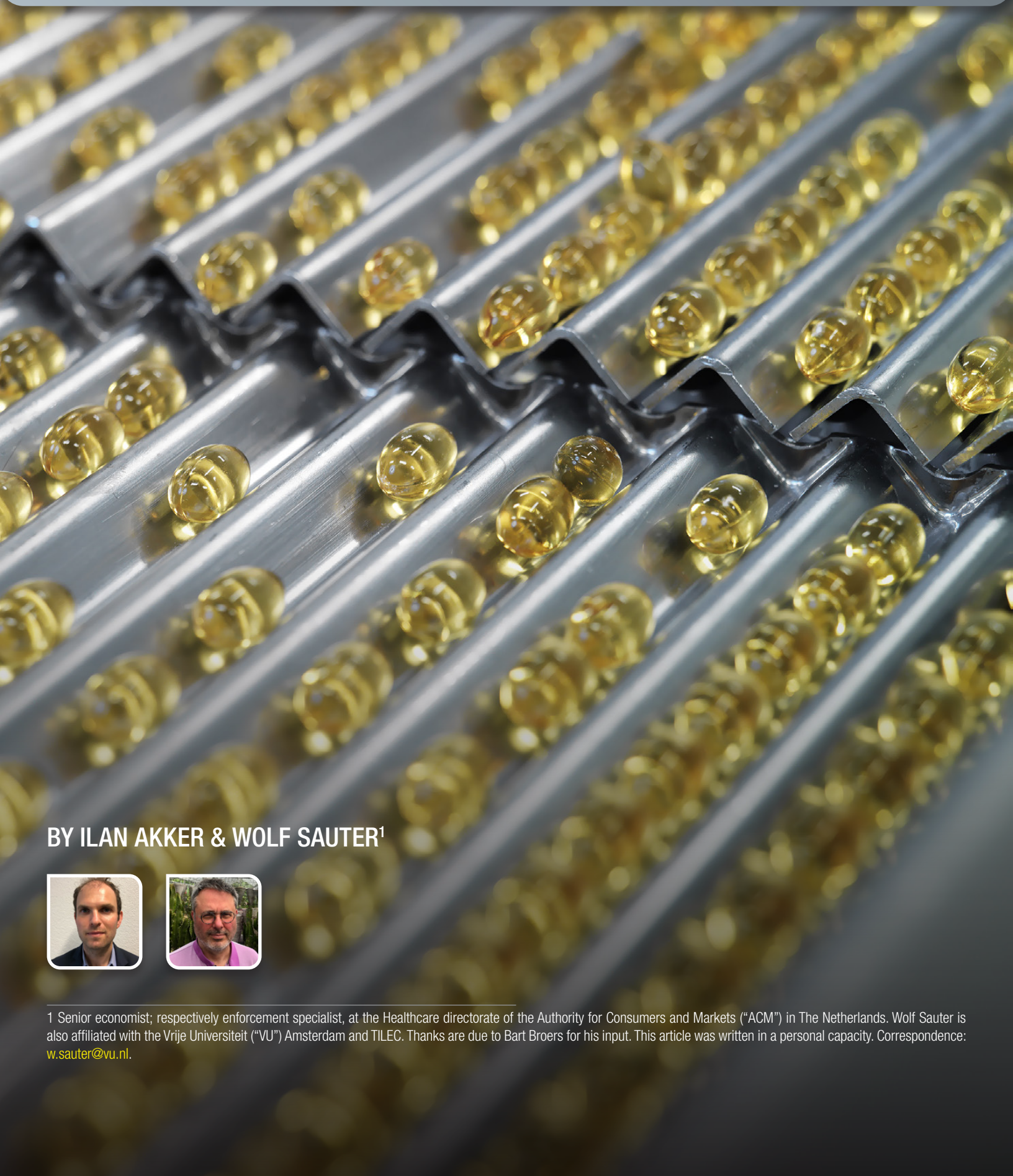
FIRST OF ALL, DO NO HARM: NEW DIRECTIONS IN EU ANTITRUST ENFORCEMENT REGARDING PHARMACEUTICALS



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I. INTRODUCTION

As parting shots across the waters to and from the UK, the recent *Paroxetine* and *CMA v. Pfizer/Flynn* cases respectively affirm the EU approach to pay-for-delay and establish a workable approach to excessive pharmaceutical pricing. We will first look at these two cases. Next, we briefly examine relevant peculiarities of pharmaceutical markets, and outline the history of EU antitrust enforcement in that sector. This sets the scene for identifying the new directions currently developing in EU antitrust enforcement with regard to pharmaceuticals. We conclude by exploring what this means for firms and antitrust authorities. In summary: first of all, do no harm.

