European Commission

Issue 1 | April 2024

ISBN 978-92-68-14914-0, ISSN: 2315-3113

Competition *policy brief*

This issue focuses on non-price competition in EU merger control:

KD-AK-24-001-EN-N, doi 10.2763/67590

More publications on: https://ec.europa.eu/competition-policy/publications_en and http://bookshop.europa.eu

European Commission

Competition *Policy Brief*

Non-Price Competition: EU Merger Control Framework and Case Practice

Alexander Iken, Terézia Kianičková, Marion Bailly, Andrea Usai, Gabor Koltay, Stephan Simon

Introduction - Why looking at non-price competition?

Mergers are long-run events that may affect important parameters of competition. Besides prices, transactions can influence available products and services, or change their quality and variety. Mergers might also influence the merging firms' production processes, technologies, and capacities. These changes might become effective immediately or only in the more distant future. But they can have profound competitive implications and the assessment of non-price parameters of competition has been gaining an increasing prominence in merger reviews by the European Commission.

In the EU, the competitive process is at the centre of the assessment of the effects of mergers. The Commission applies a broad "consumer welfare" standard, which focuses on preventing harm to the competitive process, thus ensuring competitive outcomes to the benefit of consumers. The notion of "consumers" is wide, encompassing not just end-consumers, but also customers at upstream levels of the value chain, including large and small companies that act as consumers in various markets and business transactions and that may suffer from competition harm. This standard therefore applies regardless of which parameters of competition may be adversely affected by a merger. Consumer welfare depends directly on non-price aspects of competition, such as variety, quality and availability of products and services. The Commission's scrutiny of harm to consumers includes harm to the competitive process and is integral to the significant impediment to effective competition ("SIEC") test under the EU Merger Regulation ("EUMR")[1].

To be clear, while the Commission pursues a consumer-centred enforcement approach, it does not go beyond a competition-related consumer welfare standard. Merger control is part of EU competition policy, and while it can contribute to other EU objectives, it does not typically address other societal goals if they are not related to competitive processes.[2]

Parameters of competition typically correspond to the characteristics of the (final) products and services valued by consumers, for instance price, quality, innovation, environmental impact, and the protection of personal data and privacy. But they are not limited to those: relevant parameters of competition also encompass (intermediary) processes which reflect the companies' longer-term business decisions (e.g., capacity, R&D efforts, capital expenditures) that will ultimately affect the products and services offered to consumers in the medium to long term.

In a nutshell

Mergers may affect both price and non-price parameters of competition, such as innovation, quality, capacity, data protection and privacy, sustainability, and reliability of supply.

When reviewing mergers, the Commission takes these factors into account, be it for the purposes of defining the affected markets, the competitive assessment, or potential efficiencies.

The importance of such non-price parameters depends on the specific industry and merger but has grown over the last years due to the digital and green transition and other economic changes of market realities.

[1] Council Regulation (EC) No 139/2004 of 20 January 2004 on the control of concentrations between undertakings, OJ L 24, 29.1.2004, p.1.

[2] For example, competition enforcement may impact labour conditions to the extent that anticompetitive conduct occurs on labour markets. Labour markets have thus been investigated in antitrust cases, notably with respect to wage-fixing and no-poach agreements. At the national level, the Hungarian and Portuguese competition authorities have imposed fines for antitrust infringements in no-poach agreements (case references VJ/61/2017 (Hungary) and PRC/2020/1 (Portugal)). Similarly, the Commission is looking to investigate anti-competitive conduct in labour markets (Speech by Margrethe Vestager at the Italian Antitrust Association Annual Conference, "A new era of cartel enforcement", on 22 October 2021).

Consumers have always and will continue to put an important weight on price as a parameter of competition. Nevertheless, assessing the impact of a merger beyond (short term) effects on prices allows for the capture of the negative effects for consumers on all the parameters that matter to their purchasing decisions. It thus seeks to prevent a structural negative impact of a merger in the longer term. Non-price effects of horizontal mergers amplify negative consequences for consumers through reduced competition and compound price increases.[3]

From a legal standpoint, EU law does not pose any obstacles to assessing the non-price effects of mergers. The EUMR's substantive test does not preclude the Commission from considering any particular type of effect on competition that a merger may bring. Furthermore, the Horizontal Merger Guidelines[4] indicate that it is not only the ability of the merged entity to profitably increase prices, but also to reduce output, choice or quality of goods and services, diminish innovation, or otherwise influence parameters of competition negatively in a significant way that could lead to an intervention by the Commission. The EUMR thus provides a flexible framework that allows the Commission to assess competition between the merging parties and their rivals across a spectrum of parameters that are relevant in a given market.

This brief will explore a number of aspects of the Commission's approach to assessing the non-price parameters of competition. **Section 1** provides a non-exhaustive overview of the type of non-price parameters of competition that may be relevant in a merger review, pointing to industries where the Commission would find them particularly relevant. **Section 2** explores where and how non-price parameters may be taken into account in the Commission's assessment of mergers.

1. Which non-price parameters, and in which industries?

The Commission's assessment of non-price effects is conducted on a case-by-case basis, taking into account the specificities of markets, products, and customer behaviour. In its case practice, the Commission has developed a non-exhaustive set of criteria to establish whether a non-price parameter is relevant in a specific industry or market.

1.1 Innovation

Innovation is the essential driver of economic progress that benefits consumers, businesses, and the economy as a whole. Innovation efforts range from incremental technological progress to more radical changes in how markets function, for instance in relation to renewable energy technologies and sources, computer-integrated manufacturing, digital delivery of services, and artificial intelligence.

Innovation requires competition. Undertakings normally have an incentive to innovate to gain a competitive advantage to capture sales away from each other and protect their existing sales from each other. A merger may internalise this effect and reduce the innovation incentive. In this case, the effects can be thought of as standard unilateral effects, applied in this case to innovation efforts rather than to prices or volumes. As a result, mergers between rival innovators tend to reduce innovation incentives, unless there are sufficient knowledge spillovers or other efficiencies[5]

Innovation-related harm to consumers manifests itself in three ways – (i) a discontinuation of existing pipeline products, (ii) a reduction in future R&D efforts, and (iii) a reduction in future product market competition. In its merger control practice, the Commission has thus found innovation to be an important competitive parameter in several industries, for example the pharmaceutical, medical device, agrochemical, financial services, and digital sector. Assessing the importance of innovation in a certain industry or market requires a close look at its features and structure.

Industries with a significant expenditure on R&D. A starting point and first indicator of the relevance of innovation is the amount of expenditure on R&D across a given market or industry. In its review of *Dow/DuPont*, a merger between two agrochemical companies, the Commission's analysis of innovation effects relied on the high costs of discovery and development for new active ingredients in the crop protection industry (of USD 286 million per active ingredient).[6] In *General Electric/Alstom*, the Commission examined the transaction's effects on innovation for heavy-duty gas turbines, in part because of the high R&D spend, the need for specialised engineers, and the high headcount for R&D programmes across the industry.[7] When reviewing mergers in the pharmaceutical industry the Commission also pays particular attention to effects on innovation because of its important role in the competitive process, as exemplified by the significant expenditure on R&D.[8]

Rapidly growing or evolving markets. Innovation plays a particularly important role in markets or industries which are rapidly growing or changing. This does not only apply to the areas of IT and digital services, but can extend to all kinds of industries, such as pharmaceuticals, manufacturing, transport, or energy.

[3] See e.g., Haucap/Stiebale, "*Non-price Effects of Mergers and Acquisitions*" (DICE Discussion Paper 402, 2023), Section 1, paper commissioned by the European Commission.

[4] Guidelines on the assessment of horizontal mergers under the Council Regulation on the control of concentrations between undertakings, OJ C 31, 5.2.2004, p. 5 ("Horizontal Merger Guidelines").

[5] G. Federico, "*Horizontal Mergers, Innovation and the Competitive Process*", *Journal of European Competition Law & Practice*, Volume 8, Issue 10, December 2017, Pages 668–677.

[6] M.7932 *Dow/DuPont*, paragraph 242.

[7] M.7278 *General Electric/Alstom*, paragraphs 385 – 387.

[8] See for example M.7559 *Pfizer/Hospira*, paragraphs 55 – 56, where the Commission observed development costs of up to EUR 400 million per product (in this case a biosimilar).

In its recent review of the acquisition by *Illumina*, a supplier of Next-Generation Sequencing technology ('NGS') for genetic and genomic analysis, of *GRAIL*, a customer of Illumina using NGS systems to develop cancer detection tests, the Commission found innovation to be a key parameter in the markets where the parties were active. The Commission noted that GRAIL and its rivals were engaged in an innovation race to develop early cancer detection tests. While there was still uncertainty about the exact results of this innovation race and the future shape of the market for NGS-based early cancer detection tests, it was expected to expand rapidly and to become highly lucrative.[9]

At the same time, the importance of innovation is assessed individually for each market without presuming that certain trends apply throughout a given industry. Not every 'digital market' is necessarily characterised by a high level of innovation. For example, in *Apple/Shazam*, the Commission's market investigation did not find, at that time, innovation to be a relevant parameter in the market for dedicated music recognition apps for smart mobile devices.[10]

Industries where price plays a limited role. When competition in a given market is not primarily based on price, innovation can be a key parameter of competition. Examples include the pharmaceutical industry and, more recently, digital services. While pharmaceutical products have a substantial price tag, their cost is often covered by insurances or national health systems and not by prescribing doctors or patients. Efficacy, new modes of action, new treatment options and other innovative aspects often outweigh the importance of price as a parameter of competition. Digital services, for their part, often do not require any monetary payment from consumers and suppliers instead compete by offering the most innovative, practical, or user-friendly service.

Industries with a 'need' for innovation. Certain products or markets may require a certain level of innovation for purposes other than the mere improvement of quality. For example, in *Dow/DuPont* and *Bayer/Monsanto*, the Commission found that innovation plays an important role in pesticide and herbicide development due to the adaptation of certain weeds or insects to existing products. Thus, innovation may be needed in these markets to maintain a degree of effectiveness.[11] Similarly, regulators might require suppliers to innovate. Thus, in *Dow/DuPont*, the Commission found that, due to the growing environmental and food safety requirements, some active ingredients for crop protection products are prohibited over time or the renewal of approval for use is refused.[12] In *Hyundai Heavy Industries Holdings/Daewoo Shipbuilding & Marine Engineering*, the Commission found that innovation was needed in the market for large LNG carriers to reduce the boil-off rate of the transported LNG, to improve cost/effectiveness, and reduce fuel consumption and CO_2 emissions.[13]

Industries with a high level of IP protection. The level of innovation effort in an industry can depend on the innovators' ability to protect – or appropriate – their innovation results and prevent knowledge spillovers to other firms. A firm will be less likely to invest in innovation if its competitors could free-ride off that investment by imitating. Wide-spread, efficient and lengthy IP protection in an industry usually indicates a high level of appropriability and the importance of innovation.

For instance, in *Dow/DuPont*, the Commission found that appropriability in the crop protection industry was high pre-merger. Most of the innovation takes place via the introduction of new products (i.e., new active ingredients), which are patent protected for a long time (25 years), while enjoying significant sales with high margins both during the patent period and post-patent expiry.[14] Similarly, in *General Electric/Alstom*, the Commission noted the importance of intellectual property rights and know-how in the market for heavy-duty gas turbines.[15] Therefore, in both cases, the Commission found innovation to be an important parameter of competition and specifically assessed the effects of the merger on innovation.

Industries with a high level of contestability. Markets or industries where the best product wins shares away from rival suppliers tend to incentivise innovation. When a firm knows it can gain or protect profitable sales by providing greater value to customers, it – and its rivals – will be motivated to innovate. If, on the contrary, market shares are sticky, for example, because consumers have strong brand preferences or high switching costs, relatively few sales are contestable and innovation incentives will be lower.[16]

Process innovation. Innovation can also involve the implementation of a new or significantly improved production or delivery method. This includes significant changes in techniques, equipment and/or software. Such process innovation may decrease the unit costs of production or increase the quality of products and delivery in many industries, including in mature sectors. For instance, just-in-time production in car manufacturing allowed to significantly reduce production costs by reducing automakers' working capital needs.

1.2 Quality and product differentiation

Quality often plays a central role in consumer decisions, and therefore the competitive dynamics of markets. The term "quality" can be defined as the range of product characteristics,

[9] M.10188 *Illumina/GRAIL*, press release of 6 September 2022 available at https://ec.europa.eu/commission/presscorner/detail/en/ip_22_5364.
[10] M.8788 *Apple/Shazam*, paragraph 163.
[11] M.7932 *Dow/DuPont*, paragraph 1976 and M.8084 *Bayer/Monsanto*.
[12] M.7932 *Dow/DuPont*, paragraph 1977.
[13] M.9343 *Hyundai Heavy Industries Holdings/Daewoo Shipbuilding & Marine Engineering*, Section 8.3.3.
[14] M.7932 *Dow/Dupont*, paragraph 458.
[15] M.7278 *General Electric*/Alstom, paragraph 388.
[16] C. Shapiro, "*Competition and Innovation - Did Arrow Hit the Bull's Eye?*", page 364.

other than price, which affect the value of the product to consumers. These characteristics can include functionality, design, know-how, track-record, durability, reliability, and technology. Improving product characteristics covers both providing a product of higher quality (i.e., vertical product differentiation) and serving differentiated consumer tastes (i.e., horizontal differentiation).

