# The Intersection Between Intellectual Property and Competition Laws in the Pharmaceutical Sector: A Ukrainian Perspective

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***Abstract***

*Robust protection of competition is particularly important in the field of pharmaceuticals as this may help to improve access to affordable medicines and foster medical innovation. While the Antimonopoly Committee of Ukraine (AMCU) has undertaken certain activities in the pharmaceutical sector aimed at combating price increases, these activities do not cover practices that rely on intellectual property (IP) rights that may have a negative effect on the pharmaceutical market. The aim of this chapter is to explore the current competition law approach to IP-related practices in Ukraine. It will discuss certain exemptions related to IP agreements and will suggest that the current competition law rules may require clarification. Specifically, to ensure that only genuinely procompetitive IP agreements are allowed, it will be suggested that it may be necessary to develop specific guidance on the correct interpretation of the law and its application to IP-related agreements. By way of example, the chapter will discuss anticompetitive IP-related agreements that are unique to the pharmaceutical industry, i.e. 'pay-for-delay' agreements. While such agreements have not been the subject of investigation by the AMCU, they have attracted particular attention in the EU and the US. The chapter will discuss the approaches for assessing such agreements developed in the EU and the US, and will provide some recommendations that, it is believed, will help to create more effective competition law enforcement in the field of pharmaceuticals for the benefit of Ukrainian patients. The discussion in this Chapter, while focusing on Ukraine, may also be useful to other jurisdictions that seek to improve their competition law enforcement in the field of IP to facilitate access to medicines.*

## 1 Intersection Between IP Law and Competition Policy in the Pharmaceutical Industry

### *1.1 The Role of IP Law and Competition Policy in Incentivising Innovation*

Intellectual property (IP) law is closely intertwined with competition law. The essential features of IP rights are that they confer upon their owners certain exclusivities that enable them to behave in a particular way. Taking patents as an example, patents provide exclusive

rights to their holders, allowing them to prevent others from exploiting patented inventions without their consent. In other words, patent holders are able to prevent their competitors from marketing a product protected by the patent.[1] This, in turn, allows them to charge supra-competitive prices for a limited period.[2] In the past, due to these characteristics IP rights were considered to be in conflict with competition law.[3] This is because, while IP rights create monopoly, which was seen to be contrary to competition, competition law favours free entry and asset mobility, which IP rights limit in order to create incentives.[4] However, more recently this view has been revised and these two bodies of laws are now seen as complimentary: both IP and competition laws aim at incentivising innovation, although they achieve this aim through different means. From the IP law perspective, a temporary monopoly is justified by the need to reward inventors for their innovative efforts, allowing them to recoup investments and gain profit, as well as providing further incentives to innovate. From the competition law perspective, while it generally condemns practices of monopolists that restrain competition, the grant of this exclusivity is seen as a just balance between competing interests of patent and competition laws. On the one hand, the exclusive right granted by the patent system allows the rightholder to prevent the invention from being copied and thus blocks competition by imitation (price competition); this, in turn, facilitates innovation in the form of developing alternative products and thus generates competition by substitution (dynamic competition).[5]

While preventing competitors from using the IP-protected technologies and thus gaining a competitive advantage is typically considered to be a lawful exercise of the IP rights, some IP-related practices may be considered anticompetitive as they significantly impede competition and harm consumer welfare. This raises the question of when competition law should cease to 'tolerate' the exercise of the exclusive IP rights. As could be seen from the activities of the

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1 See e.g. EGC, Case T-321/05 *AstraZeneca AB v. European Commission* (2010) EU:T:2010:266, para 362 (the possession of an exclusive right 'normally results in keeping competitors away, since public regulations require them to respect that exclusive right').

2 OECD, 'Licensing of IP Rights and Competition Law' DAF/COMP (2019) 3, 8.

3 Herbert J Hovenkamp, 'Intellectual Property and Competition' (2019) Faculty Scholarship at Penn Law 1807, 1.

4 Ibid.

5 Andreas Heinemann 'Abusive Filing of IP Rights' in Duncan Matthews and Herbert Zech (eds), *Research Handbook on Intellectual Property and the Life Sciences* (Edward Elgar Publishing Ltd 2017) 479; see also Max Planck Institute for Intellectual Property and Competition Law, 'Copyright, Competition and Development' (Report), 2013, 5: 'both IP law and competition law are designed to promote a system that creates incentives for dynamic competition ... by excluding competition by imitation and enhancing competition by substitution.'

competition authorities in the EU and the US, practices in which IP rights are used as an 'instrument of abuse' or as a tool for restricting competition[6] may raise competition law concerns and, thus, need intervening. It is this type of practice by pharmaceutical companies that will be analysed in this Chapter.

### *1.2 Competition Law as a Tool for Improving Access to Medicines*

Robust protection of competition is especially important in the field of pharmaceuticals. Active competition law enforcement in this sector may help, under certain conditions, to foster innovation in the pharmaceutical sector, as well as facilitate better access to affordable medicines. It is also widely acknowledged that competition law can supplement other tools that are aimed at promoting innovation and improving access.[7] The UN High Level Panel on Access to Medicines has emphasised the importance of using competition law.[8] It finds that 'competition policies are important levers that governments can employ to ensure that health technologies markets operate competently and that the public benefits from low prices and innovation'.[9] The need for greater use of competition law to facilitate access to medicines has also been highlighted by the Global Commission on HIV and the Law, stating that 'countries must proactively use other areas of law and policy, such as competition law, price control policy and procurement law which can help increase access to pharmaceutical products.'[10] More recently, South Africa and China have initiated a discussion on 'Intellectual Property and the Public Interest: Promoting Public Health Through Competition Law and Policy' at the WTO Council for TRIPS.[11] They urged Members 'to share their national experiences and examples of how competition law is used to achieve public health and related national objectives'.[12]

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6 Steven D Anderman and Hedvig Schmidt, *EU Competition Law and Intellectual Property Rights: The Regulation of Innovation* (Oxford University Press 2011) 6 (referring to ECJ C-85/76 *Hoffman-La Roche v. Commission* (1979) ECLI:EU:C:1979:36, para 51, and ECJ C-262/81 *Coditel SA v. Cine-Vog Films SA and others (Coditel II)* (1982) ECLI:EU:C:1982:334, para 14.

7 UNDP, 'Using Competition Law to Promote Access to Medicines and Related Health Technologies in Low- and Middle-Income Countries' *UNDP* (7 December 2017) <https://www.undp.org/publications/using-competition-law-promote-access-medicines-and-related-health-technologies-low-and> accessed 27 December 2021.

8 United Nations Secretary-General's High-Level Panel on Access to Medicine, 'Promoting Innovation and Access to Health Technologies' (Report), 2016.

9 Ibid 24.

10 UNDP, 'Global Commission on HIV and the Law: Risk, Rights and Health' (Report) 87, 2012.

11 World Trade Organization, 'Intellectual Property and the Public Interest: Promoting Public Health Through Competition Law and Policy: Communication from China and South Africa' (Communication) IP/C/W/643, 2018.

12 Ibid, para 9.

While robust competition may facilitate pharmaceutical innovation and access to medicines, restrictions of competition may have the opposite effect. In particular, certain IP-related practices by originators[13] aiming to prolong the commercial life of their existing successful products have attracted the attention of competition authorities in different jurisdictions. For example, in 2008 the European Commission undertook a major investigation into the pharmaceutical sector with a specific focus on patent strategies.[14] It identified a number of such strategies it described as aiming 'to extend the breadth and duration of [originators'] patent protection'[15] and 'to delay or block the market entry of generic medicine'.[16] These include, *inter alia*, such practices as 'pay-for-delay' agreements, life-cycle management strategies, sham litigation, divisional patent applications and strategic patenting.[17] These practices have the capacity not only to increase drug prices, making them unaffordable for patients, but also may affect dynamic competition by stifling innovation of both originators and generic companies.[18]

### *1.3 Access to Medicines in Ukraine and the Importance of Robust Competition Law Enforcement*

A 2018 WHO study revealed that public spending on health as a share of GDP had been consistently low in Ukraine, i.e. in 2014 it fell from a peak of 3.8% to 2.9% and remained at this level in 2015.[19] Until very recently, there was no system for public reimbursement of prescription medicines in the outpatient sector in Ukraine and, thus, patients provided with prescriptions had to buy medicines in pharmacies and pay their full cost out of pocket.[20] As a result, spending on medicines has been the main driver of financial hardship for Ukrainian

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13 European Commission, 'Pharmaceutical Sector Inquiry' (Final Report), 2009, 9 ('"Originator company" is defined as a company that sells originators', while '"Originator" is defined as a novel drug that was under patent protection when launched onto the market').