II. THE WATERSHED

A. Pay for Delay

On January 30, 2020, judiciously timed one day before Brexit, the CJEU handed down its preliminary ruling on a referral by the UK's Competition Appeals Tribunal ("CAT") in the *Paroxetine* pay-for-delay Case.[2] In a Transatlantic echo of the U.S. Supreme Court *Actavis* Case (2013),[3] and following the line set out by its Advocate General Kokott, in *Paroxetine* the CJEU confirmed the approach taken by the European Commission to pay for delay. In essence, it found that substantial value transfers in the context of patent settlements from originators to generic producers that lack an objective justification form by object restrictions of competition between (at least potential) competitors. It is assumed such agreements intend to delay market entry and carve up the spoils at the expense of consumers. This position is in line with the EU's General Court rulings in *Lundbeck* (2016),[4] and *Servier* (2018),[5] and forms a strong indication of where the pending appeals to the CJEU in these cases are headed. In addition, the CJEU found in *Paroxetine* that it is possible for a strategy of exclusion-based pay for delay deals to qualify both as cartel infringements under Article 101 TFEU and as an abuse of dominant position under Article 102 TFEU. (In this context too however, there is room for a defense based on objective justification.)

2 Case C-307/18 *Generics et al. v. CMA*, judgment of January 30, 2020, ECLI:EU:C:2020:52, para 140. Opinion AG Kokott January 22, 2020, Case C-307/18, ECLI:EU:C:2020:28. See [2018] CAT 4, *Generics (UK) Limited et al. v. CMA*, March 18, 2018.

3 *FTC v. Actavis, Inc.*, 570 U.S. 136 (2013). See Athanasiadou, *Patent Settlements in the Pharmaceutical Industry under US Antitrust and EU Competition Law* (Kluwer Law International, 2018).

4 Case T-472/13 *Lundbeck v. Commission*, Judgment of September 8, 2016, ECLI:EU:T:2016:449. Barazza, "*Pay-for-delay agreements in the EU pharmaceutical industry: Patent law and competition law in the light of Lundbeck*," (2017) 1 *European Pharmaceutical Law Review* 3-21.

5 Case T-691/14 *Servier v. Commission*, Judgment of December 12, 2018, ECLI:EU:T:2018:922. See Buttigieg, "The Servier judgment - the GC's evolving case law on 'pay-for-delay' patent settlement agreements," *Journal of Antitrust Enforcement* 7 (2019) 279–289.

In our view, the *Paroxetine* ruling conclusively establishes the bottom line regarding pay for delay cases throughout the EU. It that sense it forms the "end of an era" where some doubt remained in this regard. It simultaneously frees up capacity for the pursuit of new directions in antitrust enforcement regarding the pharmaceutical sector.[6]

B. Excessive Pricing

Excessive pricing, nonexistent as an abuse in U.S. competition law, has long been a contested theory in EU antitrust.[7] In the *AKKA/LAA* Case (2017) Advocate General Wahl even asked the question whether there is such a thing as an excessive price – although answering in the affirmative.[8] This view has meanwhile been confirmed by the highest relevant courts in the EU at national level regarding pharmaceuticals pricing in Italy, Denmark, and most recently (and in our view importantly) in the UK. On March 10, 2020 in its *CMA v. Pfizer/Flynn* judgment,[9] the Court of Appeals reversed, on the principles applied, a 2018 CAT judgment. The CAT had transposed the standard two steps for excessive pricing set out in the *United Brands* Case (1974)[10] – excessive returns in relation to costs and unfair prices – into an eight-pronged test, notably adding a separate requirement of establishing economic value.[11]