In some differentiated product markets, firms may offer different options of those characteristics, sometimes at different price points. This is why customers across various industries may attach a significant value to having access to high-quality products at a competitive price. In this context, quality is one of the most relevant non-price parameters of competition in markets where product differentiation plays an important role and/or where price competition is less relevant.

Industries with a (high) level of differentiation. The importance of quality often depends on whether a market is differentiated and whether quality is one of the top parameters of competition. The Commission regularly reviews mergers in differentiated markets and has found quality to be a determinative parameter of competition. This is notably true in the manufacturing industry, where industrial customers might have specific requirements in relation to the characteristics, reliability and durability of certain materials or parts.

The Commission's practice in mergers between steel manufacturers illustrates this trend, with the Commission's focus on quality as a prevailing parameter of competition being guided by the existence of certain customers' specific requirements or the distinction, across the industry, of high-end v. low-end products.[17] For example, in *Tata Steel/thyssenkrupp/JV*, the Commission found that automotive customers had particularly stringent requirements for hot-dip galvanised steel products used for the exterior parts of a car, including the product's technical capabilities in terms of surface quality, which were one of the most relevant parameters of competition.

Other examples abound. Thus, in markets for bespoke equipment manufactured in response to particular technical requirements, and set out in tender specifications by each individual customer, quality is, by definition, a top parameter of competition and determines the degree of closeness of competition.[18] In cases involving food products, products may be geographically differentiated, such that different levels of quality are attributed or perceived, depending on a product's origin.[19] The Commission thus examines a variety of aspects of quality that may be relevant depending on the industry at stake, with examples ranging from interoperability across medical equipment,[20] to network quality in mobile telecommunication services,[21] or to the composition of a specific product in the food and chemical industries.[22] Quality may also depend on the capacity of the suppliers to adapt to specific consumers' tastes.[23]

Finally, the importance of quality in differentiated markets is also manifest in situations where brands matter. In *Merck/Sigma Aldrich*, the Commission thus found that quality (chemical composition, purity of the product) was perceived by customers through brands and worked as an important parameter of competition, notably due to the strong safety hazard in the laboratory chemicals markets.[24]

Industries where price competition is less relevant. Quality also plays an important role in the assessment of mergers in markets where price competition is less relevant. In so-called 'zero-price' markets, competitors offer products and services for free and thus, the impact of a merger on prices for customers may not be the relevant metric for assessment. Instead, the potentially negative effects of such transactions lie elsewhere – for instance, in the form of quality degradation.

This phenomenon can also be observed in mergers in the digital sector that do not concern zero-price markets such as online advertising, where quality is a relevant parameter of competition. For example, in *Google/Fitbit*, the Commission considered that the target's data was bringing an additional advantage to Google's already dominant position in online advertising when competing on non-price parameters such as quality with other players.[25]

1.3 Data protection and privacy

Data is a key input into many online services. The use of data or access to data plays an important role in the assessment of

[17] See cases M.8713 *Tata Steel/thyssenkrupp/JV*, paragraph 145 et seq. and 798 et seq.

[18] See for example M.9343 *Hyundai Heavy Industries Holdings/Daewoo Shipbuilding & Marine Engineering*, paragraphs 105 and 396; M. 9779, *Alstom/Bombardier*, paragraph 345 and 378.

[19] See for example cases M.9110 *Amerra/Mubadala/Nireus/Selonda*, paragraph 161, M.6850 *Marine Harvest/Morpol*, paragraphs 27-28, M.10699 *SalMar/NTS* paragraphs 14-22, where the Commission focused on quality as a declination of fish origin, an important parameter of competition in the relevant market.

[20] M.9945 *Siemens Healthineers/Varian Medical Systems*, paragraph 116, where the Commission found that simulators and radiotherapy solutions were differentiated products and focused on interoperability as a form of quality.

[21] M.7018 *Telefónica Deutschland/E-Plus*, where the Commission found that retail mobile telecommunication services was a differentiated product and that the merging parties competed closely on the quality of their networks.

[22] See cases M.9019 *Mars/AniCura*, paragraph 90, where the Commission found that quality - in terms of ingredients and quality controls - was an important parameter of competition for veterinarians when selecting dietetic pet food and M.6813 *McCain Foods Group/Lutosa Business*, paragraphs 10 and 35 where the Commission found that potato products can be either premium or non-premium quality, when sold to the food service market, depending on frying time, different coating, and yellow colour as well as content of dry solids which impacts crispness.

[23] See case M.10433 *Vivendi/Lagardere* where the Commission found that the market for people magazines was a differentiated one on the basis of the quality of the magazine, including the way in which the information provided is treated.

[24] M.7435 *Merck/Sigma Aldrich*, paragraph 136 and ff.

[25] M.9660 *Google/Fitbit*, paragraph 452 and ff.

digital and tech mergers. In recent years, the Commission has assessed data-related effects in several cases, as part of the assessment of horizontal effects stemming from data accumulation or in vertical assessments, where data is an important input and could lead to foreclosure of rivals from an important data input.[26]

Furthermore, data protection and privacy are particularly relevant parameters of competition in mergers in the digital and technology industries, where companies use the data collected from customers/users for commercial profit. As such, the data that a company controls have in some industries become a key driver of competition and a source of competitive advantage.

While the protection of data and privacy per se are specifically regulated by data protection regulations,[27] in some cases privacy can be an important element of quality of a product or service offered and thus a parameter of competition between the merging parties and their rivals and an element of differentiation.

The Commission may also examine whether data protection regulations can pose certain limitations on the merging parties, for instance with respect to combination of datasets or rules on the collection, processing, storage and usage of personal data.

1.4 Sustainability

Merger control can play a role in supporting and complementing the green transition in all sectors of the economy, such as pharma, high technology, manufacturing, construction as well as recycling markets. Indeed, a merger could undermine sustainability goals by reducing investments in green technology. As such, the environmental effects of a merger can be assimilated to a specific form of innovation theory of harm. Sustainability can also be a very important consumer preference, for instance attached to goods produced locally or free of pesticides. While the Commission will only intervene under the EUMR to the extent that an impediment to competition induces environmental harm,[28] there is a clear trend towards the growing importance of sustainability-related aspects in the Commission's merger reviews.[29]

Sustainability in merger control is not limited to a defined set of industries. Companies across all industries strive to become more sustainable, green, and environmentally friendly. However, in order to take environmental considerations into account in merger reviews, sustainability needs to play a role in the competition between companies active in the given market.

Industries where sustainable products reflect consumer preferences. In industries where consumer preferences for (more) sustainable products are a key driver of competition, such preferences need to be taken into account. Such preferences can stem from personal preferences, ethical norms, societal norms or environmental policies and can be observed across various industries. For instance, more stringent carbon-footprint standards resulting from the Green Deal[30] are pushing car manufacturers to source 'greener' aluminium, with a low carbon footprint. Thus, the Commission's review of two recent cases in the aluminium industry, *Norsk Hydro/Alumetal*[31] and *KPS Capital Partners/Real Alloy Europe*,[32] considered customers' preferences for recycled aluminium products and production of aluminium by using renewable energy or recycling. Waste management is another example of an industry where customers care about sustainability in the form of recycling, as shown for instance by *Schwarz Group/Suez Waste Management Companies*. [33] Sustainability is also a factor to be taken into account when assessing transactions involving consumer goods, as consumers may have strong preferences based on societal or ethical norms or environmental standards.[34]

Industries driven by sustainable objectives. In some industries, companies compete to bring green(er) technologies, products, or services on the market. Such innovations can be driven by environmental policy initiatives such as the EU Green Deal and the accompanying targets included in the 'Fit for 55' package.[35] In the EU, the European climate law regulation imposes a legally binding target of cutting net greenhouse gas emissions in the EU by at least 55% by 2030 compared to 1990 levels. Meeting that target to ensure a transition to climate neutrality will require significant changes in business models and product offering across industries, which will prompt businesses to bring innovations to the market in order to stay competitive. Greener energy sources, less polluting cars and planes, energy efficient buildings, bio and organic food products, reusable materials, cleaner cities are just a few of many examples of how sustainability objectives will change (and are already changing) market dynamics. For instance, emission-heavy industries such as the construction industry and more specifically concrete production need to adapt. Recently in *Sika/MBCC,* [36] the

[26] For more details on the Commission's assessment of data in merger investigations, see the Competition Policy Brief, Issue 02/2022 "*Merger Enforcement in Digital and Tech Markets: an Overview of the European Commission's Practice*", Section 1.3.

[27] For instance, the EU's General Data Protection Regulation (Regulation (EU) 2016/679) or the Privacy and Electronic Communications Directive (Directive 2002/58/EC, as amended).

[28] See to this effect the reasoning included in M.8084 *Bayer/Monsanto* in Section XIV: Non-Competition Concerns.

[29] For more details on the Commission's approach to sustainability in merger control cases, see the Competition Merger Brief, Issue 02/2023 – September.

[30] For an overview of the EU Green Deal policy initiative, see for instance https://commission.europa.eu/strategy-and-policy/priorities-2019-2024/european-green-deal_en.

[31] M.10658 *Norsk Hydro/Alumetal*.

[32] M.10702 *KPS Capital Partners/Real Alloy Europe*.

[33] M.10047 *Schwarz Group/Suez Waste Management Companies*.

[34] See, for instance, case M.7220 *Chiquita Brands International/Fyffes,* where the Commission found that customers made a clear distinction between organic/Fairtrade and conventional bananas.

[35] For an overview of the legislation included in the Fit for 55 package, see the press release: Completion of key 'Fit for 55' legislation (europa.eu).

[36] M.10560 *Sika/MBCC*.

Commission observed that the production of greener chemical admixtures that can reduce CO_2 emissions were part of the merging parties' R&D efforts and a parameter of differentiation for customers The Commission took this into account when assessing the closeness of competition between the parties and their competitors, as well as in the assessment of the remedy proposal.

1.5 Capacity and reliability of supply

In markets where capacity cannot be expanded easily, the existence of excess capacity, capacity constraints or planned capacity expansions becomes an important non-price parameter of competition. Many basic industries are characterised by a form of price competition with capacity constraints because new plants require significant capital investment and time. In these markets capacity decisions become a variable of competition that determine market power and dynamic outcomes. For example, capacity was an important parameter of competition either for market definition or for the competitive assessment in the following industries: aluminium production *Novelis/Aleris*,[37] base and process oils in *Nynas/Shell/Harburg Refinery,*[38] PVC supply in *INEOS/Solvay/JV,*[39] crop protection in *Dow/DuPont*, beverage cans in *Ball/Rexam*,[40] titanium dioxide pigments in *Tronox/Cristal*,[41] steel production in *Tata Steel/thyssenkrupp/JV*, and stainless steel in *Outokumpu/Inoxum.*[42]

However, capacity can also be an important parameter of competition in network industries like aviation (*Ryanair/Aer Lingus*[43] *cases*) where airports can be congested, and mobile telecommunications (*Hutchinson 3G UK/Telefónica UK*[44]) where capacities might be limited by long-term contracts.

2. Where and how to take non-price competition into account?

When assessing a merger and its impact on competition, the Commission takes into account non-price parameters of competition and the non-price effects of a concentration in different parts of its assessment, namely when defining markets (2.1), assessing the competitive impact (2.2), and potential efficiencies (2.3) of a merger, as well as when assessing the suitability of remedies (2.4). This is also relevant when taking jurisdiction over certain cases which fall below the notification thresholds (2.5).

2.1 Market definition

Non-price factors influence consumers' preferences. Therefore, such factors play a role in the assessment of substitutability and whether products sold in certain geographic regions constitute effective alternatives for customers, in other words whether the conditions of competition (not only on price) are sufficiently homogeneous in a given region. As such, the Commission assesses not only price, but also non-price factors when determining the exact scope of the product and geographic market definition in merger cases.

Innovation spaces and areas. Innovation can play a role at product market level as well as on an industry-wide level. The level of innovation of a product can play a role when defining the boundaries of a relevant market, for example by informing demand and supply side substitutability.

In cases where effects on innovation are relevant, the potential output of the relevant research and discovery activities is typically several years away from commercialisation. The definition of the relevant market may therefore be based on specific innovation pipelines and pipeline products. This is particularly true in the pharmaceutical industry where the innovation activities and pipelines are often focused on specific areas of treatment or modes of action. While such products are not yet on the market, they have a pathway to commercialisation and may constitute a basis to define the relevant market.