14 Ibid.

15 European Commission, 'Executive Summary of the Pharmaceutical Sector Inquiry Report' (Communication) COM(2007)165, 2009, 10.

16 European Commission, 'Pharmaceutical Sector Inquiry' (Final Report), 2009 (n 13) 7–8 ('"Generic company" is defined as a company that sells generics', while '"Generic" is defined as a medicinal product which has the same qualitative and quantitative composition in active substances and the same pharmaceutical form as a reference (originator) medicinal product and whose bioequivalence with the reference medicinal product has been demonstrated').

17 Olga Gurgula, 'Strategic Patenting by Pharmaceutical Companies – Should Competition Law Intervene?' (2020) 51 International Review of Intellectual Property and Competition Law 1062.

18 Ibid 1071.

19 World Health Organization, 'Can People Afford to Pay for Health Care? Ukraine' (Review), WHO 2018 (this is considerably below the average for countries in the WHO European Region (5%) and the European Union (6%)).

20 Ibid 9 (in 2017, 96% of people who were prescribed outpatient medicines paid for them out of pocket). See also Tetiana Stepurko and others, 'Informal Payments for Health Care Services: The Case of Lithuania, Poland and Ukraine' (2015) 6(1) Journal of Eurasian Studies 46–58.

citizens, representing 46% of out-of-pocket payments among all households, and accounting for 69% of household spending for the poorest.[21] A similar situation exists in relation to inpatient treatment.[22] While the regional budgets cover the procurement and provision of certain inpatient medicines, constant underfunding and inefficiencies result in only a small share of the inpatient budget being spent on medicines.[23] This means that patients have to buy their medicines and other supplies in hospitals.[24]

The first pilot scheme that introduced the public reimbursement for prescription drugs to patients in the outpatient setting, which covered only antihypertensive medicines, was launched by the Ministry of Health only in 2012–2013.[25] This project was carried on until the allocated funds were exhausted.[26] More recently, in 2017, Ukraine launched the Affordable Medicines Programme (AMP), which is considered to be one of the key components of the healthcare system reform.[27] The AMP introduced public coverage for some outpatient medicines, in particular, for patients diagnosed with cardiovascular diseases, type 2 diabetes and bronchial asthma (it initially covered 23 international non-proprietary names). In 2021, the programme was broadened to include a number of treatments for several additional chronic diseases, and it currently covers cardiovascular diseases, several types of diabetes, prevention of strokes and heart attacks, bronchial asthma, mental and behavioral disorders and epilepsy.[28] The treatment for all other diseases continues to be covered by patients out-of-pocket.

In the light of the insufficient state support of patients in providing access to medicines, controlling business strategies that affect drug prices is of paramount importance in Ukraine. In this regard, as was mentioned, competition law can play a key role in facilitating access to medicines, as well as incentivising pharmaceutical innovation. However, while some countries have successfully used competition law, it is an underutilised tool in the field of healthcare in many jurisdictions, including in Ukraine.[29] The Ukrainian competition authority, the Antimonopoly Committee of Ukraine (AMCU), has been relatively active in the pharmaceutical sector, but its investigations have been focused on a small number of abusive practices by stakeholders, and it has not yet dealt with any IP-related practices by pharmaceutical companies that may have a negative effect on the market and consumers. This

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21 World Health Organization 'Evaluation of The Affordable Medicines Programme in Ukraine' (Report) WHO 2019, 3.

22 WHO 2018, (n19) 9.

23 Ibid.

24 Ibid. See also Oksana Kashyntseva, 'Patent Law Access Medicine' in this volume.

25 WHO 2019, (n 21), 2

26 Ibid.

27 Ibid 4.

28 Ministry of Health Decree No. 2077 'On the approval of the Register of Medicines which are subject to reimbursement under the Programme of State Guarantee of Provision of Medical Services for the Population, as of 1 October 2021' dated 27 September 2021.

29 Duncan Matthews and Olga Gurgula, 'Patent Strategies and Competition Law in the Pharmaceutical Sector: Implications for Access to Medicines' (2016) 38(11) European Intellectual Property Review 661.

may be because the AMCU, due to the limited resources it possesses, has been prioritising those cases it considers the most significant. However, it may also be due to an insufficient understanding of the role that the IP plays in this field. Therefore, guidance on specific IP-related anticompetitive practices in this sector, as well as studying the approaches to the assessment of such practices in mature competition law jurisdictions, including the EU and the US, may be required. This will, on the one hand, draw the attention of the AMCU to such practices, while on the other hand assisting in their appropriate analysis.

This chapter, therefore, will first discuss the anticompetitive practices that have been the main focus of the AMCU's investigative activities in the pharmaceutical sector to date. It will then explain the Ukrainian competition law rules, focusing on anticompetitive agreements and specific exemptions concerning IP-related agreements, as well as a new technology transfer block exemption regulation adopted in 2018. It will be suggested that the application of these provisions with respect to IP-related agreements may need to be clarified and may require the development of specific guidance by the AMCU on their correct interpretation. Such guidance will ensure that only genuinely procompetitive IP agreements are allowed, while also preventing pharmaceutical companies from relying on the exemptions provided by the law to immunise anticompetitive agreements that stifle competition and harm consumer welfare. The chapter will discuss a specific example of anticompetitive IP-related agreements that is unique to the pharmaceutical sector, namely 'pay-for-delay' agreements, and the approaches to the competition law assessment of such agreements taken by the competition authorities in the EU and the US. Finally, it will provide some recommendations to the AMCU, which, it is believed, will help to create a more effective competition law enforcement in the field of pharmaceuticals for the benefit of Ukrainian patients.

## 2 The Pharmaceutical Market in Ukraine and Recent Activities of the AMCU in This Field

### *2.1 The Structure of the Pharmaceutical (Supply) Market in Ukraine*

As of the end of 2020, the total volume of the pharmaceutical market amounted to USD 2.2 billion.[30] The Ukrainian pharmaceutical sector is characterised by a fair share of domestic production[31] and is dominated (in both volume and value) by generic medicines.[32] At the same time, according to the 2020 AMCU analysis, 70% of medicines in circulation in Ukraine are imported, and domestic medicines are mostly made from raw materials imported to Ukraine.[33]

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30 'The Ukrainian Pharmaceutical Market in 2020 Grew by 13%' – Experts' *Interfax* (31 March 2021) <https://ua.interfax.com.ua/news/press-conference/734294.html> accessed 27 December 2021.

31 WHO 2019, (n 21) 2.

32 Ibid.

33 AMCU, 'Recommendations on Implementing Actions Directed for Preventing Violations of the Law on the Protection of Economic Competition' 2020, No. 14-рк, para 3.16.