In *CMA v. Pfizer/Flynn* the CAT was found to have misinterpreted EU law in doing so. It had been wrong to require more than a cost-plus calculation to determine whether the drug prices that dominant companies Pfizer and Flynn had increased virtually overnight by multiples between 7 and 27 were excessive. The Court of Appeals also found that the UK competition authority ("CMA") need not establish a hypothetical benchmark price or economic value *per se*, and enjoyed a degree of freedom in selecting its methodology and use of evidence to prove excessive pricing.[12]

Significantly, these findings by the Court of Appeals were in line with the rare *amicus curiae* intervention by the European Commission that occurred in this case, and can therefore be seen as the most up-to-date statement of EU law on the issue of pharmaceutical pricing – albeit for now at national level. It is also important to note that phenytoin sodium, the generic medicine involved, served a significant captive UK patient population as an epileptic cure, but was already in use for this purpose since before the Second World War. Hence, *CMA v. Pfizer/Flynn* sets a practicable standard for excessive pricing, yet in a factual context where innovation, intellectual property and regulatory exclusivity were absent. These aspects are relevant for the future directions we identify based on this approach.

III. THE CONTEXT: PHARMACEUTICALS MARKETS

Pharmaceutical markets account for 20 percent of health care spending in Europe.[13] The prices of pharmaceutical products vary widely, with cheap generic medicines on one end of the spectrum and expensive patented drugs of over €100.000 per patient per year on the other end. Patent protection and regulatory exclusivity strongly influence the intensity of competition and consequently the ability to charge high prices. Exclusivity rights combined with high ability and willingness to pay can lead to high prices in the context of private producers and public payers. After patent expiry, prices normally drop as a consequence of generic entry, because firms' strategies shift from product differentiation and marketing to price competition. Yet low prices may also be a concern where they lead to vulnerable supply chains and shortages, a risk that is evident during the current COVID-19 pandemic.

6 MLex March 5, 2020, "GSK's pay for delay judgment could mark 'end of an era' for antitrust enforcement, EU official says."

7 Abbott, "Excessive pharmaceutical prices and competition law: doctrinal development to protect public health" (2016) 6 *UC Irvine Law Review* 281-320.

8 Opinion of AG Wahl, April 6, 2017, ECLI:EU:C:2017:286 in Case C-177/16, *AKKA/LAA v.* Konkurences padome, Judgment of September 14, 2017, ECLI:EU:C:2017:689. See Wahl, "Exploitative high prices and European competition law – a personal reflection," in Konkurrensverket (Swedish competition authority), *The pros and cons of high prices* (Stockholm 2007) 47-66.

9 [2020] EWCA Civ 339, *CMA v. Pfizer/Flynn*, March 10, 2020.

10 Case 27/76, *United Brands Company and United Brands Continentaal BV v. Commission*, Judgment of February 14, 1978, ECLI:EU:C:1978:22, paras 248-253.

11 [2018] CAT 11, *Pfizer Inc. and Pfizer Limited v. Competition and Markets Authority*, June 7, 2018. Abbott, "The UK Competition Appeal Tribunal's misguided reprieve for Pfizer's excessive pricing abuse," *IIC - International Review of Intellectual Property and Competition Law* 49 (2018) 835-853.

12 Although the CMA's fines were not reinstated, such fines may now be re-imposed by the CMA in accordance with the Court of Appeal's ruling, notably after taking into account comparable products.

13 European Federation of Pharmaceutical Industries and Associations ("Efpia"), The Pharmaceutical Industry in Figures: Key Data 2019 https://www.efpia.eu/media/413006/the-pharmaceutical-industry-in-figures.pdf.

Exclusivity rights are meant to stimulate innovation. The EU pharmaceutical industry is innovation rich with 15 percent of sales invested in R&D versus 4 percent across all major industries.[14] Yet a notable development in this context is that the largest pharmaceutical companies ("big pharma") appear to be on a path to further specialization into all the regulatory elements of bringing a drug to market – clinical studies, market registration, reimbursement, sales and marketing –leaving R&D more and more to publicly funded institutions and small and mid-size biotech firms.