However, innovation activities do not always target specific, existing, or future product markets, but may take place at an earlier stage, before any product market is identified. In such situations, while companies do compete in certain innovation activities, these can be more properly defined as "innovation areas" or "innovation spaces". The merging parties' overlaps in innovation spaces may differ from their overlaps in product markets and pipeline products.[45] In addition, the parties' importance as innovators may be different from their position in product markets. As a result, it may be necessary to identify and examine the innovation spaces in which market players apply their research efforts to determine the scope and significance of innovation competition.

The Commission's practice thus identified innovation spaces in agrochemical mergers. In *Dow/DuPont*, the Commission analysed innovation competition in the whole industry and in innovation spaces consisting of groupings of crop/pest combinations at the global or at least EEA-wide level to assess how agrochemical companies compete to discover and develop new active ingredients.[46] Similarly, in *Bayer/Monsanto*, the Commission assessed innovation competition between both companies in a number of innovation spaces, for example for traits, consisting of

[37] M.9076 *Novelis/Aleris*.
[38] M.6360 *Nynas/Shell/Harburg Refinery*.
[39] M.6905 *INEOS/Solvay/JV*.
[40] M.7967 *Ball/Rexam*.
[41] M.8451 *Tronox/Cristal*.
[42] M.6471 *Outokumpu/Inoxum*.
[43] M.4439 *Ryanair/Aer Lingus*, M.5434 *Ryanair/Aer Lingus II*, M.6663 *Ryanair/Aer Lingus III*.
[44] M.7612 *Hutchinson 3G UK/Telefónica UK*.
[45] According to paragraph 38 of the Horizontal Merger Guidelines, assessing pipelines and pipeline products is only one example of how to assess the effects of a merger on innovation.
[46] M.7932 *Dow/DuPont*, paragraphs 362 and 361.

groupings of crop/functionality combinations as well as for crop protection.[47]

The concept of innovation spaces is relevant in other industries, where innovation takes place at an early stage before a relevant market can be identified. Such is the case, for instance, in certain financial services. Thus, in *Deutsche Börse/NYSE Euronext*, the Commission found that the merger between two major stock exchanges would have limited the introduction of new products and would have reduced innovation in technology, process, and market design in relation to several types of European financial derivatives. The Commission's investigation focused on the European innovation space for equity indices.[48]

The Commission's 2024 Market Definition Notice recognizes the importance of innovation as a key parameter of competition relevant for market definition. As innovative industries characterised by significant R&D present specific characteristics affecting competitive relationships, the Commission takes such specificities into account, for instance with respect to pipeline products and innovation efforts.[49]

Relevant markets by quality standard. Quality can play an important role at product or geographic market level and can lead to the Commission identifying separate markets. The Market Definition Notice relies on quality as one of the parameters of competition that the Commission takes into account when defining markets – for instance, when assessing demand substitution in product market definition, when analysing barriers and costs associated with switching demand to potential substitutes (e.g., due to uncertainty about the quality of alternative products), or when defining markets in the presence of discrimination between customers or customer groups by offering different level of quality of products.[50] In its decisional practice, the Commission has defined distinct markets based on quality considerations in a wide variety of sectors. For example, for hot dip galvanised steel products for the automotive industry,[51] farmed seabream seabass of Turkish origin[52] and premium frozen potato products.[53]

Sustainability as a factor affecting substitutability. The Commission takes into account customers' sustainability preferences when defining markets. [54] Sustainability-driven customer preferences can determine the extent of demand-side substitutability. Thus, for example, in *Marine Harvest/Morpol*, customer preferences for sustainably farmed salmon were one of the factors that led to the conclusion that farming and primary processing of Scottish salmon is not part of the same market as Norwegian salmon [55] In *Novelis/Aleris*, [56] the Commission concluded that aluminium and steel for car body parts were not part of the same market, particularly in view of CO_2 emission reduction targets, that required fuel savings and that were driving 'light weighting' of vehicles (since lighter vehicles consume less fuel) and thus demand by car manufacturers of aluminium ABS (body sheets) of a high grade and performance. In another aluminium case, *Norsk Hydro/Alumetal,*[57] the Commission found that low carbon is at least an element of differentiation that plays a role at product and geographic level when it comes to solid advanced aluminium foundry alloys.

Sustainability also plays a role in the definition of the relevant geographic market, as observed in *Schwarz Group/Suez Waste Management Companies*. The investigation in that case showed that Dutch customers tried to avoid transporting lightweight packaging for sorting over long distances in order to minimise the associated CO_2 emissions. The environmental cost of transport was also a factor taken into account in tender procedures, where more distant lightweight packaging sorting plants were penalized in tenders due to the increased CO_2 emissions associated with longer transport.[58] Ultimately, the relevant geographic market was defined as national, i.e., the Netherlands.

Privacy and data protection. In some cases, where privacy is an important consideration for consumers and a parameter of competition between the merging parties, the Commission will consider the level of privacy protection afforded when defining product and geographic markets.[59] Such considerations are likely to be particularly relevant in cases involving digital, technological, or communication products and services, where consumers' data forms part of the product. One example of such products are professional social networking sites. In *Microsoft/LinkedIn*, the Commission considered privacy requirements and the data protection regulatory framework in the geographic market definition assessment. The Commission's investigation highlighted differences in the regulatory and privacy requirements among EEA countries, which stakeholders viewed as examples of differences when it comes to the provision of social network services across the EEA. More specifically, with respect to professional social networks, certain stakeholders considered privacy considerations to play an important role as a requirement demanded by local customers, as privacy rules vary among jurisdictions.[60]

[47] M8084 *Bayer/Monsanto*, theory of harm outlined in paragraphs 80-88.
[48] M.6166 *Deutsche Börse/NYSE Euronext*, paragraph 923.
[49] Commission Notice on the definition of the relevant market for the purposes of Union competition law (OJ C 1645, 22.02.2024), "Market Definition Notice".
[50] Market Definition Notice, paragraphs 23, 27, 57, 88.
[51] M.8713 *Tata Steel/ThyssenKrupp/JV*, paragraphs 145-259.
[52] M.9110 *Amerra/Mubadala/Nireus/Selonda*, pargraph 68.
[53] M.6813 *McCain Foods Group/Lutosa Business*, paragraph 35.
[54] Market Definition Notice, paragraph 15.
[55] M.6850 *Marine Harvest/Morpol*.
[56] M.9076 Novelis/Aleris.
[57] M.10658 *Norsk Hydro/Alumetal*, press release of 4 May 2023 available at https://ec.europa.eu/commission/presscorner/detail/en/ip_23_2566.
[58] M.10047 *Schwarz Group/Suez Waste Management Companies*, paragraphs 44, 56-58.
[59] Market Definition Notice, paragraph 15.
[60] M.8124 *Microsoft/LinkedIn*, paragraph 121.

2.2. Competitive assessment

In markets where companies offer differentiated products, customers base their purchasing decisions on parameters that go beyond the mere price of a given product. Whether it is the innovativeness of products, the quality of products, product choice or the ability to offer a good level of security of supply, shorter lead-times or sustainable products, such non-price elements have an impact on the way companies compete against each other.

Therefore, when assessing whether a merger would harm competition, the Commission carries out a holistic assessment of the factors driving the competition between the parties and their competitors. Non-price parameters of competition have therefore played a role in the assessment of closeness of competition and barriers to entry and expansion. Moreover, the Commission has developed a case practice on how to review horizontal as well as non-horizontal mergers that would lead to loss, reduction and/or harm to innovation, quality, and capacity.

Closeness of Competition

Closeness of competition between companies is determined not only by comparing the prices of their products, but also by assessing the non-price competition between them. Thus, while non-price factors may not always justify a definition of a narrower product or geographic market, the Commission takes these factors into account in its competitive assessment and in particular in the assessment of closeness of competition between the merging parties and vis-à-vis their competitors.

Innovation rivalry between merging parties. Closeness in innovation can manifest itself through competitive overlaps within each R&D stage (e.g., overlapping discovery targets/lines of research, overlapping pipelines in the discovery stage, and overlapping pipelines in the development stage), and across different stages of the lifetime of a product (e.g., discovery pipelines-to-development pipelines, overlaps, discovery pipelines-to existing product overlaps, and development pipelines-to-existing product overlaps). The existence of such overlaps between the merging parties indicates that absent the merger the merging parties expected to divert future sales from each other by innovating.

While lines of research or pipelines at the discovery stages have an uncertain outcome, such inherent uncertainty should not be confused with whether or not competition concerns are present. Even in the presence of uncertainty as to the outcome of the innovation process, a merger between firms with competing lines of research is likely to affect the incentives to invest in research, leading to either delay, reorientation, or discontinuation of lines of research or pipelines and ultimately the chance of an innovation outcome.[61]

Quality. Quality can play an important role as both a parameter of differentiation and of competition when assessing closeness of competition between the merging parties and their competitors. A merger between two quality-leaders, i.e., companies offering products or services of a particularly high quality, might result in market power going beyond what is indicated by the parties' market shares. As a result of a merger, these firms could profitably raise prices precisely because of the quality-related divide that will separate them from competitors or possible entrants, without necessarily reducing quality. In prior cases, the Commission thus found that a merger of companies with a particularly good quality record in industries where quality was of great importance to customers would have resulted in higher prices.[62]

Conversely, a merger between companies offering products of inferior quality may also result in market power going beyond what is indicated by the parties' market shares, especially vis-à-vis certain customer groups. For example, in *Telefónica Deutschland/E-Plus* the Commission argued that the merging parties were close competitors because their networks were "*perceived of being of lower quality than the networks of Deutsche Telekom and Vodafone*" [i.e., the only other two operators of an own mobile network in Germany] and concluded that the parties were "*close competitors for mobile products that offer a network quality below the level achieved by the networks of Deutsche Telekom and Vodafone*". The Commission thus found that because of the perceived lower network quality, Telefónica and E-Plus would compete for the same subset of customers that do not place as high a value on network quality.[63]

Merging parties' efforts to bring more sustainable products to the market. As demand for more sustainable and environmentally-friendly products grows, companies face pressure to meet that customer and societal demand, which can be observed in the companies' innovation efforts as well as potential M&A strategies. Differences in sustainable product positioning and related R&D capabilities influence how closely companies compete with each other. Sustainability is therefore a parameter of differentiation when assessing closeness of

[61] For example, in *Dow/DuPont*, the Commission found that both parties were competing head-to-head for a significant number of innovation spaces in herbicides, insecticides, and fungicides with specific and similar discovery targets and past innovations. This analysis was based on the parties' internal documents and their patents. See case M.7932 *Dow/DuPont*, paragraphs 1123 – 1245.

[62] For example, in M.9343 *Hyundai Heavy Industries/Daewoo Shipbuilding & Marine Engineering* for large LNG carriers; in M. 8900 *Wieland/Aurubis Rolled Products/Schwermetall* for rolled copper products; and in M.7435 *Merck/Sigma Aldrich* for catalogue solvents and inorganics.

[63] M.7018 *Telefónica Deutschland/E-Plus*, paragraphs 292-293.

competition between the merging parties and their competitors.[64] For instance, the Commission can assess how closely the parties' products compete based on the products' emission levels.[65] If parties are strong innovators, the Commission also assesses their green R&D capabilities and technological advancements, notably when the investigation shows that green innovation is a key challenge in the industry going forward.[66] Moreover, customers' sustainability preferences, for instance, in terms of environmental costs can also be relevant for the assessment of the merging parties' geographic closeness.[67]

Important competitive force

Some firms may have more of an influence than that which their market share would suggest.[68] Their capacity to disrupt the market may not only result from their (aggressive) pricing strategy but also relate to other competitive dynamics, such as innovation, or quality.

Innovation. Innovation capabilities are of course a critical parameter of competition which is not (yet) reflected in (actual) sales or turnover. Hence, an innovative player would typically be considered as an important competitive force, having more influence than reflected in its market shares.[69] This has also been reflected in the Commission's case practice. To give one example, in *Dow/Dupont*, the Commission considered that by removing two out of three main R&D integrated players, the transaction would remove an important competitive force.

Quality. Quality can play an important role in the assessment of whether one of the merging parties is an important competitive force and may grow going forward. For example, in *Hutchison 3G UK/Telefónica UK*, the Commission found that Three, was an important competitive force, not only due to its aggressive device prices but also in light of its generous data offers and attractive voice/text bundles.[70] This approach was confirmed by the CJEU, finding that "*price is often not the only important parameter for assessing competitive dynamics, in particular in differentiated product markets in which quality and innovation could play a key role in the positioning of the products concerned. Therefore, an exclusively price-focused approach for the purposes of classifying an undertaking as an 'important competitive force' would necessarily be incomplete.*"[71]

Sustainability. A company offering greener products may also be considered as an important competitive force, especially if the sector and customers' preferences are becoming more sensitive to environmental aspects. In this context, the company might be expected to grow in the near future, and its market share would not reflect its full competitive potential. This consideration has been assessed in the Commission's past cases.[72]

Barriers to entry and expansion

Higher barriers to entry or expansion are likely to result in fewer successful entrants in a market or industry. Non price elements, such as innovation and capacity, often constitute significant barriers to entry or expansion due to the significant costs and time associated with those intermediary processes.