This makes the market dependent on the import, and the price of both imported and domestic drugs dependent on fluctuations in the exchange rate of the Ukrainian hryvnia to foreign currency.[34]

According to the type of activities at different levels of the system that supplies medicines ready for use by Ukrainians, the AMCU identifies several groups, which include local producers of medical products, representatives of foreign producers, importers (distributors), wholesalers and retail.[35] The participants in the medicine supply chain act on different product markets.[36] At the level of production/import of medicines, the main participants in the markets of relevant medicines are domestic manufacturers of medicines, representative offices of foreign manufacturers and importers.[37] The AMCU found that at this level concentration can be high if a medical product is patent-protected (i.e. generics are not available) or the number of brand name products with the same active ingredient is limited.[38] During the past several years at the distribution/wholesale level there have been three large local distributors that have significant market power in the supply of wholesale batches of a wide range of medicines and that have not experienced significant competition due to the relatively small shares owned by competitors.[39] Finally, retail markets for medicines are regional and are mostly competitive.[40] However, within certain territorial boundaries, such markets may have structural features of a monopoly position/collective monopoly.[41]

According to the AMCU the main competitive concerns with the pharmaceutical market in Ukraine include the establishment of administrative barriers to entry into markets by the regulators; the ability of the regulator to omit or exercise power to give preference to individual market participants; market consolidation processes; creation of economic barriers to entry by monopolists; the possibility of transferring financial risks to the patient at each stage of the medicinal product turnover; and rising prices for medicines.[42]

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34 Ibid, para 3.16 (This means that changes in exchange rates and the devaluation of the hryvnia lead to the increase in drug prices at all levels of supply, which, however, affects the expenditure of only the final consumer. At the same time, the consumer has a fixed wage, pension and other social benefits in national currency, and this income does not change along with the changes in the exchange rate of the Ukrainian hryvnia to foreign currency); Ibid, para 4.28.

35 Ibid, para 2.4.

36 Ibid, para 2.5.

37 Ibid, para 2.7.

38 Ibid, para 2.8.

39 Ibid, para 2.10.

40 Ibid, para 2.12.

41 Ibid.

42 OECD, 'Excessive Pricing in Pharmaceutical Markets – Note by Ukraine' DAF/COMP/WD(2018)119, 2018, para 60.

### *2.2 Recent Activities of the AMCU: Distribution Agreements in the Ukrainian Pharmaceutical Sector*

In recent years, the AMCU has increased its activities in the field of pharmaceuticals, conducting market analysis[43] and issuing guidelines[44] and recommendations to relevant stakeholders,[45] including recommendations to market participants to restrain from raising the prices on pharmaceutical products during the COVID-19 pandemic.[46] In addition, the AMCU has been actively investigating specific anticompetitive practices in this sector.[47] One type of such cases relates to pricing practices by pharmacies.[48] For example, during its 2016 market analysis, the AMCU found that there had been a number of violations of state price regulations by local pharmacies.[49]

However, perhaps the most important investigations to date concern vertical agreements between pharmaceutical market participants, which the AMCU suspects represent anticompetitive concerted practices. In this respect, the AMCU has devoted particular attention to distribution agreements between foreign pharmaceutical companies (or their subsidiaries) and large domestic wholesale distributors.[50] The investigations of the AMCU revealed that some of these agreements related to medicines for which the price is specifically regulated.[51] Importantly, the agreements included, among other things, a non-transparent system of discounts provided by a foreign pharmaceutical company for the benefit of its distributors.[52]

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43 AMCU 'Report on the Results of the Analysis of the Pharmaceutical Markets (For the Period of 2014 – the First Half of 2016)' (Report) (2016).

44 AMCU, 'Recommendations on the Application of Legislation on the Protection of Economic Competition by the Participants of the Medicinal Products Markets in Vertical Relationships of Supply and Promotion of Medicines' (2019), No. 5-pp.

45 AMCU, 'Recommendations on Implementing Actions Directed for Preventing Violations of the Law on the Protection of Economic Competition' (n 33).

46 AMCU, 'Report on the Detection and Termination of Anti-Competitive Practices During the Quarantine Measures Implemented Due to Covid-19. The Implementation of Compliance Control Legislation on Economic Protection of Competition by Participants of Pharmaceutical Markets During the Increase of Covid-19 Infections in Ukraine' (Report), 2020.

47 See e.g. Annual Reports of the AMCU from 2020, 2019, 2018 and 2017 <https://amcu.gov.ua/pro-nas/zvitnist/richni-zviti> accessed 27 December 2021.

48 AMCU 'Report on the Results of the Analysis of the Pharmaceutical Markets (For the Period of 2014 – the First Half of 2016)' (n 43).

49 Ibid, 5.3.3, para 28.

50 Decision of the AMCU No. 628-p of 14 November 2017 (in which it fined Sanofi-Aventis Ukraine in the amount of UAH 69,547,184 and its two wholesale distributors in the amount of approx. UAH 800,000 each); Decision of the AMCU No. 377-p of 2 August 2018 (in which it fined Roche Ukraine in the amount of UAH 9,115,817 and its distributors BaDM – UAH 5,407,948, Business Centre 'Farmacia' – UAH 3,207,361 and Alba Ukraine UAH 339,999); Decision of the AMCU No. 680-p of 30 November 2020 (in which it fined Novo Nordisk A/C and its several distributors in the total amount of UAH 188,130,255).

51 AMCU 'Report on the Results of the Analysis of the Pharmaceutical Markets (for the Period of 2014 – the First Half of 2016)' (n 43) 5.1, para 9.

52 Ibid 5.1, para 11 (other terms of these agreements included export ban of medicines outside Ukraine; the obligation to prevent third parties from exporting goods outside Ukraine; the obligation to provide reports

The AMCU concluded that such agreements may lead to negative consequences in the form of restriction of competition in the pharmaceutical market by distorting the price regulation resulting in the increase of drug prices that are sold through public procurement procedures.[53]

One recent AMCU decision,[54] which was confirmed by the first instance[55] and appellate[56] courts, concerned the distribution agreements that were concluded between GlaxoSmithKline LLC (GSK), which was a part of the GlaxoSmithKline group companies and the sole importer of the GSK medicines in Ukraine, and several large wholesale distributors in Ukraine. In this case the AMCU investigated the setting of prices for GSK drugs when imported to Ukraine and the subsequent resale by distributors of such medicines through public procurement procedures. Specifically, drug prices are subject to state regulation in Ukraine. During the period under investigation (2011–2016), this was done by setting a maximum level of wholesale and retail margins. In particular, the maximum price margins of drugs purchased through public procurement procedures could not exceed 10% of their wholesale price.[57]

The key problematic issue in these distribution agreements, according to the AMCU analysis, were discounts. These discounts were set at two different levels. Specifically, GSK's activity on import and distribution of medicines was carried out on the basis of foreign economic agreements with its foreign suppliers. The AMCU found that the discounts received by GSK from the suppliers (that were also part of the GSK group) reduced the total amount of the cost of imported drugs and the GSK's debt before these suppliers. Thus, already at the stage of importing the GSK medicines, the price setting with respect to all GSK medicines imported to Ukraine envisaged the difference between the purchase price established in the contracts between GSK and its foreign suppliers and the real price paid for these medicines due to the existent discount system.

In turn, GSK was selling its products in Ukraine through local distributors, five of which were buying the majority of the supply. The distribution agreements included a system of incentives, including discounts, which were not reflected in the pricing.[58] The size of the discount for achieving the quarterly goal directly depended on the volume of actual purchases of the distributor and its share in the total sales of GSK: the larger the share – the greater the amount of the discount for the distributor.[59] There were a variety of discounts, which were provided by

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and the introduction of payment terms that ensure the control of the pharmaceutical company over the flow of goods in the medicinal markets of in Ukraine).

53 Ibid 5.1, para 12.

54 Decision of the AMCU (2019) No. 830-p regarding a competition law violation and imposition of a fine.

55 Commercial Court of Kyiv, Decision (2020) 910/4801/20.

56 Northern Appellate Commercial Court, Decision (2021) 910/4801/20.

57 Decision of the AMCU No. 830-p (n 54), paras 103–109.

58 Other conditions included restrictions on export by the distributors of GSK medicines and a control system of distributors' compliance with the relevant terms of contracts.