In view of the above, it is important to note that the EU competition and intellectual property rules apply in parallel.[15] This is firm case law since the landmark *Consten/Grundig* ruling of the CJEU in 1966,[16] as well as its early case law regarding pharmaceuticals.[17] Competition is key both to promoting innovation and controlling prices. The protection of intellectual property rights promotes *competition for new markets* (innovation) while also limiting the scope for *competition in existing markets* that could reduce prices. Holding a patent as such constitutes enjoying a temporary exclusivity, but does not by definition imply dominance in a particular relevant market (although it may sometimes lead to such dominance), let alone an antitrust abuse.[18] Yet restrictions of competition may be found illegal even in the presence of a patent, as we have seen in the pay for delay cases.[19]

IV. PAST AND PRESENT EU ANTITRUST ENFORCEMENT REGARDING PHARMACEUTICALS

A. Exclusion

Regarding pharmaceuticals, as elsewhere, the two basic categories of EU antitrust enforcement (exclusion and exploitation) have been pursued sequentially. Initially, the focus was on protecting the process of competition. It has shifted only more recently to protecting consumers directly.[20] The exclusion dimension came out clearly in the first generation of cases under Articles 101 and 102 TFEU, where pharmaceuticals producers used various methods of blocking parallel trade.[21] This form of arbitrage exploits differential pricing related to the differences in purchasing and bargaining power between the EU Member States by directing medicines from "cheap" to "expensive" Member States. These practices are protected under the competition rules as a matter of principle due to the EU's focus on unhampered cross-border trade. However apart from a degree of price competition in "expensive" Member States the parallel trade of pharmaceuticals may also have deleterious health effects if it leads to shortages for essential medicines in the "cheap" Member States from which supplies are diverted.

The next generation of exclusion cases followed in the wake of the DG COMP Sector inquiry that took place in 2008-2009, and fueled a 10 year enforcement effort, broadly up to the Commission's Report on competition enforcement regarding pharmaceuticals in 2019.[22] The 2019 Report states that in the EU, over an eight year period, the 28 national competition authorities (NCAs) plus the Commission jointly pursued over

14 *Ibid.*

15 See Case T-472/13 *Lundbeck v. Commission*, Judgment of September 8, 2016, ECLI:EU:T:2016:449; Case C-170/13 *Huawei v. ZTE*, Judgment of July 16, 2015, ECLI:EU:C:2015:477; Case C-457 *AstraZeneca v. Commission*, Judgment of December 6, 2012, ECLI:EU:C:2012:770.

16 Joined cases 56 and 58-64 *Consten/Grundig v. Commission*, Judgment of the Court of July 13, 1966, ECLI:EU:C:1966:41, at p. 345.

17 Case 24/67 *Parke, Davis v. Probel, Reese, Beintema-Interpharm and Centrafarm* Judgment of February 29, 1968, EU:C:1968:11; Case 15/74 *Centrafarm v. Sterling Drug*, Judgment of October 31, 1974, EU:C:1974:114, paras 9, 39.

18 Fonteijn, Akker & Sauter, "Reconciling competition and IP law: the case of patented pharmaceuticals and dominance abuse," in: Muscolo and Tavassi (eds), *The interplay between competition law and intellectual property: An international perspective* (Kluwer Law International, Alphen a/d Rijn 2019) 411-425.

19 See also Directive 2004/48/EC of the European Parliament and of the Council of April 29, 2004 on the enforcement of intellectual property rights, DIRECTIVE 2004/48/EC OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL of 29 April 2004 on the enforcement of intellectual property rights (Text with EEA relevance) DIRECTIVE 2004/48/EC OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL of 29 April 2004 on the enforcement of intellectual property rights (Text with EEA relevance) OJ 2004, L157/45, recital 12: "This Directive should not affect the application of the rules of competition, and in particular Articles 81 and 82 [now 101 and 102] of the Treaty. The measures provided for in this Directive should not be used to restrict unduly competition in a manner contrary to the Treaty."

20 Hancher & Sauter, "A dose of competition: EU antitrust law in pharmaceuticals," *Journal of Antitrust Enforcement* 4 (2016) 381-410.

21 Art. 102 TFEU e.g. Joined Cases C-468/06 to C-478/06 *Sot. Lélos v. GlaxoSmithKline*, Judgment of September 16, 2008, EU:C:2008:504. Art. 101 TFEU e.g. Joined Cases C-501/06 P, C-513/06 P, C-515/06 P and C-519/06 P *GlaxoSmithKline Services Unlimited v. Commission*, Judgment of October 6, 2009, EU:C:2009:610.