Innovation. Industries with high levels of innovation are often characterised by high barriers to entry as well. Innovation-intensive industries, markets, or products require significant expertise, know-how and financial investments. For example, in *Pfizer/Hospira*, the Commission found that higher concentration levels could dampen innovation for the discovery and development of certain biosimilars due to high barriers to entry. Biosimilars are biologic medical products which exhibit high molecular complexity and may be quite sensitive to changes in manufacturing processes. The Commission found that barriers to entry for biosimilars are typically higher than for generics and the pool of potential entrants upon patent expiry is typically smaller for biological drugs than for small-molecule chemical drugs.[73]

Mergers can thus increase innovation-related barriers to entry or expansion, for example if a rival is partially foreclosed and

[64] See, for example, M.8829 *Total Produce/Dole Food Company*, paragraphs 81, 91.

[65] In *General Electric/Alstom*, the Commission concluded that the merger would have eliminated a significant and close competitor of GE in the overall market for 50Hz heavy-duty gas turbines, given that GE and Siemens had developed machines which are relatively close to Alstom's machines in terms of emissions. See M.7278 *General Electric/Alstom*, paragraphs 511 and ff.

[66] In *Sika/MBCC*, the Commission found that innovation efforts and R&D capabilities to develop new polymers and bring more sustainable chemical admixture formulations to the market played a key role in the concrete/cement industry. Sika and MBCC were both strong innovators, including on green R&D, which was seen as important to meet sustainability challenges. The parties' innovation capabilities were one of the main factors taken into account by the Commission when assessing the closeness of competition between them and vis-à-vis other players. See M.10560 *Sika/MBCC*, paragraphs 210-226. In *Hyundai Heavy Industries/Daewoo Shipbuilding & Marine Engineering*, the Commission found that the parties were each other's close competitors on a number of key parameters of competition such as innovation and that both parties were important innovators in vessel technologies including those technologies allowing for lower fuel consumption and lower emissions. See M.9343 *Hyundai Heavy Industries/Daewoo Shipbuilding & Marine Engineering*, paragraphs 400 and ff, 491 and ff.

[67] In *Schwarz Group/Suez Waste Management Companies*, sorting plants for lightweight packaging waste (LWP) located further away from collection points imply more CO_2 emissions and therefore higher long-term environmental costs. Therefore, the parties were considered to compete closely with one another for Dutch LWP sorting contracts while sorting plants located in Germany were competing less closely. See M.10047 *Schwarz Group/Suez Waste Management Companies*, paragraph 118.

[68] Horizontal Mergers Guidelines, paragraph 37.

[69] Horizontal Mergers Guidelines, paragraph 38.

[70] M.7612 *Hutchinson 3G UK/Telefónica UK*, paragraph 764 and ff.

[71] CJEU, judgement of 13 July 2023, Case-376/20 P, paragraph 165.

[72] For example, in *Norsk Hydro/Alumetal*, the Commission concluded that given the sustainability trend, automotive customers may increasingly turn to recycled aluminium providers such as Alumetal in the future, so that the latter may be an important competitive force. However, on balance, and considering the capabilities of other suppliers, the Commission ultimately concluded that it would likely not be the case.

[73] M.7559 *Pfizer/Hospira*, paragraph 54.

cannot reach the necessary scale to continue investing in innovation.

Sustainability. In industries undergoing a green transition due to customer demand or the need to meet various sustainability goals and new environmental standards, sustainability can represent a barrier to entry and expansion for market players. This may be due to high capex investments needed to become active on a certain market, the need to obtain regulatory permits and meet, often demanding, regulatory requirements.[74]

Innovation loss theories of harm

Economic literature suggests that less competition typically reduces market-wide innovation, in particular in concentrated markets. Specifically, the vast majority of ex post evaluations of horizontal mergers estimate large negative effects on innovations inputs and outputs.[75]

The literature on patent races in the presence of uncertainty supports the view that a reduction in rivalry in the process of introducing innovation can be expected to lead to less innovation, and thereby to consumer harm. For example, economic models indicate that a reduction in the number of firms racing to be the first to patent a new product leads to a delay in the expected arrival date of a new invention.[76]

In addition to these general observations, there are a number of criteria or factors which can indicate that a transaction would have a particularly strong effect on innovation activities and product innovation. The Horizontal Merger Guidelines specify that if a merger combines two important innovators, or eliminates a firm with promising pipeline products, the transaction can eliminate an important competitive force and thus lead to a significant impediment of effective competition against which the Commission should intervene.[77] The innovation potential of the merging firms is taken into account regardless of the current market position of the companies.[78] Instead, the Commission has in its case practice relied on several forward-looking criteria.

R&D 'input'. The R&D investments of a company as well as the headcount and capabilities of its R&D function – especially in comparison to its competitors – can provide useful insights into a company's innovation strength and importance. For example, in *GE/Alstom*, the Commission found that Alstom's innovation output was understated by its market shares. Its R&D spent, headcount and testing infrastructure were proportionately greater than its market share. Alstom's large installed base also helped it to develop and introduce a range of improvements and modifications to its products.

R&D 'output'. The number of patents, product launches and pipeline projects can also provide an indication of a company's innovative strength. Such quantitative factors should be complemented by a qualitative assessment. For instance, in *Dow/DuPont*, the commission carried out a comprehensive assessment of the parties R&D 'output'. First, the Commission found that both companies had ambitious targets for innovation efforts and output (number of new products and innovative impact in terms of new mode of actions, chemical classes, and favourable regulatory profile). Second, the Commission calculated the patent shares of Dow, DuPont and their competitors. This calculation was based on the number of patents adjusted by their quality. Such adjustment is important as patents can have very different qualities. The quality of each patent was measured by the number of citations accumulated in subsequent patents.[79] Third, the Commission assessed the firms' capabilities to develop and distribute active ingredients on a large scale in the market based on their past commercial performance.

Killer acquisitions. Specific evidence of discontinuation of R&D efforts by the merging parties may play a role in the investigation of the effects of a merger. Such evidence can, for example, relate to the closure of plants, the reduction of innovation targets, or a cut in R&D budgets or investments. Incumbent firms may acquire innovative targets solely to discontinue the target's innovation projects and pre-empt future competition. For example, pharmaceutical industry data shows that acquired drug projects are less likely to be developed when they overlap with the acquirer's existing product portfolio, especially when the acquirer's market power is large because of weak competition or distant patent expiration.[80]

Reactions of competitors. The competitive role played by non-merging parties also needs to be assessed before concluding on the significance of any loss of innovation competition from the merger. If only a few non-merging parties effectively constrain the merging parties, then it is more likely that the merger will lead to a significant loss of innovation competition. Moreover, in a concentrated market, any reaction of non-merging parties to the loss of innovation competition between the merging parties is unlikely to fully offset the reduction in innovation, in particular when competitors' innovative capabilities differ from those of the merging parties.

[74] In *KPS Capital Partners/Real Alloy Europe*, the market investigation showed that there were high barriers for entry and expansion for a company to become active and maintain presence in dross recycling and slag recycling, in particular due to the capex investment needed, the need to obtain an operating permit, as well as national requirements regarding waste treatment and air pollution. See M.10702 *KPS Capital Partners/Real Alloy Europe*, paragraphs 183 – 187 and 217 – 219. Similarly, in *Hyundai Heavy Industries/Daewoo Shipbuilding & Marine Engineering*, the Commission assessed how certain innovative vessel technologies including those allowing for lower fuel consumption and lower emissions could represent barriers to entry or expansion. See M.9343 *Hyundai Heavy Industries/Daewoo Shipbuilding & Marine Engineering*, paragraphs 1052 and ff.

[75] Haucap/Stiebale, "*Non-price Effects of Mergers and Acquisitions*" (2023), Section 2.1, paper commissioned by the European Commission.

[76] See M.7932 *Dow/DuPont*, paragraph 48 for sources.

[77] Paragraph 38 Horizontal Merger Guidelines.

[78] See paragraphs 38 and 20b Horizontal Merger Guidelines.

[79] M.7932 *Dow/DuPont*, paragraph 387.

[80] Cunningham/Ederer/Ma, *"Killer Acquisitions"*, Journal of Political Economy, Volume 129, Number 3, March 2021.

Previous or historic developments. Past events can provide a useful indicator for assessing the relationship between increased concentration levels and innovation in a certain industry or market. In *Dow/DuPont* for example, the Commission observed that previous waves of consolidation were accompanied by a certain reduction in the innovation intensity and output, as demonstrated by lower R&D spend and fewer active ingredients for pesticide products brought to the market.[81]

Overlaps in pipeline products. When assessing the effects of a merger on innovation the Commission may look at the merging parties' and their competitors' pipeline products. Such assessment is of particular relevance in the research-intensive pharmaceutical industry with its clear and often standardised development and regulatory approval processes. In *J&J/Actelion*[82], the Commission thus found that both companies were developing a promising drug with a similar new mode of action to treat insomnia. Both drugs were at an early stage of clinical trials (so-called Phase II), but close in their expected efficacy and safety profiles. In *Novartis/GSK's oncology business*[83], the Commission found that both companies had R&D programmes for innovative drugs aimed at treating skin and ovarian cancer with the same mechanism of action. In *Pfizer/Hospira*, the Commission found that Pfizer was developing a competing medicine to Hospira's biosimilar for the treatment of chronic inflammatory diseases. In all three cases, the Commission's concern was that the merged entity would have fewer incentives to continue the overlapping or duplicate research programmes, not only for cost reasons but also in light of a heightened risk of future cannibalisation.

Non-horizontal effects. Innovation concerns can also arise in non-horizontal mergers, where the parties' activities are vertically linked or complementary to each other. In particular, foreclosure risks can manifest themselves in a reduction of innovation activity. Recently, in *Illumina/GRAIL*, the Commission found that customer foreclosure strategies could have stifled innovation on the emerging downstream markets for NGS-based cancer detection tests. According to the Commission's in-depth investigation, following the acquisition of GRAIL, Illumina would have had the ability and incentive to foreclose GRAIL's competitors from its high-throughput NGS systems. It could for instance refuse to supply its NGS systems to GRAIL's rivals, increase the prices, or degrade quality and delay supplies. This could have had severe and negative effects on the innovative capabilities of early cancer detection test developers and of this emerging industry as a whole – at a very critical stage of development. [84] In another case, *Broadcom/Brocade,* the Commission assessed the innovation impacts of a potential interoperability degradation between networking products (upstream) for communications and datacentre infrastructures and applications (downstream).[85] The risk that merging parties might implement interoperability degradation strategies and thus negatively impact innovation is higher in fast-developing and fast-growing industries, in particular those driven by technology and data.

Dynamic effects. Foreclosure cases in dynamic industries are often about preventing future innovation. A dominant firm in one market may foreclose a rival in a neighbouring market, preventing it from becoming an innovative force that competes better in the neighbouring market or that would innovate into the market where the dominant firm is already active.[86] Both *Broadcom/Brocade* and *Illumina/GRAIL* concerned dynamic industries and the Commission was concerned that foreclosure strategies could lead to a reduction of future competition on the respective downstream markets.

Quality degradation

A merger can result in a degradation of quality and product variety. The results of empirical studies indicate that merger-induced market power increases tend to reduce incentives to provide high-quality products.[87] Merging firms might also have an incentive to drop competing varieties within the newly combined firm to avoid cannibalisation and save fixed costs. The effects of a merger on quality tend to be very industry-specific and the Commission found that a merger would result in a degradation of quality in a number of cases, for example concerning the quality of food,[88] of medias content,[89] of medical devices[90] and of mobile communication networks.[91]

Data driven theories of harm

Privacy as a competitive parameter and element of quality. In cases where privacy and data protection play a role in the competitive dynamics, the Commission assesses the extent to which the parties compete with respect to privacy and whether the transaction could have a negative impact on privacy-related competition. For instance, in *Apple/Shazam*, privacy was considered an important element of competition between music streaming service providers. The Commission assessed how the companies treated user data and their relevant data collection practices/transmission of personal data.[92] In *Microsoft/LinkedIn*, the market investigation confirmed that privacy was an important parameter of competition and a driver of customer choice in the

[81] M.7932 *Dow/DuPont*, paragraphs 2124 - 2158.
[82] M.8401 *J&J/Actelion*.
[83] M.7275 *Novartis/GSK's oncology business*.
[84] M.10188 *Illumina/GRAIL*.
[85] M.8314 *Broadcom/Brocade*, paragraph 205.
[86] For more details on the Commission's assessment of dynamic effects in merger investigations, see the Competition Policy Brief, Issue 02/2022 "*Merger Enforcement in Digital and Tech Markets: an Overview of the European Commission's Practice*".
[87] See e.g. Haucap/Stiebale, "*Non-price Effects of Mergers and Acquisitions*" (2023), page 32, paper commissioned by the European Commission.
[88] M.9019 *Mars/AniCura*, paragraph 125.
[89] M.10433 *Vivendi/Lagardere*, paragraphs 1910 and ff.
[90] M.9945 *Siemens Healthineers/Varian Medical Systems*, paragraph 108.
[91] M.7612 *Hutchinson 3G UK/Telefónica UK*, paragraph 2308 and ff.
[92] M.8788 *Apple/Shazam*, paragraphs 313 – 315.

market for professional social networking services.[93] The Commission took this factor into account when assessing the impact of foreclosure concerns – if a competitor which offers a greater degree of privacy protection to users than LinkedIn were to be marginalized (or entry of any such competitor would be made more difficult as a result of the merger), the transaction would also restrict consumer choice in relation to this important parameter of competition.[94] Similarly, in *Facebook/WhatsApp*, privacy and security were considered as important parameters of competition in relation to consumer communication services, and an element of differentiation between the parties' offering.[95] These cases illustrate that in sectors where data, and in particular personal data, is a source of value, the privacy protection offered by companies to that data is an important competitive parameter. The potential impact of the transaction on this parameter of competition is therefore not overlooked.