59 Commercial Court of Kyiv, Decision (2020) (n 55).

signing of debt reconciliation acts and were subject to fulfilling the terms of the corresponding agreement. By signing these acts, the distributor could reduce its debt to GSK by the amount of this discount. This essentially meant that such discounts did not reduce the price of medicines, including the medicines that were sold by distributors through state procurement procedures, but rather were an additional income of the distributors. In other words, this system of granting discounts between GSK and its distributors created conditions for further sale of medicines by distributors under which discounts received from GSK were not taken into account when forming the price of medicines during their sale through public procurement procedures. Namely, during such a sale, the distributors were able to set the maximum possible margins within the state regulation based on the purchase price of drugs from GSK, i.e. the nominal price. At the same time, the distributors were able to offset part of their costs incurred during the purchase of the medicines by later receiving the discounts when signing acts of debt reconciliation. This, while increasing their income, did not reduce the price for the final consumer, i.e. the state.

Therefore, the AMCU found that the system of contractual relationships between the GSK group companies and GSK on the one hand, and between GSK and its local distributors on the other hand, created conditions for establishing nominal and real prices for the purchase of medicines on the territory of Ukraine at two levels: first, at the stage of importing medicines into the territory of Ukraine and, second, at the stage of the sale of medicines on the wholesale market in Ukraine. The differences between the nominal and actual prices led to an unjustifiable increase in sales prices of GSK drugs, as sales prices for medicines through public procurement procedures were set taking into account the registered wholesale prices, i.e. the nominal price, and not the actual price. For example, the margins set by one of the distributors for Ventolin Nebula based on the nominal price, which it sold through public procurement procedures, was close to 10% (the maximum allowed margin under the law); however, considering the actual purchase price of this drug the margin exceeded 29%.

The AMCU concluded that the parties to these distribution agreements deliberately introduced a mechanism to circumvent the rules of price regulation and inflated prices during the sale of GSK drugs through public procurement procedures. In view of the above, the AMCU found that these distribution agreements between GSK and its several distributors, which introduced a non-transparent mechanism of discounts, led to unjustified overpricing of GSK drugs sold through public procurement procedures and, thus, violated Article 6(1) of the Law on the Protection of Economic Competition, which prohibits anticompetitive concerted actions.[60]

To provide some guidance on the assessment of vertical agreements, the AMCU issued the 2019 Recommendations ‘On the application of legislation on the protection of economic competition by the participants of the medicinal product markets in a vertical relationship of

[60] This provision will be discussed in more detail in the following section.

supply and promotion of medicines'.[61] In these Recommendations, while the AMCU acknowledges that the use of discounts is a common commercial practice and can have many procompetitive effects, it notes that discounts can also have anticompetitive effects.[62] In particular, the AMCU noted the following anticompetitive effects:[63]

- discounts as an element of a mechanism to exclude competitors from the market by setting prices below production costs and the sale of goods;
- discounts as a tool to circumvent price regulation thereby overpricing bids in public procurement;
- discounts as a dealership tool (restriction of access to customers) and as a tool to increase the costs of competitors;
- discounts as a means of restricting access to key resources, which can be raw materials or access to the main supply links, in particular, access to powerful distributors;
- discounts on bulk goods may have the effect of strengthening the market power of the supplier in competitive markets, by including in one list that is subject to discounts both unique drugs and drugs that have many substitutes. The use of such discount lists along with the conditions for achieving certain levels of sales has an additional exclusivity effect;
- discounts on lists of goods can have the effect of imposing a wider range of goods compared to the situation when the discount is set for each drug separately.

The Recommendations further explain that agreements between manufacturers/suppliers (importers) and distributors may qualify as anti-competitive concerted actions if they contain provisions on: providing benefits to individual distributors (unless such conditions are expressly permitted under the Standard requirements [in accordance with the law][64]); introduction of non-transparent pricing mechanisms (discounts, bonuses, credit notes), the purpose or consequence of which is: restriction, elimination, prevention of competition from generics; market sharing (except where allowed according to the Standard requirements); fixing a certain inflated level of market prices; and overpricing of drugs sold through public procurement procedures.[65]

It is outside of the scope of this chapter to analyse the correctness of the approach taken by the AMCU in relation to this type of agreement by pharmaceutical companies. However, it is clear that in pursuing them the AMCU seems to focus on practices that affect the trade of drugs in

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61 AMCU, 'Recommendations on the Application of Legislation on the Protection of Economic Competition by the Participants of the Medicinal Products Markets in Vertical Relationships of Supply and Promotion of Medicines' (n 44).

62 Ibid, para 28.

63 Ibid, para 30.

64 Ukrainian Law on the Protection of Economic Competition 2001, art 11.

65 AMCU, 'Recommendations on the Application of Legislation on the Protection of Economic Competition by the Participants of the Medicinal Products Markets in Vertical Relationships of Supply and Promotion of Medicines' (n 44), para 31.

terms of their pricing and availability in Ukraine. The ultimate goal is, thus, to improve access to medicines in Ukraine, which, of course, in the light of the current critical level of access, is crucial. It remains to be seen how the practice in this area will develop in the future. At the time of writing the AMCU decision in this case is under appeal at the Supreme Court and GSK has also initiated an investment litigation against Ukraine to protect its interests as a result of this decision.[66]

## 3 IP-Related Anticompetitive Agreements

While the AMCU has been actively investigating certain anticompetitive practices in the pharmaceutical sector, it has considered no IP-related practices in this field to date. The following sections, therefore, will discuss the competition law rules in Ukraine with the focus on anticompetitive agreements. While analysing these provisions, guidance on their application with reference to case law in the EU and the US will be provided.

### *3.1 Regulation of Anticompetitive Agreements in Ukraine*

#### 3.1.1 The Prohibition of Anticompetitive Concerted Actions and Specific Exceptions

The main law that regulates anticompetitive practices in Ukraine is the Law 'On the Protection of Economic Competition'[67] (LPEC), which was adopted in January 2001 and largely follows the model of EU competition rules, aligning Ukrainian law more closely with international standards.[68] It applies to practices that influence or may influence economic competition in the territory of Ukraine.[69] Article 6 LPEC contains a prohibition of anticompetitive concerted actions that 'have led or may lead to the prevention, elimination or restriction of competition'.[70] The rules set in Article 6 LPEC follow the same approach as Article 101 of the Treaty on the Functioning of the European Union (TFEU) and Section 1 of the Sherman Act as they do not

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66 Roman Bryl 'Pharmaceutical Giant GSK has Filed an Investment Lawsuit Against Ukraine' *Liga Business* (17 December 2021) <https://biz.liga.net/ua/ekonomika/all/novosti/farmatsevticheskiy-gigant-gsk-podal-investitsionnyy-isk-protiv-ukrainy> accessed 27 December 2021.

67 Ukrainian Law on the Protection of Economic Competition 2001 (LPEC), 2210-III.

68 Michael Emerson and Veronika Movchan, '*Deepening EU–Ukrainian Relations. What, Why, How?*' (Centre for European Policy Studies, 2018); Malgorzata Jakubiak, 'Analysis of Factors Contributing to the Adoption of Competition Law in Ukraine. Implications for Other Developing Countries' (2005) CASE Doradcy.