22 The Commission's Final Report concerning the pharmaceutical sector inquiry of July 8, 2009 is to be found at http://ec.europa.eu/competition/sectors/pharmaceuticals/inquiry/staff_working_paper_part1.pdf. The follow up at EU and national (NCA) level is found in the Commission's Report on Competition enforcement in the pharmaceutical sector (2009-2017) of January 18, 2019, at http://ec.europa.eu/competition/sectors/pharmaceuticals/report2019/report_en.pdf.

100 pharmaceuticals cases. Of these, 29 led to antitrust decisions, including five binding commitment decisions and 21 fining decisions for over one billion Euros in total.[23] Twenty cases were recorded as still ongoing.

Starting with its *Fentanyl* Decision,[24] the Commission itself notably launched a number of then groundbreaking pay for delay (also dubbed reverse payments) cases already cited above, where generic producers settled patent suits with originators, effectively staying out of the market in exchange for consideration. In our view the *Paroxetine* Case settles the Commission's approach as good law, marking the end of an era. In addition, during this period the Commission prosecuted exclusion in abuse of patent procedure in *Astra Zeneca*, that was confirmed by the CJEU (2010).[25] At the national level decentralized enforcement of the EU competition rules regarding exclusionary practices in the pharmaceutical sector took off,[26] branching out into novel abuses such as disinformation and disparagement regarding off-label use and generic products.[27]

B. Exploitation

Toward the end of the abovementioned time-period, exploitation cases affecting consumers directly were taken up, initially by competition authorities at national level: in Italy (*Aspen*, 2016), the UK (*Pfizer/Flynn*, 2017), and Denmark (*CD Pharma*, 2018), based on applications of the *United Brands* test that have now all been confirmed at the highest judicial level in the respective jurisdictions.[28] The Commission itself has meanwhile opened a wide-ranging excessive pricing investigation covering now 26 Member States, following on the 2016 Italian Aspen case.[29] All these excessive pricing cases concerned extreme price increases for long established generic products with locked-in populations and no credible innovation context. The UK Court of Appeal's recent *CMA v. Pfizer/Flynn* ruling – with Commission *amicus curiae* advice – sets out a workable approach for the standard of proof in such cases. It may be based on a cost-plus analysis, provided defenses such as objective justifications raised by the undertakings involved are addressed in a credible manner. This leaves considerable discretion to the competition authorities. The next question is how to deal with cases regarding high prices for pharmaceuticals where intellectual property and regulatory exclusivity do play a role – which brings us to the new directions in this field.

V. NEW DIRECTIONS IN SUBSTANCE

A main strength of competition enforcement is its flexibility, as the relevant rules are simple and may be applied to all types of competition issues in very different settings. The challenge for NCAs and the European Commission alike is focusing their resources on those problems where competition enforcement can make a difference. Below, we highlight three substantive trends in this respect: (i) increasing scrutiny of biosimilar markets; (ii) excessive pricing as a permanent feature; and (iii) the increasing importance of digital services related to drug provision.

A. Increased Scrutiny for Biosimilar Markets

The first trend is in line with the traditional concern for speeding up (or combating delays in) the transition to generic markets. Although biological medicine is not novel from a medical perspective, antitrust's involvement with it is relatively recent. Several anti-inflammatory drugs with high levels of turnover, notably TNF-alpha inhibitors, have faced generic entry since 2015. The TNF-alfa inhibitor Remicade (with the active substance infliximab) faced antitrust scrutiny from the CMA for their volume-based rebate scheme. In its no grounds for action decision, the CMA pragmat-

23 The Commission also examined over 80 pharmaceuticals mergers during this period and demanded remedies in 19 of them, notably regarding competition for generics in *Teva/Allergan* (Decision 7746 in 2016) and biosimilars in *Pfizer/Hospira* (Decision M.7558 in 2015).

24 Case AT.39685 – Fentanyl, Decision of the European Commission of December 10, 2013 based on Article 7 of Regulation 1/2003, https://ec.europa.eu/competition/antitrust/cases/dec_docs/39685/39685_1976_7.pdf.