Using customer data to put competitors at a disadvantage. When assessing mergers involving companies that collect customer data, it is also important to look at the potential use of that data post-transaction as the merged entity could have the ability and incentive to use such data and information to put competitors at a disadvantage. For example, in *Apple/Shazam*, the Commission assessed whether, through the acquisition of control of the Shazam app and Shazam database, Apple could gain access to certain data on its competitors. The Commission considered that the customer information to which Apple would gain access constituted commercially sensitive information. When assessing whether Apple would have the ability and incentive to use the customer information to put competitors at a disadvantage, the Commission took into consideration the legal obligations imposed on Apple by the relevant privacy and data protection regulations.[96]

Combination of datasets. In some cases, limitations posed by data protection rules can restrict or prevent certain data-related actions by the parties, such as combination of datasets. If the Commission finds that the applicable rules do not pose such limitations, the Commission examines the competitive effects stemming from such combination of datasets. For instance, in *Microsoft/LinkedIn*, the Commission concluded that the data protection rules that Microsoft and LinkedIn were subject to, limited their ability to process the dataset they maintain.[97]

Capacity-related theories of harm

The immediate effect of any merger is a reallocation of production capacities, which can lead to price effects if rivals face capacity constraints.[98] Moreover, as regards non-price competition, e.g., where capacity expansion is a variable of competition, a merger can have dynamic effects on capacities should it change the merged company's incentives to expand capacity and rivals' reaction to it.

Merging producers may compete less aggressively on capacity expansions post-transaction, as they will take account of the negative effect that new capacity in the market has on the sales of the respective merging partner. Stated differently, pre-transaction each merging party only took into account the negative impact that new capacity would have on its own sales (via the decrease in overall market price due to the additional capacity) but did not take into account the negative effect on the sales of the other merging party. This effect is internalised post–transaction, which results in a loss of competition on the market. The merger might not only change the future capacity extensions, or lead to a plant closure and a reduction in capacity, but also change the geographic distribution of capacity if competition has a strong local aspect.

Dynamic competition in capacities was an important element in the Commission's decisional practice. For example, in *Novelis/Aleris*, the Commission concluded that the transaction would have dynamic effects in the medium/long term, because Novelis' limited incentive to increase overall market capacity would be further weakened. The decision argued both that post-transaction Novelis would have less incentive to increase capacity than an independent Aleris, and that Novelis would have fewer incentives to implement its own expansion plans. The investigation analysed in detail the past capacity expansions in the market, as well as the future expansion plans of Novelis and Aleris. In *Ball/Rexam*, the investigation focused similarly on future capacity expansions. Absent the transaction, it was likely that Rexam would have increased capacity in North-East Europe and consequently reduced market concentration. This future capacity expansion of Rexam was a key factor in determining the size and geographical distribution of the commitments. In *INEOS/Solvay/JV*, the history of output and capacity reductions provided evidence on the likely effects of the merger. Earlier mergers of INEOS were followed by output reductions in North-West-Europe and increased exports, and finally plant closures that reduced the effective capacity of the merged entity. These capacity reductions likely lead to increased market power, since the decision also found that margins in North-West-Europe increased compared to the rest of Europe after the second previous merger.

Whether these theories of harm apply in a concrete case depends both on the level of the parties' capacity shares and the extent of spare capacities held by rivals. All else being equal, anti-competitive effects are more likely if merging parties control a large part of the available capacity after the transaction and rivals have little excess capacity.

[93] M.8124 *Microsoft/LinkedIn*, footnote 330.
[94] M.8124 *Microsoft/LinkedIn*, paragraph 350.
[95] M.7217 *Facebook/WhatsApp*, paragraphs 87, 102 and footnote 79.
[96] M.8788 *Apple/Shazam*, paragraphs 209 – 259.
[97] M.8124 *Microsoft/LinkedIn*, paragraphs 177, 178.
[98] For example, in M.8451 *Tronox/Cristal,* the Commission found that the ability of existing suppliers to increase production in response to a price increase by the merging Parties is limited by the low levels of spare capacity and competitors' existing commitments to other customers.

Finally, capacity constraints can often be local, especially in the case of products of basic industries that require costly transportation. The result is geographic product differentiation that sometimes makes detailed assessment of local competition necessary. For example, in *Ball/Rexam,* a case involving beverage cans, the Commission's assessment focused on customers and their potential suppliers: capacity-based market shares for catchment areas around customers with filling locations were the basic tools of the competitive assessment. Based on an assumption about the feasible transport distance, the Commission was able to assess which potential suppliers and with what capacity could serve customers in a given geographic area.[99]

2.3 Efficiencies

In addition to negative non-price effects, the Commission recognises that mergers may also result in non-price benefits to consumers, such as bringing new and improved products. Such positive effects are typically assessed by the Commission in the context of efficiency claims. To be accepted, the claimed efficiencies have to benefit consumers, be merger specific and be verifiable. Under the Horizontal Merger Guidelines, efficiencies should, in principle occur within the markets where competition concerns are found.

Innovation efficiencies. Mergers may in some circumstances enhance innovation, for example by allowing the parties to share knowledge more effectively and by internalising knowledge spill overs. The Horizontal Merger Guidelines specifically mention "new or improved products or service resulting from efficiency gains in the sphere of R&D and innovation".[100]

In its review of agrochemical mergers (*Dow/DuPont* and *Bayer/Monsanto*), the parties did not provide evidence of case-specific innovation efficiencies. The Commission observed that in the relevant innovation spaces the protection against imitation was strong already pre-merger, thanks to effective IP rights and product lifecycle management techniques. Hence, it was less likely that each of the two mergers would increase the incentive to innovate by internalising significant involuntary knowledge spillovers.

Quality efficiencies. In several mobile telecom mergers, the parties argued that their transaction would result in quality improvements, such as larger networks, better coverage and faster roll-out of the newest-generation mobile network with better quality and higher data speeds. In *Orange/MásMóvil*, the Commission considered that network roll-out efficiencies could be accepted in principle, if they are incremental to the roll-out plans absent the merger. If accepted, these efficiencies would have to be weighed against the anti-competitive harm of the merger in terms of the share of consumers benefiting from higher network quality and consumers' willingness to pay for higher quality. However, in line with earlier cases, the Commission found that these improvements were subject to an uncertain timeline, not verifiable and not merger-specific because the Parties would have realistic alternatives to expand capacity on a stand-alone basis or enter into network-sharing agreements as a less anti-competitive alternative to the merger.[101]

Green efficiencies. A merger may have positive effects on sustainability, for instance by improving product quality, by decreasing the level of toxicity of a product or by enabling cost reductions resulting from generating less waste or requiring the use of fewer raw materials. Efficiencies can also result in the development of newer technologies, novel "green" products and more generally "green" innovations. For example, in *Aurubis/Metallo*, a case that concerned access to copper scrap in the EEA, the Commission looked at positive technological synergies associated with the transaction, in particular improved combined metal extraction capabilities and know-how of the merged entity, the benefits of which could in part be passed on to suppliers of the merged entity.[102]

2.4 Remedies

Remedies should eliminate the competition concerns identified by the Commission entirely. To do so, the Commission accepts proposals that resolve the issues on a lasting basis, and this is why structural divestments of activities as a going concern to suitable buyers are the preferred option.[103] Given the importance of non-price competition, the Commission makes sure that all relevant assets are included in the divestment, in particular R&D and pipeline projects, so that it will continue its activities and development as envisaged absent the merger. The Commission therefore must ensure that the buyer will have the ability and incentives to continue investing in ongoing projects. Non-price competition, including digitalisation, also raises certain theories of harm related to interoperability and data for which non-structural remedies exceptionally may appear as equally effective as[104] - and potentially more appropriate than - a divestment, with the objective to open markets on a lasting basis.

R&D and pipeline projects. When divesting a business, the assets should comprise on-going pipelines or R&D projects. The commitments generally specify that all know-how, patents, IP, materials, data, documentation and proprietary information be

[99] M.7567 *Ball/Rexam*, Sections 9.2.1 and 9.2.2.
[100] Horizontal Merger Guidelines, paragraph 81.
[101] Cases M.10896 Orange/MásMóvil, M.6497 *Hutchison 3G Austria/Orange Austria*; M. 6992 *Hutchison 3G UK/Telefónica Ireland*; M.*7018 Telefónica Deutschland/E-Plus*; M.7612 *Hutchison 3G UK/Telefónica UK*.
[102] M.9409 *Aurubis/Metallo*, paragraphs 831 and ff. See also the Competition Merger Brief, Issue 02/2023 – September, which provides more details on the Commission's assessment of the efficiencies submitted in M.9409 *Aurubis/Metallo*.
[103] Commission Notice on Remedies, paragraphs 10 and 15.
[104] Commission Notice on Remedies, paragraphs 17 and 61.

included.[105] To ensure that the purchaser will have the ability and financial incentives to pursue the ongoing projects, the Commission ensures that the divestment will be supported by sufficient expertise – including by requiring the purchaser to be already active in the sector[106] -, as well as sufficient staff – via possible secondment of personnel or new hires as needed – and funds.[107] The commitments may also foresee a temporary obligation from the merged entity to provide transitional support to the purchaser.[108] Importantly, considering that R&D and pipelines are typically developed at global level, the commitments may need to include the global R&D organisation, either because the theories of harm relate to global R&D markets, as was the case in *Dow/Dupont*, or because global R&D is necessary to ensure the viability and competitiveness of the divestment business going forward. Thus, in *Sika/MBCC*, while the relevant problematic markets for the supply of chemical admixtures were national in scope, the divestment of MBCC's business included all global R&D assets, sites, personnel, IP, and other relevant assets to fully address the Commission's concerns in the EEA, and make sure the divestment business would continue developing innovation contributing to reducing CO_2 emissions.

In cases where products are co-developed, the commitments may also consist in giving more rights to the partner.[109] On the other hand, commitments falling short of a transfer such as providing only licenses on R&D and pipeline projects to the remedy taker are typically rejected considering that competition will not be preserved on a lasting basis.[110]

By allowing the preservation of innovation competition, merger remedies may even have positive effects beyond what the divestment business had planned to develop and invest in absent the merger. For example, in *General Electric/Alstom*, the remedy constituted of a divestiture of the main, technologically most advanced parts of Alstom's heavy duty gas turbines business, including pipeline technology. The remedy package thus equipped the remedy taker to successfully finalise the development of Alstom's highly efficient gas turbines. Moreover, using its know-how and capabilities, Ansaldo (the remedy taker) was in fact able to go even further in innovating those turbines by using hydrogen as a fuel, which can significantly decrease CO_2 emissions. Thus, the remedy package in the hands of a suitable purchaser led to positive effects on the environment by ensuring continued innovation in energy efficient electricity generation.

Access and interoperability. When mergers raise non-horizontal competition issues related to degradation of interoperability or access to data, the Commission accepted in the past, exceptionally, non-structural remedies. The objective is to ensure that the markets will remain open and competitive in the long run, and that the ability and incentives of competitors to develop their products and compete effectively are preserved. While the assessment is very case specific, certain factors are typically relevant to decide whether non-structural remedies would be appropriate in a specific case, including that (i) the likely problematic conducts are well-identified, (ii) the number of access or interoperability seekers is reasonable and (iii) standard terms of access or interoperability can be defined. In previous cases, the merged entity committed to make – or continue making - its product interoperable with competitors' products.

For example, in *Siemens Healthineers/Varian Medical Systems,* Siemens committed to adhere to industry-wide interoperability standards and make its medical imaging and radiotherapy solutions compatible with rivals' radiotherapy and imaging solutions, including by providing the relevant information and technical assistance to third parties and customers. In other cases, the merged entity committed to make – or continue making - certain data available to competitors. For example, in *Google/Fitbit*, Google committed to maintain access to users' health and fitness data to software applications, and to continue licensing public web Application Programming Interfaces (APIs) to ensure that wrist-worn devices will interoperate with Android smartphones.[111] More recently in *BroadCom/VMWare*, BroadCom committed to ensure interoperability of competitors' products with its server virtualisation software, and provide competitors access to relevant information, including the source code.[112]

To consider those remedies suitable in specific cases, the Commission also needs to conclude that there are effective monitoring mechanisms. In the past, the Commission did not accept non-structural remedies considering that they were not removing the competitive concerns entirely, especially as they could not be properly and effectively monitored. Recently, in *Illumina/Grail*, the Commission rejected the proposed

[105] See for example in the pharmaceutical industry, M.7746 - *Teva/Allergan Generics*; and M.7559 – *Pfizer/Hospira*; and M.7917 – *Boehringer Ingelheim/Sanofi animal health business*.