69 LPEC, art 2(2).

70 OECD, 'OECD Reviews of Legislation and Policy in the Field of Competition: Ukraine' (Report), 2016, 36 ('Article 6 makes no distinction between horizontal and vertical concerted actions, but does include a non-exclusive list of anticompetitive practices that constitute potential violations. The list covers price-fixing, market division, restriction of outputs or inputs, discrimination between similarly situated parties and tying, and adds bid-rigging, boycotts and other conduct restraining market entry or exit, and actions designed to impede the competitive ability of other companies "without an objective basis"').

distinguish between horizontal and vertical restraints, prohibiting both of them.[71] Article 10 LPEC contains an exception to the prohibition of Article 6 LPEC. This is subject to obtaining an individual authorisation from the AMCU or the Cabinet of Ministers of Ukraine with respect to concerted actions if the parties can prove that such actions facilitate: the improvement of production, purchase or sale of goods; technical, technological or economic development; development of SMEs; optimisation of export or import of goods; development and application of unified technical conditions or standards for goods; or rationalisation of production, if such concerted actions do not lead to a substantial lessening of competition in the entire market or a part thereof.[72]

At the same time, the LPEC contains certain specific exemptions to the Article 6 prohibition in Articles 7, 8 and 9. These exemptions reflect similar provisions contained in the German Act against Restraints of Competition at a time when a draft Ukrainian law was being prepared (which were later removed from German law).[73] In particular, the exemptions include:

(a) Concerted actions of SMEs relating to joint purchase of goods that do not lead to substantial restriction of competition and facilitate increased competitiveness of SMEs (Article 7);
(b) Concerted actions relating to the supply and use of goods if such concerted actions do not lead to substantial restriction of competition on the whole market or a part thereof, do not restrict access of other economic entities to the market, and do not lead to an economically unjustified price increase or a shortage of goods (Article 8);
(c) Concerted actions relating to intellectual property rights (Article 9);
(d) Other concerted actions meeting the standard requirements established by the AMCU under Article 11.

As these types of potentially anticompetitive actions are exempted from the general prohibition set in Article 6, their performance is not considered illegal.[74] However, the exemptions in

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71 UNCTAD, 'Voluntary Peer Review of Competition Law and Policy: Ukraine' (Report) UNCTAD/DITC/CLP/2013/3, 2013, 18.

72 This is similar to the approach taken by European Union law, i.e. in Article 101 TFEU. In particular, under Article 101 TFEU, an agreement that falls within Article 101(1) TFEU is not necessarily unlawful, because Article 101(3) provides for an exception to the general prohibition of Article 101(1) by stating that this provision may not apply to agreements that satisfy four conditions. Specifically, the provisions of Article 101(1) may be 'declared inapplicable in the case of [an agreement] which contributes to improving the production or distribution of goods or to promoting technical or economic progress, while allowing consumers a fair share of the resulting benefit, and which does not: (a) impose on the undertakings concerned restrictions which are not indispensable to the attainment of these objectives; (b) afford such undertakings the possibility of eliminating competition in respect of a substantial part of the products in question.' However, currently undertakings are not required to notify the European Commission and obtain an exception. Such a system of 'individual exemptions' under Article 101(3) TFEU was abolished by Council Regulation 1/2003 of 16 December 2002 on the implementation of the rules on competition laid down in Articles 81 and 82 of the Treaty (2002) OJ L1/1, which established the principle that undertakings must self-assess whether their agreements comply with Article 101 TFEU.

73 OECD, 'Competition Law and Policy in Ukraine: An OECD Peer Review' (Report) 2008, 109.

74 UNCTAD/DITC/CLP/2013/3, (n 71) 19.

Articles 7 and 8 would only be applicable if the concerted actions do not present a substantial threat to competition on the market while having a concrete positive effect on the economic development of Ukraine.

At the same time, Article 9 LPEC limits the exemption with respect to concerted practices related to the transfer and use of IP rights less strictly than the other two specific exemptions in Articles 7 and 8. It allows any restrictions imposed on the party to which the IP right is transferred if they do not go beyond legal rights of the rightholder.[75] The restrictions not considered to go beyond such rights are those concerning the scope of rights, the term and territory of the licence, the type of activity, the field of use and the minimum volume of production.[76] Importantly, as will be explained below, there are no specific thresholds for applying this provision.

The rationale of Article 9 essentially reflects the so-called 'scope of the patent' concept, under which restrictions in patent licensing agreements are allowed provided that they do not go beyond the scope of the patent rights of the licensor.[77] In the US, this concept takes its roots from the patent misuse doctrine that had evolved from patent law and was later adopted by antitrust law to condemn clauses that extend the scope of the exclusivity granted by the patent and considered these to be a patent abuse.[78] Similarly, in the past, the German Act against Restraints of Competition, which, as mentioned, inspired the drafters of Article 9, contained a provision that forbade practices which extended exclusivity beyond the rights granted by the patent.[79] Such practices were considered illegal *per se*, and included, for example, tie-ins of non-patented products with patented products and post expiration royalties.[80]

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75 LPEC, art 9(1): 'The provisions of Article 6 of this Law shall not apply to agreements on the transfer of intellectual property rights or on the use of the object of intellectual property insofar as they restrict the party to the agreement to which the right is transferred, if these restrictions do not exceed limits of legal rights of the [holder] of intellectual property rights.'

76 LPEC, art 9(2): 'It is considered that restrictions on the scope of rights transferred, the term and territory of the permit for use of the object of intellectual property rights, as well as the type of activity, field of use, minimum amount of production do not go beyond the rights specified in part one of this article.'

77 Anderman and Schmidt (n 6) 235.

78 See e.g. US Supreme Court *Mercoid Corp v. Mid Continent Investment Co.* (1943) 320 U.S. 661.

79 Anderman and Schmidt (n 6) 235 (Section 20(1) of the [German] Act against Restraints of Competition 1957 provides that patent licensing agreements are void to the extent that they impose restraints on the licensee which exceed the scope of the patent grant. Certain restrictions are deemed not to exceed the patent right).

80 See e.g. EC, Judgement C-193/83 *Windsurfing International v. Commission of the European Communities* (1986) ECR 61, that concerned restrictions in a patent licence which went beyond the specific subject matter of a patent by tying a patented product with a non-patented product. This case law still remains good law and was referred to by the Commission in its most recent decisions in CASE AT.39226-*Lundbeck.*

### 3.1.2 New Block Exemptions on Technology Transfers in Ukraine and Article 9 LPEC

As part of its obligations under the Association Agreement with the European Union,[81] which was signed in 2014, Ukraine undertook an obligation to fill certain gaps in Ukrainian legislation with respect to the lack of a block exemption system, in particular, for agreements on technology transfer.[82] In the EU, these were to be found in EU Regulation 772/2004[83] and after its expiry such technology transfer agreements have been governed by Commission Regulation (EU) No. 316/2014 of 21 March 2014 on the application of Article 101(3) TFEU to categories of technology transfer agreements. This technology transfer block exemption regulation (TTBER 316/2014) provides a 'safe harbour' type of exemption for licensing agreements, while the Commission's Guidelines on the application of Article 101 TFEU to technology transfer agreements (TTA Guidelines)[84] explain how to apply the TTBER 316/2014.[85] Importantly, the TTA Guidelines also provide guidance on the application of Article 101(3) TFEU[86] to licensing agreements that fall outside the scope of TTBER 316/2014.[87] Following the signing of the Association Agreement with the European Union, the AMCU, responsible for implementing Chapter 10 'Competition law' provisions, undertook steps to harmonise Ukrainian competition law with the EU standards by drafting block exemptions on technology transfers.[88] In 2018, Ukraine adopted, among other things, the AMCU Resolution on the Standard Requirements of Concerted Practices of Undertakings concerning Technology Transfer Agreements.[89]

According to this Resolution, a technology transfer agreement is exempted if either: (a) it is concluded between competitors and their combined market share does not exceed 20% of the relevant market(s), or (b) it is concluded between non-competitors and the market share of each of the parties does not exceed 30% of the relevant market(s). The Resolution also states that a technology transfer agreement, as a whole, will not benefit from the exemption if it contains hardcore restrictions (subject to certain exceptions), specifically: (a) in agreements between

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81 Association Agreement between the European Union and its Member States, of the one part, and Ukraine, of the other part 2014, OJ L161/3 (EU–Ukraine Association Agreement).

82 Kseniya Smyrnova, 'Enforcement of Competition Rules in the Association Agreement between the EU & Ukraine' (2014) 7(10) Yearbook of Antitrust and Regulatory Studies; see also Kseniya Smyrnova, 'Europeanisation of Competition Law' in this volume.

83 Commission Regulation 772/2004 of 27 April 2004 on the application of Article 81(3) of the Treaty to categories of technology transfer agreements (2004) OJ L123/11.