25 Case T-321/05 *AstraZeneca AB and AstraZeneca plc v. Commission*, Judgment of 1 July 2010, ECLI:EU:T:2010:266.

26 See Thill-Tayara & Provost, "Dominance in the pharmaceutical sector: An overview of EU and national case law," *e-Competitions Pharma & Dominance*, Art. N° 88025 (*Concurrences*, November 21, 2019). https://www.concurrences.com/en/bulletin/special-issues/pharma-dominance-en/dominance-in-the-pharmaceutical-sector-an-overview-of-eu-and-national-case-law-en.

27 Notably in France, but also in Spain and Italy. At EU level see Case C-179/16 *F.Hoffmann-La Roche v. Autorià Garante della Concorrenza e del Mercato*, Judgment of January 23, 2018, EU:C:2018:25.

28 Colangelo & Desogus, "Antitrust scrutiny of excessive prices in the pharmaceutical sector: A comparative study of the Italian and UK experiences," *World Competition* 41 (2018) 225–254.

29 *Antitrust: Commission opens formal investigation into Aspen Pharma's pricing practices for cancer medicines*. Commission press release IP/17/1323 (May 15, 2017).

ically concluded that the rebate scheme had not worked as impact of clinical caution turned out to be less strong than had been envisioned by MSD. The Romanian competition council was the first to fine an originator producer for delaying entry of competitors, by strategically using the Romanian public procurement rules.

Crucial differences from a competition perspective between biosimilar competition and traditional generic competition are that for the former (i) entry is more expensive and riskier and (ii) the contestable share of the market is often smaller.

Regarding entry, biologicals are "alive," far more complex in structure, much larger in size and therefore less stable than synthetic drugs. The production process itself is demanding, generally takes more than six months, and fewer companies are able to develop and produce biosimilars than synthetic drugs. Crucially, unlike generics which can simply rely on the data of the original product, registering a biosimilar requires new clinical studies to prove equivalency. Hence, bringing a biosimilar to the market is more risky and costly than doing so for traditional generic drugs. To achieve and maintain a healthy market structure it is therefore important to maintaining the investment incentives for biosimilar producers. Especially for drugs aimed at smaller populations, it remains to be seen if the incentives to invest into biosimilars are sufficient.

The second crucial difference is the often smaller contestable share. Even though clinical caution for switching patients to biosimilars has decreased significantly,[30] hospitals are unable to switch all their patients for certain types of drugs – especially those administered subcutaneously. In some cases there are medical reasons for this, but caution on the side of patients themselves remains an important factor.[31] At the same time, clinical caution from doctors has far from disappeared and there is a general consensus that switching more than once every so many years is undesirable. Switching barriers in biosimilar markets affect the type and duration of anti-competitive behaviors. Using rebates on locked in patients to strengthen the originator's position on the contestable markets share may be anticompetitive. As buyers are likely to choose for a product for two years or longer such rebates can have a long-lasting effect.

We expect NCA's and the European Commission to be vigilant on biosimilar markets as the traditional concern for the transition to generics is combined here with vulnerable incentives to develop biosimilars.

B. Excessive Pricing is Here to Stay

The direct concern with consumer exploitation through excessive pricing has developed from an antitrust rarity to an instrument that may well be applied regularly. The often-cited argument that regulation and buying power should be the preferred tools to correct very high prices and not competition policy is making way for a for more nuanced view. Although alternative solutions may exist in theory, action against excessive pricing does have a role in a world where regulation can never be perfect. Additionally, compensating buying power for monopolistic drugs is limited because denying patients an effective drug is close to impossible.

So far, the excessive pharmaceuticals pricing cases that have been successful all concern old drugs that regressed from once competitive markets or price regulated markets to free pricing in relatively small and non-competitive markets. The price increases involved generally followed a transfer of ownership or distribution rights – used in Pfizer-Flynn case to bypass price regulation. The transfer of such rights can also be part of a strategy to avoid reputational damage. Switching barriers, size of the market and acquisitions may all contribute to the monopoly position of the drug.

In the *Pfizer/Flynn* case, a loophole in the NHS' price regulation scheme facilitated the price hike. A new type of concern has arisen regarding the EU orphan drug regulation, which grants a ten-year exclusivity for rare diseases.[32] It is meant to stimulate the development of drugs for small patient populations. A clear shortcoming of this regulation is that it can be gamed, creating opportunities for charging high prices for long existing drugs even when used for well-established practices. The recent successful application of Gilead for orphan status in the U.S. (which

30 The so called Norswitch study played an important role in decreasing clinical caution. Jørgensen et al., "Switching from originator infliximab to biosimilar CT-P13 compared with maintained treatment with originator infliximab (NOR-SWITCH): a 52-week, randomised, double-blind, non-inferiority trial," *The Lancet* 389 (2017) 2304-2316.