[106] See for example M.10506 - *Parker/Meggitt* where the purchaser needed to be an existing manufacturer of aerospace components; and M.10560 *Sika/MBCC* where the purchaser needed to demonstrate its proven incentive to continue investing in the R&D activities of the Divestment Business globally.

[107] See for example on staff, M.10506 - *Parker/Meggitt*, and M.11043 - *Novozymes/Chr Hansen Holding*, and on financing, M.8401 *J&J/Actelion*. See also commitments foreseeing a CAPEX escrow account to be funded by the merged entity to make sure the envisaged investment projects – including into plants – will be continued by the buyer, for example M.10702 *KPS Capital Partners/Real Alloy Europe*.

[108] See for example. M.7559 – *Pfizer/Hospira*.

[109] In *Novartis/GSK Oncology Business,* the Commission accepted the remedies proposed by the parties, whereby Novartis committed to fully return one of the treatments where the Commission raised competition concerns to its owner and licensor Array BioPharma Inc. (Array) and to divest the other treatment of concern to Array. See also for example M.8401 *J&J/Actelion* whereby J&J granted new rights to its partner Minerva over the global development of a pipeline product.

[110] See for example M.10188 – *Illumina/GRAIL*.

[111] Google also committed not to use the users' health and fitness data collected from wrist-worn wearable devices via sensors for Google Ads (search ads, display ads, ads intermediation) and to maintain technical separation. The data will be stored in a "data silo" which will be separate from any other dataset maintained by Google and available for advertising.

[112] See also M.10262 - *Meta/Kustomer*.

commitment by Illumina to give access to rivals to its next-generation sequencing systems as (i) they did not effectively address all the possible foreclosure strategies that Illumina could engage in; (ii) it would have been easy for Illumina to circumvent its obligations and grant preferential treatment to GRAIL, and (iii) it would have been difficult to monitor them due to their complexity and the fact that GRAIL's rivals would hardly have been able to detect breaches.

2.5 Suitability of referrals

The Commission recently evaluated the effectiveness of its turnover-based jurisdictional thresholds, considering that the sales generated by a company may not fully reflect its competitive potential.[113] This is typically the case due to non-price competition, with high-value digital or biotech companies being acquired by large firms even if they generate little to no turnover (yet). Following this evaluation process, the Commission concluded that this "jurisdictional gap" could be addressed effectively by inviting Member States to refer potentially problematic cases falling below national or EU notification thresholds to the Commission, using the powers under Article 22 of the EUMR.[114] As per the Commission's guidance,[115] EU Member States are able to refer to the Commission acquisitions or merger cases below EU or national thresholds when the turnover of at least one of the undertakings concerned does not reflect its actual or future competitive potential.[116]

As a consequence, non-price elements such as innovation or data play a decisive role in the assessment on whether a merger case is a suitable candidate for a referral. By way of examples, a referral would be appropriate in cases where the undertaking at issue is (i) a start-up or recent entrant with significant competitive potential that has yet to develop or implement a business model generating significant revenues (or is still in the initial phase of implementing such business model); (ii) is an important innovator or is conducting potentially important research; (iii) is an actual or potential important competitive force or (iv) has access to competitively significant assets (such as for instance data or intellectual property rights).

In two of the three referrals which the Commission accepted under its revised approach to Article 22 EUMR to date, innovation aspects played an important role. In *Illumina/GRAIL*, the Commission accepted the referral request because of concerns that the transaction could result in a discontinuation of the access to Illumina's products for GRAIL's competitors and thus impede the innovation efforts of GRAIL's rivals. The other referral case, *Qualcomm/Autotalks,*[117] concerns the development of vehicles-to-everything communication (V2X) technology, which is key to improving road safety, traffic management and reducing CO_2 emissions as well as for the deployment of autonomous vehicles.

Conclusion

In pursuit of its goal, preventing competitive harm to consumers, the Commission uses several competition parameters in assessing mergers. While price will continue to play a pivotal role, other parameters of competition have played an increasingly important role in recent years, such as quality, innovation, data protection and privacy. Among the newer developments is sustainability.

All these parameters of competition can play a decisive role at every stage of the Commission's decision-making process, from market definition to the competitive assessment., efficiency claims and remedies.

In its assessment, the Commission applies its consumer welfare standard approach, which includes intervention in cases which would otherwise do harm to the competitive process, covering all parameters of competition, in order to contribute to a strong and vibrant European economy, to the EU consumers' benefit.

The Commission continues refining its assessment and is keen to ensure that consumers are not denied non-price benefits of competition in reflection of market changes and realities.

[113] Commission Staff Working Document, Evaluation of procedural and jurisdictional aspects of EU merger control; 26 March 2021.

[114] This approach was endorsed by the General Court in T-227/21, *Illumina v Commission*.

[115] Commission Guidance on the application of the referral mechanism set out in Article 22 of the Merger Regulation to certain categories of cases, paragraph 19.

[116] Commission Guidance on the application of the referral mechanism set out in Article 22 of the Merger Regulation to certain categories of cases, paragraph 19.

[117] M.11212 *Qualcomm/Autotalks*, see European Commission, Daily News 18 August 2023 (accessible via https://ec.europa.eu/commission/presscorner/detail/en/mex_23_4201).

European Commission

Competition *Policy Brief*

Assessing Innovation Competition in Pharma Mergers

Vasiliki Dolka, Susanna Kärkelä, Aiste Slezeviciute, Zsolt Vertessy

Introduction

The review of mergers and acquisitions in the pharmaceutical industry is a high-stakes endeavour presenting unique challenges. Merger control ensures that consolidation does not lead to higher prices for patients and health systems. In parallel, competition agencies must also assess the impact on innovation.[1] This assessment is crucial so that pharma companies continue to be incentivised to tackle public health challenges by researching, developing, and commercialising promising new products. Not only are there persisting unmet medical needs, but the nature of threats to health also changes due to the emergence of new diseases (such as Covid-19), as well as a reduction in the efficacy of existing products, for instance through antimicrobial resistance. Innovation is key to tackling evolving and unmet medical threats.

The commercial reward for successful innovation in the pharmaceutical sector is a *de facto* monopoly through the patent system. This results in high rewards during the period of protection which can bear a direct relationship to M&A strategies in the sector. Large pharmaceutical companies facing the expiration of the main patents covering their blockbuster drugs in the coming years may turn to acquisitions of promising pipelines still benefitting from patent protection to help safeguard their future growth.[2] Other companies have amassed major cash reserves during the pandemic which can now be used to fuel M&A.[3]

These acquisitions may result in the purchaser entering new markets but may also result in competitive overlaps between the purchaser and the target with products at the same or different stages of the product lifecycle. Any competitive assessment needs to be tailored taking these dynamics into account.

In this context, the Commission continues to apply merger control rules vigorously and rigorously in the pharmaceutical sector to ensure that innovation and competition on the merits is preserved, and in turn preserving choice and quality at competitive prices. This Brief aims to summarise the key developments and recent experiences in the European Commission's extensive practice of reviewing pharmaceutical mergers, with a focus on innovation.

This Brief will firstly summarise the Commission's well-established framework for defining markets in pharmaceutical cases. A vast range of different treatments may target the same disease while being highly differentiated. Thus, the task of establishing the boundaries of the market can be complex, but nevertheless remains an essential one to ensure that the merger

In a nutshell

Innovation in the pharmaceutical sector is essential to having new and competitively priced medical products.

The EU framework for merger control empowers the Commission to assess the impact of pharmaceutical mergers on innovation. The Commission's assessment is carried out on a case-by-case basis – where early-stage pipelines may merit close scrutiny and issues on innovation spaces are assessed.

The issues are often global, and the Commission regularly cooperates closely with other agencies.

[1] The benefits of innovation for competition are discussed in detail in the Commission's Competition Policy Brief of April 2016, available at https://op.europa.eu/en/publication-detail/-/publication/764b96c6-9a82-11e6-9bca-01aa75ed71a1/language-en/format-PDF/source-195709315.

[2] Patent expiries are being estimated to result in a 46% decline in revenues for the 10 largest global pharmaceutical companies by 2030. For instance, 2023 saw the end of exclusivity in the US for AbbVie's Humira, the best-selling drug worldwide with global revenues of USD 21 billion in 2022. AbbVie's CEO indicated in early 2023 that investors should "expect us to act" on M&A opportunities if the right one should arise (AbbVie Q4 2022 Earnings Call). This has played out with its (proposed) acquisitions of Immunogen (USD 10 billion), Cerevel (USD 8.7 billion). Likewise, Merck is also preparing for the expiry in 2028 of patents for Keytruda, which accounted for more than a third of its sales in 2022, by acquiring other promising treatments to strengthen its product pipeline (https://www.economist.com/business/2023/04/20/big-pharmas-patent-cliff-is-fast-approaching).

[3] Pfizer's sales of its Covid vaccines drove it to record a record revenue of USD 100.3 billion in 2022, while engaging in a number of high-profile acquisitions during 2022-23 (inter alia, it acquired Global Blood Therapeutics for USD 4.7 billion, Biohaven for USD 11 billion and Seagen for USD 43 billion).

review can capture the dynamics of the market. The pharmaceutical sector is highly regulated, including pricing and reimbursement schemes at national level, which drives a delineation of relevant geographic markets for marketed drugs along national borders, while at the innovation or development stage competition is often far wider, potentially at least EEA-wide, or global.

In the second and third sections, this Brief will focus on the substantive assessment of horizontal and non-horizontal effects in pharmaceutical mergers with particular focus on their impact on innovation. Given the high risk / high reward nature of pharmaceutical research and development ("R&D") and the transparency regarding pharmaceutical pipeline products years before they reach the market,[4] a transaction's rationale may give important insights into the parties' expectations regarding their future potential and the development of the competitive landscape. A "big pharma" company buying a start-up may grant the target the financial and operational capability to effectively bring a product to market, with pro-competitive effect. However, this ability to identify the new drugs' characteristics, prospects and target market also means that, in some cases, there is a risk that the impact of the deal could be less positive. In the presence of horizontal overlaps, the transaction could result in a concentration of market power in the purchaser's hands by combining competing marketed (or soon-to-be marketed) products, leading to higher prices or reduced quality. Alternatively, the result of the acquisition could be that the purchaser discontinues its own or the target's R&D efforts, which can lead to price increases or reduced choice. Indeed, academic studies have suggested that some pharmaceutical companies may use early-stage acquisitions as a way to 'kill' potential competitive threats that may emerge in future.[5] Even if the target does not compete with the purchaser in the same market, non-horizontal concerns may arise: the combination of the merging parties may enable the merged entity to foreclose rivals and capture a greater market share once its product reaches the market.

Given the high stakes for patients and health systems, it is imperative that competition concerns be resolved in a way that ensures a competitive market structure on a lasting basis. In view of this, the Commission's remedies policy in pharmaceutical mergers is outlined in the fourth section.

The fifth section summarises the recent evolution of the Commission's approach to jurisdiction. An unusual feature of pharmaceutical transactions is the lengthy development process for medicines – on average, it takes 12-15 years from discovery to bring a drug to market.[6] However, the promise and potential of new medicines is at times clear at an early stage in this process, meaning that even years before a product has been launched, a start-up can be valued in the billions. The potential competitive impact is therefore reflected in a target's valuation by the purchaser but not in its revenues, which is the metric used for the notification thresholds set out in the EU Merger Regulation ("EUMR"). This fifth section outlines the Commission's recalibrated approach to referrals pursuant to Article 22 of the EUMR, which enables it, in cooperation with EU Member States, to ensure that transactions involving low-turnover but highly innovative targets do not escape review.

Finally, in the sixth section, this Brief highlights the importance of international cooperation and dialogue. Given that blockbuster medicines are developed and commercialised at global scale, competition agencies should ensure a consistent and coherent approach to examining pharmaceutical mergers. Notably, the sixth section outlines the recent conclusions of the inter-agency working group between the Commission and the Canadian, UK and US competition authorities.

1. Market definition

Whilst market definition in pharmaceutical mergers for marketed drugs follows a well-established framework, the assessment of innovation elements is more complicated because the precise features of pipeline products may not yet be realised.