84 Communication from the Commission – Guidelines on the application of Article 101 of the Treaty on the Functioning of the European Union to technology transfer agreements (2014) OJ C 89/03 (TTA Guidelines).

85 Anderman and Schmidt (n 6) 255.

86 If an agreement is caught by Article 101(1) prohibition, it can nevertheless be saved from non-enforceability by being exempted under Article 101(3) if it meets its conditions.

87 Anderman and Schmidt (n 6) 255.

88 OECD, 'OECD Reviews of Legislation and Policy in the Field of Competition: Ukraine' (n 70) 70.

89 OECD, 'Competition Provisions in Trade Agreements – Contribution from Ukraine' DAF/COMP/GF/WD (2019).

competitors, restrictions on resale prices, limitation of output, allocation of markets or customers, restriction of the licensee's ability to exploit its own technology rights or the restriction of the ability of any of the parties to carry out research and development; and (b) in agreements between non-competitors, restrictions on resale prices, restrictions of passive sales or restriction of active or passive sales to end-users by a licensee which is a member of a selective distribution system and which operates at the retail level.[90]

It should be noted that this Resolution on technology transfer does not cover the transfer and use of such IP rights as trade marks and copyright (except for software copyright).[91] The rationale for this seems to be that the licensing of such IP rights would not typically entail the transfer of technology.[92] Therefore, Article 9 is broader in this respect, as it covers the transfer and use of all IP rights. Moreover, considering the content of the new Resolution and Article 9, their mutual operation may need to be clarified. While Article 9 establishes general exemption from Article 6 prohibition for agreements on the transfer or use of IP rights, if they impose restrictions that do not go beyond the scope of legitimate rights of the rightholder, the Resolution has a different approach. The latter (mirroring the TTBER 316/2014), as was discussed above, establishes certain thresholds with respect to market shares of the parties to the agreement, along with the prohibition of certain hardcore restrictions. As per the rationale of the TTBER 316/2014, if an agreement meets these requirements there is a presumption that it generally leads to an improvement in production or distribution and allows consumers a fair share of the resulting benefits.[93] Therefore, in contrast with the provisions of Article 9 LPEC, exemptions under the Resolution from the prohibition on restrictions with respect to the territory of the licence for the use of IP rights, the scope of their use or the volume of production apply subject to certain conditions.[94] This may lead to a situation in which some restrictions set out in technology transfer agreements may be exempted from the prohibition by Article 9 LPEC, while they are not permitted under the Resolution.[95] The provisions of Article 9 and the Resolution, however, have not been applied in practice and there is no guidance on their application available from the AMCU or the courts.

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90 Section 4 of the Resolution; see also Igor Svechkar and others, 'Restraints of Trade and Dominance in Ukraine: Overview' *Thomson Reuters Practical Law* (1 February 2021) < https://ca.practicallaw.thomsonreuters.com/7-569-9990?transitionType=Default&contextData=%28sc.Default%29> accessed 27 December 2022.

91 See recital 2 of the Resolution.

92 See, however, para 47 of the TTA Guidelines, which states that '[p]rovisions in technology transfer agreements relating to the licensing of other types of intellectual property such as trademarks and copyright, other than software copyright …, are only covered by the TTBER if, and to the extent that, they are directly related to the production or sale of the contract products … For instance, where a licensor authorises a licensee to use its trademark on the products incorporating the licensed technology, this trademark licence may allow the licensee to better exploit the licensed technology by allowing consumers to make an immediate link between the product and the characteristics imputed to it by the licensed technology rights.'

93 See recitals 10 and 11 TTBER No. 316/2014.

94 See e.g. Explanatory Note on Ukrainian Draft Law on the Amendments to Certain Laws of Ukraine on the Protection of Economic Competition 2017, No. 6723.

95 Ibid.

### 3.1.3 Guidance Regarding the Application of Article 9 LPEC Is Needed

To improve the operation of legal provisions relating to the transfer and use of IP rights it may be necessary to clarify their application. One option would be to remove Article 9 and follow the EU approach to the assessment of this type of agreement. In the EU the law, first, provides exemptions for a technology transfer agreement under the TTBER 316/2014 that meets certain market thresholds and does not contain hardcore restrictions. Second, if such an agreement falls outside the scope of the safe harbour provided by the TTBER 316/2014, it may nevertheless be exempted under Article 101(3) TFEU.[96] In Ukraine, the latter could be done under Article 10 LPEC by seeking authorisation from the AMCU if the parties are able to meet the requirements of this provision. To assist the AMCU in deciding on an exception with respect to a particular IP agreement under Article 10 LPEC guidance similar to that discussed below may need to be developed. Another option is to provide guidance on the appropriate interpretation of Article 9 to avoid granting exemptions to IP agreements that may in fact be anticompetitive. As the TTA Guidelines explain:

> The fact that intellectual property laws grant exclusive rights of exploitation does not imply that intellectual property rights are immune from competition law intervention. Article 101 of the Treaty is in particular applicable to agreements whereby the holder licenses another undertaking to exploit its intellectual property rights.[97]

While competition law acknowledges that the process of technology transfer in the form of IP licensing is in principle procompetitive as it 'helps to increase the reward for innovative effort and the incentives for others to invest in R&D',[98] some restrains in an IP licensing agreement may be used as a tool to create restrictions of competition. In particular, 'some IP licensing agreements have the potential to create conditions of dominant market power or collusion in the licensed market which foreclose competitors from entering that market' and, thus, can be used to exclude competitors from markets and may harm consumers.[99] Therefore, it is paramount to develop guidelines that would assist the AMCU and the courts in interpreting the boundaries of Article 9 application. In particular, such guidance would need to define what is actually meant by licensing and what will fall outside of the scope of this term. In addition, certain factors that would help to make the scope of licensing clear, such as market definition, would need to be explained. The latter, for example, is important when assessing whether the cross-licensing of competing technologies may in fact be entered into for the purpose of market allocation to avoid the scrutiny of competition law. The explanations would need to elaborate

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96 See e.g. Commission Regulation 330/2010 of 20 April 2010 on the application of Article 101(3) of the Treaty on the Functioning of the European Union to categories of vertical agreements and concerted practices (2010) OJ L102/1, 1–7, and Commission Notice on Guidance on Vertical Restraints (2010) OJ C130/1, 1; Anderman and Schmidt (n 6) 204.

97 TTA Guidelines (n 84), para 7.

98 Anderman and Schmidt (n 6) 202.

99 Ibid 203.

on what should be taken into account when assessing whether the licence itself does not serve a specific purpose for the parties to escape the prohibition of competition law (such as licensing in the context of pay-for-delay agreements, which will be discussed below). It needs to convey to the AMCU and the courts that IP licensing that falls under the Article 9 exemption should be genuine in the sense that it serves a clear economic and existing purpose for both the licensee and the licensor. A clear application of this provision within the context of technology transfer will give investors, including foreign companies, confidence to license their technologies to Ukrainian business.

As was mentioned, Article 9 is broader than the Resolution as it also covers IP rights that do not entail the transfer of technology, such as trade marks and copyright (except for software copyright). Therefore, it may be necessary to develop guidance on the application of Article 9 to these types of IP rights as well. Typically, agreements concerning trade marks relate to distribution and resale of goods and services, which may include such restrictions as resale prices and territorial restrictions. The former would likely be outside of the scope of Article 9, because the trade mark holders cannot impose prices on a licensee as this would go beyond the scope of their legitimate rights. This would also restrain the economic freedom of the licensee, which would be against the fundamental principle of competition law. With respect to the territorial restrictions, it may be permitted to put restrictions on active sales outside the territory, but it is unlikely that Article 9 can restrict passive sales. This is because passive sales by definition are unsolicited sales. Therefore, to create a harmony between Article 6 and Article 9 it is advisable that the AMCU exclude passive sales from the exception of Article 9 because they restrict the actions of third parties and are essentially restrictions on consumers. The analysis in relation to copyright agreements would follow in general the same logic as the assessment of patent-related agreements, but the particularities of this right would need to be taken into account (including the difference between performing and non-performing rights).[100]

## 4 The EU and US Approaches to the Assessment of Pay-for-Delay Agreements

Despite the recent legislative and investigative activities of the AMCU in the pharmaceutical sector, there have been no cases with respect to IP-related practices by pharmaceutical companies. Therefore, considering the limited experience of the AMCU in investigating IP-related practices and virtually non-existent practice in this regard in the field of pharmaceuticals some possible guidance on the application of competition law rules to certain types of IP-related agreements in the pharmaceutical sector will be considered in this section. In particular, this section will focus on pay-for-delay agreements.