31 On the nocebo effect: Colloca et al., "The clinical implication of nocebo effects for biosimilar therapy," Frontiers in Pharmacology 10 (2019) 1-11 https://doi.org/10.3389/fphar.2019.01372.

32 Regulation (EC) No 141/2000 of the European Parliament and of the Council of December 16, 1999 on orphan medicinal products, Regulation (EC) No 141/2000 of the European Parliament and of the Council of 16 December 1999 on orphan medicinal products Regulation (EC) No 141/2000 of the European Parliament and of the Council of 16 December 1999 on orphan medicinal products OJ 2000, L18/1.

provides similar protection) for a potential COVID-19 vaccine likewise suggests gaming of orphan drug regulations.[33]

In this context, the application of excessive pricing can be a further lock on the door, even if prevention would be preferable. An excessive pricing case would ideally serve the dual role of correcting an excess while pointing at ways to prevent similar future cases arising. Yet our view is that the excessive pricing cases are here to stay as prevention is not always feasible and new loopholes may always be found. Especially in a context of patents and regulatory exclusivity, this means incentives for innovation should be taken on board in an appropriate manner. A suitable topic for a separate paper, it appears likely that this would involve taking an investment perspective into account, including in a cost-plus context.[34]

C. "Beyond the Pill"

The third trend parallels issues that come up in the digital economy and that is the development towards pharmaceuticals not only providing drugs, but also related (digital) health services. Such services could consist of self-monitoring devices, tools to improve patient compliance, diagnostic devices, and platforms with information or help from specialists or nurses. Technology firms from outside the pharmaceutical industry are often involved jointly with a pharmaceutical company.

Those services – which are sometimes labelled as "beyond the pill" – have obvious advantages for patients and health care systems. At the same time, such services also have the potential to lock in patients and prescribers. Neither may elect to switch to a competing drug if that means losing certain services, having to get used to new apps or devices or losing personal data. Additionally, prescribers may not want to work with different platforms and different services for different patients. Lastly, control over data itself may lead to dominance that can then be transferred to drug provision.

For a future healthy competitive environment, it is essential that switching remains possible and that either a wide array of companies is able to offer integral packages of medicines and services, or that platforms provide access to competing drugs. Portability of data across platforms and interoperability between platforms are essential here.[35] Antitrust enforcement will likely focus on deliberate efforts to hinder switching.

VI. NEW DIRECTIONS IN ENFORCEMENT

Having explored topics for future antitrust enforcement regarding pharmaceuticals, in this final section we address the need for an ability to act quickly, the role of purchasers, and the relationship to regulation.

A. The Need for Speed

Swift action can be crucial for preserving competitive markets and incentives. Producers may be deterred from developing new biosimilars by successful strategies from originator companies to keep them out. Similarly, lack of access to the essential platforms or raw materials may already discourage competitors as early as the pipeline stages. The need for speed contrasts with the average duration of antitrust investigations. Therefore, we believe there may be a structural need for using interim measures and injunctions more frequently.

When the heat is turned up solids liquefy – see the Commission's April 2020 guidance regarding pharmaceutical cooperation in the context of the COVID-19 epidemic. It reached back to the future by producing within days its first comfort letter in the 17 years since antitrust modernization under Regulation 1/2003.[36] The current public health crisis may yet lead to new views on the need for planning and coordination between market parties in the healthcare sector. Conversely it may also lead to fresh perspectives both on what is required and feasible in terms of speeding up antitrust intervention.

33 Public outrage made Gilead withdraw their application. The FDA takes the current number of patients into account for deciding on orphan status applications.

34 This could involve taking a life cycle approach, and integrating the probability of success when assessing investments in innovation, as well as comparing the internal rate of return ("IRR") and the weighted average cost of capital ("WACC").

35 Portability of data was also an important element in the merger decision of the EU in the joint venture between Sanofi and Google. Case M.7813 - *SANOFI / GOOGLE / DMI JV* 2016.