For commercialised products, in line with the Market Definition Notice,[7] the Commission assesses substitutability from the demand and supply sides. The general starting point for pharmaceutical products is the Anatomical Therapeutic Chemical (ATC) Classification System devised by the European Pharmaceutical Market Research Association ("EphMRA").[8] From this starting point, the Commission assesses further whether it is appropriate to distinguish between over-the-counter ("OTC") and prescription ("Rx") medicines, indication denoted by the ATC 3 level,[9] the mode of action (such as topical or systemic), the mode of delivery (such as oral or injectable) and, where relevant, the

[4] In the pharmaceutical industry, pipeline drugs go through several development stages, starting with preclinical trials in laboratories on animals, and later moving on to clinical trials on humans. Clinical trials in humans (so called "Phase I", "Phase II" and "Phase III" clinical trials, see further footnote 16) are strictly regulated to ensure the protection of trial subjects and the reliability of the results. The results of these trials are published.

[5] See, for example, Cunningham, C., Ederer, F. and Ma, Song, Killer Acquisitions, J. of Political Econ., (Mar. 2021), vol. 129, no. 3: 649–702. The Commission has commissioned an *ex post* evaluation to assess the prevalence of killer acquisitions in the pharmaceutical industry and determine what are the key features of such killer acquisitions – this study is in progress. The risk that M&A can result in the discontinuation of pipelines is also identified in European Commission, Directorate-General for Research and Innovation, Pang, T., Folwell, B., Osborne, A. et al., Study on the impact of mergers and acquisitions on innovation in the pharmaceutical sector, Publications Office of the European Union, 2020, https://data.europa.eu/doi/10.2777/323819.

[6] OECD, Pharmaceutical Innovation and Access to Medicines (2018).

[7] Commission Notice on the definition of the relevant market for the purposes of Union competition law (OJ C 1645, 22.02.2024), "Market Definition Notice".

[8] The ATC system is a hierarchical and coded four-level system which classifies medicinal products by class according to their indication, therapeutic use, composition, and mode of action. In the first and broadest level (ATC 1), medicinal products are divided into the 16 anatomical main groups. The second level (ATC 2) is either a pharmacological or therapeutic group. The third level (ATC 3) further groups medicinal products by their specific therapeutic indications. Finally, the ATC 4 level is the most detailed one (not available for all ATC 3) and refers for instance to the mode of action (e.g. distinction of some ATC 3 classes into topical and systemic depending on their way of action) or any other subdivision of the group. Medicinal products are classified according to the ATC system in the IMS Midas data base.

[9] For OTC-sold drugs, the Commission may also use the Consumer Health Classification ("CHC", administered by IQVIA, an American multinational company serving the combined industries of health information technology and clinical research), which is equivalent to ATC. See, e.g., Commission decision of 22 October 2021 in Case M.10247 *CVC/Cooper*.

line of treatment.[10] This assessment is informed by the views expressed by so-called "key opinions leaders" in the medical field, submissions from the merging parties and other evidence on the file, such as the parties' internal documents.

However, these elements are less likely to be known when a merger assessment is required either for pipeline products or for new or nascent markets. For pipeline products, the further the development cycle of a product is advanced, the more can be known about the product's features and the more certain the assessment can be about market definition. For example, the ATC 3 code and mode of action will normally be clear from the outset of clinical trials but only by Phase III or later will the line of treatment be known. In this case, the market definition cannot assess whether a segmentation of that market by line of treatment would be relevant. Earlier in the development cycle, it may not be known for which applications the pipeline product may succeed, and in turn whether it will replace or compete with any existing products or create new demand.

The assessment of market definition is more complicated when it comes to products in development that do not fall within the established 'pipeline' assessment, but rather concern innovation and development in entirely new or nascent markets.

For example, in the recent *Illumina/GRAIL*[11] case, the Commission found that GRAIL and its rivals were engaged in an innovation race to develop and commercialise early cancer detection tests. The Commission concluded that while there was still uncertainty about the exact results of this innovation race and the future shape of the market for early cancer detection tests, protecting current innovation competition was crucial to ensure that early cancer detection tests with different features and price points would come to the market. As such, the product market definition assessment focused on the innovation race. The relevant question in defining the market in such cases is whether there is a meaningful competition between the companies engaged in R&D at the development stage of the product. Such competition may take place for funding or resources, and is evidenced by the product's 'race towards commercialisation' (for example evidenced by various 'prelaunch activities', such as regulatory filings, clinical trials, engagement with the health care systems, etc.). The exact nature of the product and parameters of competition at the commercialisation stage may not yet be determined at the development stage. As such, product market definition at the development and commercialisation stages differs.

In terms of geographic scope, medical products are generally sold in accordance with the national regulatory and reimbursement regimes and the relevant markets are deemed national in scope. Innovation markets on the other hand are generally found to be wider than national and may be at least EEA-wide or even global. In past decisions, the Commission found that, when innovating in drug pipelines and medical devices, companies tend to track their competition globally or EEA-wide and may compete on a worldwide basis for funding opportunities and talent.[12]

2. Horizontal mergers: assessment of innovation competition

The Horizontal Merger Guidelines[13] recognize "the effect on innovation" as one of the elements to be assessed, equating the potential competitive harm that may be caused by a reduction of innovation with price increases and reduction of output, choice or quality of goods and services. The Horizontal Merger Guidelines specify that a merger between important innovators, for instance between two companies with pipeline products related to a specific product market can eliminate an important competitive force and thus lead to a significant impediment to effective competition.[14] Given that the pharmaceutical sector is driven by innovation, it has always been important to identify and intervene against pharmaceutical mergers that have the potential to compromise R&D efforts and hamper the launch of innovative new products. The Commission applies a four-layer competitive assessment framework,[15] with the aim of ensuring that all potential effects of pharmaceutical mergers, and especially innovation effects, are carefully scrutinised.

The **first layer** takes into account actual competition, assessing the overlaps between the parties' existing marketed products. The **second layer** considers potential competition assessing the overlaps between: (i) the parties' existing marketed and pipeline products at advanced stages of development; and (ii) the parties' pipeline products at advanced stages of development.[16] [17] The

[10] Line of treatment refers to the setting for which a specific drug is indicated. For example, a drug indicated for second-line treatment should be used only after another therapy (the first-line treatment) has proven ineffective or if this other therapy cannot be prescribed to a specific patient.

[11] Case M.10188 – *Illumina/GRAIL*. See press release: https://ec.europa.eu/commission/presscorner/detail/en/IP_22_5364.

[12] For example, M.9461 *AbbVie/Allergan*, Commission decision of 10 January 2020, paragraph 13. M.9294 *BMS/Celgene*, Commission decision of 29 July 2019, paragraph 8.

[13] Guidelines on the assessment of horizontal mergers under the Council Regulation on the control of concentrations between undertakings, Official Journal C 31, 5.2.2004. p. 5-18.

[14] Horizontal Merger Guidelines, para. 38.

[15] This framework was first introduced in cases involving the agricultural sector (M.7932 *Dow/Du Pont,* Commission decision of 27 March 2017*;* M.8084 *Bayer/Monsanto,* Commission decision of 21 March 2018), before being applied to the pharmaceutical sector too (e.g. in M.7275 *Novartis/GSK Oncology,* Commission decision of 28 January 2015; M.9294 *BMS/Celgene*, Commission decision of 29 July 2019 as well as in M.8084 *Bayer/Monsanto*, Commission decision of 21 March 2018 and M.7932 *Dow/Dupont,* Commission decision of 27 March 2017).

[16] The phases of clinical development for pipeline products can be described as follows. Phase I starts with the initial administration of a new drug into humans, with trials carried out on a small number of people. The focus of Phase I trials is to confirm that the drug is safe to use in humans and to identify the appropriate dosage and exposure-response relationship. Phase II usually starts with the initiation of studies to explore therapeutic efficacy in patients. Studies in Phase II are typically conducted on a small group of patients that are selected based on stricter criteria for indications. Phase III trials aim to demonstrate or confirm therapeutic benefit in a larger group of patients (Phase III trials will typically have hundreds of patients and may have over a thousand, for example for autoimmune diseases). Studies in Phase III are designed to confirm the preliminary evidence accumulated in Phase II that a drug is safe and effective for use in the intended indication and recipient population. Phase IV begins after drug approval to monitor possible adverse reactions and/or new side effects over time.

third layer consists of an analysis of innovation competition in relation to the parties' ongoing pipeline products, assessing the risk of significant loss of innovation competition resulting from the discontinuation, delay or redirection of the overlapping pipelines (including early stage pipelines). The **fourth layer** takes into account innovation competition in relation to the capability to innovate in certain innovation spaces, assessing the risk of a significant loss of innovation competition resulting from a structural reduction in the overall level of innovation.

Innovation competition involving late-stage pipelines

Overlaps involving late-stage pipelines (in Phase III clinical trials or later), are assessed under the second layer of the Commission's framework. This involves investigating the overlap between one party's advanced pipeline(s) with the other party's existing or advanced pipeline product(s) ("pipeline-to-marketed" and "pipeline-to-pipeline" overlaps, respectively). At this late stage of development, it is usually possible to identify the specific product market within which these pipeline drugs will compete. The assessment of such cases takes into account the effects on potential competition by considering: (i) the potential adverse effects on future prices that may occur even if the merged entity would bring all of the potentially competing pipeline products to market; and (ii) the likelihood of discontinuation of a pipeline product that could lead to the reduction of product choice and higher future prices.

This approach can be seen more recently in the cases of *Abbvie/Allergan*[18] and *Takeda/Shire,*[19] both concerning biologic medicines[20] for inflammatory bowel disease. In *Takeda/Shire*, the Commission assessed the pipeline-to-marketed overlap between Takeda's leading biologic treatment for IBD, which was the only product available in the EEA at the time, and Shire's pipeline biological product for the treatment of IBD, which was expected to launch prior to the patent expiry of Takeda's product. The Commission focused its analysis on the potential loss of innovation and future competition in case Takeda were to stop developing Shire's new treatment post-Transaction, ultimately finding that Takeda would be unlikely to continue developing Shire's new IBD treatment, as it would compete closely with Takeda's biologic treatment for IBD. Similarly, when assessing a pipeline-to-pipeline overlap in *Abbvie/Allergan*, the Commission found that brazikumab, a treatment for IBD that Allergan was developing was likely to compete closely with a product Abbvie was developing (risankizumab), as both products had the same mode of action and line of treatment and were in the late stages of development. The Commission thus found that AbbVie would be likely to discontinue the development of Allergan's pipeline product post-transaction. The Commission's investigation revealed that the merger would likely lead to a loss of innovation for the relevant treatments, as both products were part of a promising class of biologics for which only two other competing pipeline products existed. The transaction would likely have had the effect of preventing a promising drug from reaching the market, which could have led to the reduction of choice on the market, and price increases for patients and healthcare systems.

Innovation competition involving early-stage pipelines

The third layer involves evaluating the competitive effects of transactions involving pipeline products in the early stages of development.[21] In *AstraZeneca/Alexion Pharmaceuticals,*[22] the Commission conducted a comprehensive competitive analysis of horizontal overlaps between the parties' pipeline drugs for the treatment of lupus nephritis, follicular lymphoma, and peripheral T-cell lymphoma, many of which were in Phase I and early Phase II clinical trials. It concluded that no competition concerns were likely to arise because the parties' pipeline products were expected to be sufficiently differentiated such that effective competition would remain in the market post-transaction. Similarly, in *BMS/Celgene,*[23] the Commission considered the horizontal overlap between Celgene's already marketed drug Otezla and BMS' pipeline treatments, one in Phase III and one in Phase I clinical trials for the treatment of severe psoriasis and psoriasis arthritis. Prompted by concerns from competitors, the Commission went even further to assess an overlap involving a drug in preclinical stage (in which Celgene had a financial option) with a Phase III pipeline held by BMS. The Commission carefully considered whether the parties' pipeline products (as well as products in preclinical stages i.e. before human clinical trials) could replace existing treatments or generate new demand and concluded that the merged entity would have no incentive to disrupt the development of BMS's pipeline treatments especially because the parties' drugs were sufficiently differentiated.

While in this case the Commission undertook a very thorough analysis of the potential competitive constraints between BMS' Phase III pipeline and Celgene's preclinical stage programme because of the concerns raised in the market investigation, in most cases potential competitive constraints exerted by drugs in preclinical stages are only exceptionally assessed. This is because at a very early stage the indication and therapeutic use of the pipeline may still be undetermined, and it may be difficult to predict the competitive interaction between the various drugs.

[17] For pharmaceutical products, the Commission in principle considers programmes in Phase III clinical trials as being at an advanced stage of development.
[18] M.9461 *AbbVie/Allergan*, Commission decision of 10 January 2020.
[19] M.8955 *Takeda/Shire*, Commission decision of 20 November 2018.
[20] Biologics refer to any type of medical therapy that is derived from living organisms such as humans, animals, or microorganisms.
[21] M.7275 *Novartis/GSK Oncology*, Commission decision of 28 January 2018, where the Commission assessed for the first time all phases of clinical research being carried out, including those concerning drugs in early stages of development.
[22] M.10165 *AstraZeneca/Alexion Pharmaceuticals*, Commission decision of 5 July 2021.
[23] M.9294 *BMS/Celgene*, Commission decision of 29 July 2019.