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[100] Richard Whish and David Bailey, *Competition Law* (Oxford, 8th edn,2015) 819; Anderman and Schmidt (n 6) 244.

### *4.1 The Assessment of Pay-for-Delay Agreements in the EU and the US*

While many IP-related agreements are usually procompetitive and lawful, certain agreements that involve IP rights may be considered anticompetitive. One type of problematic agreement in the pharmaceutical field is the so-called 'pay-for-delay' or 'reverse payment' agreement.[101] This type of agreement has attracted the attention of competition authorities in a number of jurisdictions, including in the US and the EU. These agreements are typically entered into to settle patent litigation between the originator company (the patent holder who alleges patent infringement) and the generic company (the potential competitor who asserts that the patent is invalid or not infringed). A salient element of these agreements is that they involve some kind of consideration flowing from the originator to the generic company[102] in exchange for the promise by the latter to refrain from entering the market. The competition law concern is that the originator uses its patent in an anticompetitive way in order to extend its monopoly by paying a generic company for staying out of the market, and thus eliminating its direct competitor. This, therefore, stifles competition and harms consumers, who are deprived of access to a cheaper generic version of the drug, which could have entered the market in the absence of such an agreement.[103]

In the US, pay-for-delay agreements have been one of the top priorities for the Federal Trade Commission (FTC).[104] In the last several decades, the courts have applied various tests to assess these agreements,[105] the most commonly applied of which, up until recently, was the 'scope of the patent' test. This, however, changed when the US Supreme Court delivered its decision in *FTC v Actavis*.[106] This case concerned a pay-for-delay agreement between an originator company Solvay and a generic company Actavis, under which the latter agreed not to bring its generic to the market for nine years (but 65 months before Solvay's patent expires) and promised to promote Solvay's patented drug AndroGel to doctors in exchange for millions of dollars.[107] The FTC challenged this agreement, but its complaint was dismissed by the district

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101 Matthews and Gurgula (n 29); Josef Drexl, '"Pay-for-Delay" and Blocking Patents – Targeting Pharmaceutical Companies Under European Competition Law' (2009) 40 International Review of Intellectual Property and Competition 751; Joseph Straus, '"Pay for Delay" – A Subtly Hidden, Overlooked or Ignored Transatlantic Divide: Exemplified on the *Actavis* Decision of the US Supreme Court and the *Servier* Decision of the EU Commission' (2016) 76 Zbornik Znanstvenih Razprav 197; Michael A Carrier, 'Drug Patent Settlements Around the World' (2017) 62(4) The Antitrust Bulletin 770.

102 Hence 'reverse payment', as normally it is the alleged infringer who pays the patent holder.

103 Matthews and Gurgula (n 29).

104 Federal Trade Commission, 'Pay-For-Delay: When Drug Companies Agree Not to Compete' *Federal Trade Commission* <https://www.ftc.gov/news-events/media-resources/mergers-competition/pay-delay> accessed 27 December 2021.

105 Olga Gurgula, 'US Supreme Court Decision on Reverse Payment Agreements: New Era in Patent Litigation Settlements – *FTC v. Actavis, Inc.*, 570 US' (2013) 3(4) Queen Mary Journal of Intellectual Property 325; Olga Gurgula, 'Restrictive Practices in the Pharmaceutical Industry: Reverse Payment Agreements Seeking for a Balance between Intellectual Property and Competition Law' (2012) 5 Global Antitrust Review.

106 US Supreme Court, *Federal Trade Commission v. Actavis, Inc.*, (2013) 570 U.S. 136.

107 Ibid, at 5.

court.[108] On appeal, confirming the dismissal, the Eleventh Circuit concluded that 'as long as the anticompetitive effects of a settlement fall within the scope of the patent's exclusionary potential, the settlement is immune from antitrust attack'.[109] The Appellate Court explained that patent holders have a 'lawful right to exclude others from the market,'[110] and, therefore, a patent 'conveys the right to cripple competition.'[111] Such an approach, which was largely followed by other courts, essentially gave an almost automatic immunity to this type of agreement.[112] However, the Supreme Court disagreed with the lower courts. It explained that the payment allowed the originator to eliminate the 'risk of competition' and 'induce[d] the generic challenger to abandon' its patent challenge in return for 'a share of [the originator's] monopoly profits that would otherwise be lost in the competitive market.'[113] The Court noted that lawfulness of these agreements depends on whether the payment can be justified by 'traditional settlement considerations, such as avoided litigation costs or fair value for services' that the generic has agreed to perform.[114] The Court also indicated that patent and antitrust policies are both relevant to determining the scope of the patent monopoly. It stated that:

> Although the anticompetitive effects of the reverse settlement agreement might fall within the scope of the exclusionary potential of Solvay's patent, this does not immunize the agreement from antitrust attack. For one thing, to refer simply to what the holder of a valid patent could do does not by itself answer the antitrust question…It would be incongruous to determine antitrust legality by measuring the settlement's anticompetitive effects solely against patent law policy, and not against procompetitive antitrust policies as well.

It therefore concluded that these agreements must be analysed, along with other antitrust cases, under the antitrust 'rule-of-reason' test.

Similarly, in the EU, in the aftermath of its 2008 pharmaceutical sector inquiry, the European Commission launched several investigations against originators and generic companies for entering into pay-for-delay agreements, alleging violations of Articles 101 and 102 TFEU.[115]

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108 US District Court for Northern District of Georgia, Atlanta Division *In re Androgel Antitrust Litigation (No. II)* (2010) 687 F. Supp. 2d 1371, 1379.

109 US Court of Appeals for the Eleventh Circuit *Federal Trade Commission* v. *Watson Pharmaceuticals*, *Inc*., (2012) 677 F.3d 1298, 1312.

110 Ibid.

111 Ibid, at 1310.

112 US Supreme Court, *Federal Trade Commission v. Actavis, Inc.*, (2013) 570 U.S. 136, at 158.

113 US Supreme Court, *Federal Trade Commission v. Actavis, Inc.*, (2013) 570 U.S. 136, at 154, 157.

114 Ibid, at 156; See e.g. US Court of Appeals for the Fifth Circuit, *Impax Laboratories, Inc. v. Federal Trade Commission* (2019) 19-60394.

115 For example, in 2014, the European Commission fined Servier EUR 330 million and several producers of generic medicines EUR 97 million for delaying the market entry of generic perindopril, a medicine used to treat high blood pressure. In 2013, it fined Johnson & Johnson and Novartis EUR 16 million for delaying the market entry of generic pain-killer fentanyl.

The Commission concluded that these agreements caused consumer harm by delaying generic entry and maintaining unjustifiably high prices. The current approach to the assessment of this type of agreement in the EU is reflected in the *Lundbeck* case, which, at the time of writing, is the latest agreement reviewed by the Court of Justice of the European Union (CJEU). On 25 March 2021, the CJEU dismissed the appeals against the Commission's decision to fine Lundbeck and several other companies for entering into anticompetitive pay-for-delay agreements.[116] The case concerned the blockbuster antidepressant containing the active pharmaceutical ingredient (API) citalopram. Lundbeck obtained patent protection for the API and two processes for its manufacture in several European countries. While its compound patent expired in January 2002, Lundbeck still had a number of process patents that covered certain ways to produce citalopram. Four generic companies had been planning to enter the market with their generic versions of citalopram after the expiration of the compound patent. However, Lundbeck initiated or threatened to initiate patent infringement proceedings against them, and generics, in turn, raised arguments of non-infringement or invalidity of the patents. Eventually, Lundbeck entered into an agreement with each generic company (Merck, Alpharma, Arrow, and Ranbaxy), according to which it transferred to them a significant consideration in exchange for a promise not to enter the citalopram market for a certain period of time.