36 Communication from the Commission, Temporary Framework for assessing antitrust issues related to business cooperation in response to situations of urgency stemming from the current COVID-19 outbreak, April 8, 2020; and *Antitrust: Commission provides guidance on allowing limited cooperation among businesses, especially for critical hospital medicines during the coronavirus outbreak*, Commission press release, IP/20/618 (April 8, 2020).

B. An Active Role for Purchasers

Another way to speed up is in the hands of purchasers. This works in two ways. First and most obviously, with early warning signs from within the sector itself some competitive damage could be prevented rather than cured. Especially when it comes to bundling health care services and drug provision, early warnings may prevent the transfer of dominance from services to drugs or vice versa. Equally important however is the responsibility that purchasers have in avoiding or addressing problems in the market, such as by ensuring all competitors all have a fair chance in tender procedures, and taking the effects on market structure into account in their purchasing decisions.

Purchasers may also contribute to enforcement and deterrence. Follow-on actions, private damages suits predicated on antitrust infringements established in public enforcement proceedings, have already been pursued by public health authorities, for example in the UK.[37] Now the standards for the pursuit of pay for delay and standard excessive pricing cases have been established, public enforcement is more likely to be successful. At the same time private enforcement in the EU is coming into its own.[38] Consequently private health insurers and public health authorities are increasingly likely find their way to court to claim damages. This may change the calculus for anticompetitive behavior.

C. The Relationship with Regulation

Especially prior to the expiration of intellectual property rights and regulatory exclusivity, the relationship between antitrust and regulation is likely to remain complex. In our view, win or lose, competition authorities in the EU should at least attempt enforcement at all stages in order to develop the requisite experience and track record. Even if lost, a case may be useful to trigger regulatory action and/or reform.[39]

The need for such reform is already obvious. The EU orphan drug regime could make the criteria for admission – either prevalence or demonstrable lack of profitability – fully cumulative requirements instead of alternative options. If a would-be orphan product could potentially be profitable by itself, why provide 10 years of regulatory exclusivity? If not, then let's see the evidence. Likewise, introducing a common methodology for health technology assessment at EU level would enhance consistency and predictability for pharmaceutical producers and purchasers alike. This would be useful even if the relevant thresholds – what a society is willing to pay for an added quality adjusted life year – remain the province of national decision making.

Finally, antitrust and regulatory relief alike may come to rely more frequently on compulsory licensing under Article 31 TRIPS, including test data access.[40] This could liberate captive patient populations by adding a competitor to the market, and therefore allow pricing problems to be resolved by competition, not detailed price regulation.

VII. CONCLUSION

"First of all, do no harm": in the present context, this Hippocratic adage is a double-edged sword.[41] It applies to pharmaceutical firms and antitrust enforcement regarding such firms alike. For antitrust authorities this means foremost taking account of the balance between safeguarding innovation and access to affordable medicines while applying the antitrust rules in an equitable manner. This involves looking at both static and dynamic effects. For firms it means competing on merit – and to be seen doing so – not gaming the system to entrench their market power and maximize profits. In other words, for both sides the interests of patients and consumers must come first.

37 Bourke, Chapter 16 "United Kingdom," in Kobel, Këllezi & Kilpatrick (eds), *Antitrust in pharmaceutical markets and geographical rules of origin* (Springer, 2017), at 310-311.

38 Rodgers, Sousa Ferro & Marcos, "A panacea for competition law damages actions in the EU? A comparative view of the implementation of the EU Antitrust Damages Directive in sixteen Member States," *Maastricht Journal of European and Comparative Law* 26 (2019) 480-504.

39 An example from telecommunications is the EU regulation of mobile call termination and roaming, which was based on market definition principles and the need for a remedy that were established in failed dominance abuse cases.

40 't Hoen et al., "Medicine procurement and the use of flexibilities in the agreement on trade-related aspects of intellectual property rights, 2001–2016," *Bulletin of the World Health Organization* 96 (2018) 185–193.

41 "ὠφελέειν ή μὴ βλάπτειν" in the Hippocratic treatise on Epidemics (Book I part 2, para 5); "In illnesses one should keep two things in mind, to be useful and at least cause no harm." Ratsis, "First do no harm: the impossible oath," *British Medical Journal* 179 (2019) 366; https://doi.org/10.1136/bmj.l4734.

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