The Commission found that Lundbeck and the generic companies were at least potential competitors, and that the agreements restricted competition 'by object' since the amounts that Lundbeck paid to the generic companies roughly corresponded to the profits that the generic companies anticipated making had they entered the market. It fined Lundbeck EUR 93.7 million and the generic companies EUR 52.2 million for delaying market entry of the generic antidepressant citalopram. In September 2016, the General Court upheld the Commission's decision, which was appealed by Lundbeck to the CJEU. The CJEU agreed with the General Court that the agreements were characterised as restriction by object, since it was the payments by Lundbeck, rather than its patents, that induced the generic companies to delay their market entry. The CJEU rejected Lundbeck arguments that the settlement agreements were limited to the scope of Lundbeck's new process patents, stating, with reference to the GC's judgment, that patent rights do not include 'the right to conclude agreements by which actual or potential competitors were paid not to enter the market.'[117]

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116 Judgment in Cases ECJ C-586/16p *Sun Pharmaceutical Industries and Ranbaxy (UK) v. Commission* (2021) ECLI:EU:C:2021:24; ECJ C-588/16p *Generics (UK) v. Commission* (2021) ECLI:EU:C:2021:242; ECJ C-591/16p *Lundbeck v. Commission* (2021) ECLI:EU:C:2021:243; ECJ C-601/16p *Arrow Group and Arrow Generics v. Commission* (2021) ECLI:EU:C:2021:244; C-611/16p *Xellia Pharmaceuticals and Alpharma v. Commission* (2021) ECLI:EU:C:2021:245; and C-614/16p *Merck v. Commission* (2021) ECLI:EU:C:2021:246.

117 Ibid, para 122.

### *4.2 Specific Considerations When Applying Article 9 to Pay-for-Delay Agreements*

Considering the practice of assessing pay-for-delay agreements in the EU and the US, it seems that while the patent may allow its holder to prevent competitors from using its patented product, it does not allow it to collude with competitors by paying them off for not entering the market. It is important to note that some pay-for-delay agreements may include not only a value transfer in the form of a monetary payment, but also a licence to use a patent held by the originator. The provisions of such an agreement may include certain limitations on the generic's ability to sell its generic version of the drug. Viewing such an agreement separately, it may potentially fall within the exemption provided by Article 9 LPEC, which allows the licensing of IP if it falls within the scope of the IP rightholder. However, such an agreement must be analysed as part of the overall anticompetitive strategy by the originator to delay or eliminate generic competition. As the European Commission explains in its TTA Guidelines:

> 'pay-for-delay' type settlement agreements often do not involve the transfer of technology rights, but are based on a value transfer from one party in return for a limitation on the entry and/or expansion on the market of the other party and may be caught by Article 101(1). If, however, such a settlement agreement also includes a licensing of the technology rights concerned by the underlying dispute, and that agreement leads to a delayed or otherwise limited ability for the licensee to launch the product on any of the markets concerned, the agreement may be caught by Article 101(1) and would then need to be assessed in particular in the light of Articles 4(1)(c)[118] and 4(1)(d)[119] of the TTBER [….] If the parties to such a settlement agreement are actual or potential competitors and there was a significant value transfer from the licensor to the licensee, the Commission will be particularly attentive to the risk of market allocation/market sharing.[120]

The European Commission categorises patent settlement agreements based on two main criteria: (a) whether the agreement foresees a limitation on the generic company's ability to market its own medicine, and (b) whether it foresees a value transfer from the originator to the generic company.[121] Licences may fulfil both criteria. With respect to the first criterion, the Commission noted that a licence granted by the originator company allowing the generic to be on the market counts as limiting generic entry if the generic company cannot enter the market with its own product or it cannot set the conditions for the commercialisation of its product freely.[122] Therefore, the generic company's entry is at least partly controlled by the originator

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118 TTBER, art 4(1)(c) 'the allocation of markets or customers'.

119 TTBER, art 4(1)(d) 'the restriction of the licensee's ability to exploit its own technology rights or the restriction of the ability of any of the parties to the agreement to carry out research and development'.

120 TTA Guidelines (n 84), paras 238–239.

121 European Commission, '8th Report on the Monitoring of Patent Settlements (Period: January-December 2016)' (Communication) (2018), para 8.

122 Ibid, para 9.

company through the terms of the licence agreement.[123] With respect to the second criterion, a value transfer could be in the form of a licence to the generic company enabling it to enter the market.[124] The Commission concludes that agreements that restrict the generic company's ability to market its own product and provide for a value transfer from the originator to the generic company are likely to attract the highest degree of antitrust scrutiny.[125]

Commenting on this type of agreement Hovenkamp explains: [126]

> [O]ne thing that makes an *Actavis* style pay-for-delay settlement unusual is that it does not involve a license at all, but at most an agreement to license at some future date. That is why Justice Breyer's opinion for the Court observed that, while the Patent Act explicitly permits licensing, the agreement providing for delayed entry was not authorized by the Patent Act. Indeed, an equilibrium agreement under the scope-of-the-patent test advocated by the dissenters would *never* be a license: for the entire remaining duration of the patent the generic would not produce. Once the patent expires the generic is free to produce without a license. Until actual production under a license occurs, the settlement is nothing more than a naked market division agreement.

Therefore, based on these principles it is important to differentiate between genuine patent licences and licences that mask other agreements, such as pay-for-delay agreements. In the latter case, a licensing agreement must be analysed in the context of the overall strategy to delay generic entry. In such a scenario, Article 9 LPEC must not apply, to avoid a plainly anticompetitive agreement being saved by this provision. Thus, the AMCU should construe this provision appropriately, i.e. in some cases even a seemingly lawful exercise of IP rights under IP laws may still be a violation of competition law, and therefore the AMCU should not be prevented from intervening. These considerations may also be useful beyond the assessment of pay-for-delay agreements and should be taken into account by the AMCU when assessing any IP-related agreement.

## 5 Conclusions

Competition law may be a useful tool in facilitating better access to affordable medicines and incentivising medical innovation. However, it is not sufficiently utilised in many jurisdictions, including in Ukraine. Some IP-related practices that have been condemned by competition authorities in other jurisdictions have not yet attracted the attention of the AMCU. Therefore,

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123 Ibid.

124 Ibid, para 12.

125 Ibid, para 17.

126 Herbert J Hovenkamp, 'Intellectual Property and Competition' (2019) Faculty Scholarship at Penn Law 1807 (n 3)10.

to ensure robust and healthy competition in the pharmaceutical market the AMCU may need to take a proactive role in promoting competition and innovation, as well as raising awareness of the right holders about the limits that competition law imposes on the utilisation of their IP rights. Importantly, the AMCU must pay closer attention to the IP-related practices that may delay or block competition in the pharmaceutical market. These include such practices as pay-for-delay agreements, which have been the subject of special attention by both the European Commission and the US Federal Trade Commission. To avoid this type of anticompetitive agreement being exempted under Article 9 LPEC it is advisable to develop guidance on its application, so that only genuinely procompetitive IP agreements that serve a clear economic purpose for both the licensee and the licensor would be allowed, while anticompetitive agreements would fall outside of this provision. It is believed that the combination of an active enforcement of the competition law rules by the AMCU in the pharmaceutical sector and the development of specific guidance on the correct application of such rules to IP-related practices, following the approaches to the assessment of these agreements in mature jurisdictions, will help to ensure the timely arrival of an affordable generic treatment for the benefit of Ukrainian patients.

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