Both cases affirm the importance of analysing innovation competition and simultaneously reveal the underlying difficulties of evaluating early-stage pipelines, as often the exact profiles and prospects of these drugs remain speculative due to their early stage of development and the limited availability of data.

Innovation spaces

With the fourth and final layer of assessment, the Commission broadens the analytical scope by introducing the notion of competition over innovation spaces.[24,25] This assessment goes beyond examining specific potential products; it considers early stage R&D efforts in relation to ideas or products which are undefined or are years away from reaching the market.[26] In each innovation space the Commission assesses overlaps between the merging parties' lines of research (encompassing the set of scientists, patents, assets and equipment which are dedicated to a given discovery target) and early and late stage pipeline products.[27] This assessment usually takes into account the parties' and their competitors' general innovation capabilities beyond the competitive situation of specific marketed and pipeline products. The Commission seeks to avoid a reduction in innovation competition, for example if the merger results in there being: (i) less competitive pressure between the players remaining in the market, which therefore have a reduced incentive to invest in or prioritise R&D; or (ii) the merged entity's innovation capabilities attaining such a size and strength that its rivals could no longer effectively compete.

This framework of assessment has been applied in animal healthcare and pharmaceuticals cases. In *Elanco Animal Health/Bayer Animal Health Division*, [28] which concerned pharmaceutical products for pets and livestock, the Commission considered whether the transaction could lead to a reduction in competition in certain innovation spaces but concluded that the transaction would not result in a significant reduction in innovation competition, as the parties were not considered to be particularly strong innovators in the animal health space, especially in comparison to their competitors. [29] In *AstraZeneca/Alexion Pharmaceuticals,* [30] the Commission considered that the transaction was unlikely to raise competition concerns in this respect because the parties were not active in the same R&D spaces, as Alexion's R&D mainly focused on rare diseases, which were outside the scope of the main drug portfolio of AstraZeneca.[31] In *Pfizer/Seagen*,[32] the Commission found that the transaction would not lead to a loss of innovation in the field of oncology in general and in antibody drug conjugates ("ADCs") in particular,[33] given that a significant number of players engaged in R&D activities would remain in the market.

3. Non-horizontal mergers: assessment of innovation effects

Non-horizontal pharmaceutical mergers may raise competitive concerns from the viewpoint of innovation by creating the ability and incentive for the merged entity to engage in foreclosure strategies that hinder innovation post-transaction. For instance, the vertical link could enable the acquirer to profitably foreclose competitors' access to an important input, thereby reducing their ability to develop a new downstream product.

This was the case in *Illumina/GRAIL*,[34] which the Commission blocked for innovation-related vertical competition concerns. The Commission concluded that the acquisition of GRAIL, a development company that uses Illumina's next generation sequencing ("NGS") systems to develop its innovative and promising cancer detection tests, would enable and incentivise Illumina, the unrivalled supplier of NGS systems, to engage in foreclosure strategies against GRAIL's rivals with a consequence of hindering the development and commercialisation of early cancer detection tests to the detriment of competition in the internal market. As Illumina's NGS technology was found to be a "must-have" input on which GRAIL and its rivals depended, the transaction would have allowed Illumina to cut GRAIL's rivals access to the technology, or to increase prices, degrade quality or delay supplies of its systems. These actions would have allowed GRAIL's product to reach the market first, thereby boosting its competitive position to the detriment of its rivals.

Although Illumina would benefit from its anticompetitive behaviour only at a later stage following the commercialisation of GRAIL's cancer detection tests, the Commission found that the significant market potential and the ongoing innovation race in the development and commercialisation of early cancer detection tests gave Illumina an incentive to foreclose already at the time of the transaction. In the absence of suitable remedies to ensure that early cancer detection tests with different features and price

[24] For instance, in M.7932 *Dow/Dupont*, Commission decision of 27 March 2017, the Commission found that the transaction would be likely to significantly impede effective competition as regards innovation both in innovation spaces where the parties' lines of research and early pipeline products were overlapping and overall in innovation in the crop protection industry. In order to conduct this assessment, the Commission looked at the parties' lines of research and early pipeline products.

[25] M.8084 *Bayer/Monsanto*, Commission decision of 21 March 2018, footnote 23. As the Commission has explained R&D players do not innovate for all the product markets composing a sector at the same time, but tend to target specific spaces within that sector ("discovery targets").

[26] M.7932 *Dow/Dupont*, Commission decision of 27 March 2017; M.8084 *Bayer/Monsanto*, Commission decision of 21 March 2018.

[27] M.8084 *Bayer/Monsanto*, Commission decision of 21 March 2018.

[28] M.9554 *Elanco Animal Health/Bayer Animal Health Division,* Commission decision of 8 June 2020.

[29] M.9554 *Elanco Animal Health/Bayer Animal Health Division,* Commission decision of 8 June 2020, paragraphs 315-321.

[30] M.10165 *AstraZeneca/Alexion Pharmaceuticals*, Commission decision of 5 July 2021, footnote 15.

[31] See also similar analysis in M.9294 *BMS/Celgene*, Commission decision of 29 July 2019, footnote 28.

[32] M.11177 *Pfizer/Seagen*, Commission decision of 19 October 2023 (not yet published).

[33] ADCs are a class of biopharmaceutical drugs designed as a targeted therapy for treating cancer. They are made up of a monoclonal antibody chemically linked to a cytotoxic agent (the payload), enabling the payload to target specific cancer cells whose receptors or proteins bind with that antibody.

[34] M.10188 *Illumina/GRAIL*, Commission decision of 6 September 2022 (not yet published). While this case is not strictly in the pharmaceutical sector, rather relating to medical devices and diagnostic tools, the assessment is nevertheless of interest in the pharmaceutical context too.

points would come to the market, the Commission prohibited the transaction.[35]

4. Remedies

The Commission's remedies practice in the pharmaceutical sector follows the principles of the Commission Remedies Notice. The Notice specifies that structural commitments, such as the divestment of a self-standing business unit, are typically preferable to meet the objective of preventing a significant impediment to effective competition by eliminating the concerns entirely in a comprehensive and effective manner. [36] Nevertheless, non-structural remedies may be appropriate in specific cases, provided they achieve this objective, are capable of effective implementation and monitoring, and are not so extensive and complex that it cannot be determined with the requisite degree of certainty that they will be fully implemented and are likely to maintain effective competition.[37] Regardless of the type of remedy, its suitability must be examined on a case-by-case basis, having regard to the structure and characteristics of the market to assess whether they meet the basic aim of ensuring a competitive market structure post-transaction.

In the Commission's practice, structural remedies have been the most common means to prevent problematic pharmaceutical mergers from giving rise to a significant impediment to effective competition. Since 2015, all conditional clearance decisions of pharmaceutical transactions have involved a structural component (whether a divestment or other arrangement to terminate structural or licensing links), and in the vast majority of cases a divestment of existing or pipeline pharmaceuticals was the only commitment necessary to remove the concerns.[38] This reflects the fact that divestitures are the best way to eliminate concerns.[39]

The fundamental importance of innovation in the pharmaceutical industry is a key aspect that influences the Commission's remedies practice. In several cases, the commitment accepted was not the divestment of an existing business generating sales, but rather of a drug development pipeline. For example, having found that Allergan's IBD treatment in development was likely to compete closely with AbbVie's marketed treatment for IBD (see further the paragraphs under the heading "Innovation competition involving late-stage pipelines" above), the Commission's clearance was conditioned on the divestment of the global rights to develop, manufacture and market Allergan's pipeline product.[40]

However, development cycles for innovative drugs are long, risky and require substantial investment before pipeline products are brought to market and begin to turn a profit. Even for more advanced drug development projects, the risk of failure in phase III clinical trials was reported to be around 45% across all pipelines in 2011-2020 (and over 50% for oncology trials).[41] This means that finding a suitable and motivated purchaser for a divested pipeline can be challenging. There are several safeguards that can maximise the prospects of success. Firstly, the parties can mitigate the implementation risk of the divestment by including a so-called upfront buyer clause, as was done in the *AbbVie/Allergan* case, to ensure that the main transaction can only be implemented once the parties have found and proposed a suitable purchaser for the pipeline and the Commission has approved this purchaser. [42] Secondly, the Commission routinely finds that specific purchaser criteria are necessary to ensure that the buyer of pharmaceutical assets has the capabilities to develop, obtain approvals for and commercialise the products successfully.[43] Thirdly, as in other sectors, the Commission places considerable weight on a robust market test of a proposed remedy, to capitalise on pharma stakeholders' expertise to identify the remedy's prospects of effectively resolving the concerns, as well as potential shortcomings.[44]

Another particularity of the sector is the prevalence of partnerships, which have led to less traditional structural remedies. Pharmaceutical partnerships take various forms, such as co-development, co-marketing, or licensing agreements, which enable pharmaceutical companies to share the risks and costs of R&D (knowing that only a small proportion of candidate drugs will ultimately reach the market) as well as to maximise sales by relying on the global or regional distribution capabilities of others. In some merger cases, such competitive links gave rise to horizontal overlaps that carried the risk that the merged entity may compete less vigorously with its partner, or vice versa. To resolve these concerns, the Commission has in the past accepted remedies to prevent the merged entity from having the ability or incentive to discontinue its own pipelines or projects with its partners. For example, in *Novartis/GSK Oncology*, Novartis had exclusively licensed the right to develop a particular pipeline from Array, which was in phase III clinical trials and overlapped with GSK's marketed drug. The Commission found that this overlap was likely to lead to discontinuation of the pipeline, so Novartis committed to return these rights to Array (as well as divesting an

[35] Appeal pending at the EU General Court under Case T-709/22 *Illumina v Commission*.

[36] See Commission notice on remedies acceptable under Council Regulation (EC) No 139/2004 and under Commission Regulation (EC) No 802/2004, (2008/C 267/01) "Commission Remedies Notice"), paragraphs 10, 15 and 17.

[37] Commission Remedies Notice, paragraphs 13-14.

[38] Beyond the pharmaceutical sector, the Commission's interventions in healthcare related mergers have involved non-divestiture remedies, such as in the field of medical imaging (M.9945 *Siemens Healthineers/Varian Medical Systems*, Commission decision of 19 February 2021) or dental equipment (M.7822 *Dentsply/Sirona*, Commission Decision of 25 February 2016).

[39] Commission Remedies Notice, paragraph 17.

[40] M.9461 *AbbVie/Allergan*, Commission decision of 10 January 2020.

[41] '*Clinical Development Success Rates and Contributing Factors 2011–2020*', joint report by BIO, Informa, QLS dated 17 February 2021.

[42] See, for example, M.9461 *AbbVie/Allergan*, Commission decision of 10 January 2020.

[43] See, for example, M.9274 *GlaxoSmithKline/Pfizer Consumer Healthcare Business*, Commission decision of 10 July 2019 and M.9461 *AbbVie/Allergan*, Commission decision of 10 January 2020.

[44] Commission Remedies Notice, paragraphs 12, 15-16.

additional Novartis pipeline that was being developed as a combination treatment with Array's pipeline).[45] Similarly, in *J&J/Actelion*, the commitments required the merged entity to divest its minority shareholding in a partner company whose activities overlapped with those of the merged entity, as well as restricting the parties' access to competitively sensitive information from this partner. The parties also committed to waive the merged entity's royalty rights over a pipeline run by the partner company.[46] This removed the merged entity's influence over its partners' strategic decisions, as well as its incentive to negatively influence the development of its own research programmes, thereby avoiding the risk of discontinuation of the merged entity's or its rivals' pipelines.

The above safeguards mean that the remedies accepted by the Commission in pharmaceutical cases are robust. Nevertheless, the inherent uncertainties in the multi-year, multi-million (or billion) euro process of developing new pipelines means that unforeseen circumstances can arise. Pharmaceutical mergers are therefore one field where the Commission has had to resort in exceptional circumstances to the flexibility of the review clause to waive, modify or substitute the commitments.[47] Such waivers are exceptional and must only be accepted if market circumstances have changed significantly and permanently.

This was the case following the Commission's conditional approval of the *Takeda/Shire* deal.[48] To resolve the identified concerns, Takeda committed to divest Shire's pipeline for treating ulcerative colitis and Crohn's disease, including the right to develop and commercialise the product. The market test indicated that there was strong interest in acquiring the pipeline and confirmed its viability and competitiveness. However, shortly after the conditional clearance decision, the pipeline faced major setbacks including significant challenges in recruiting patients for the planned clinical trials, problematic results from clinical trials that indicated higher than foreseen risks in certain patient populations and the emergence of a novel and more promising treatment pipeline. These issues meant that the product would reach the market many years later than anticipated, likely in a very different competitive landscape and would compete less closely with Takeda's product than anticipated in the decision. These issues also significantly diminished any interest from potential purchasers. These factors, which only developed after the conditional clearance decision, cumulatively meant there was a significant and permanent change in the market, which could not have been foreseen at the time of the approval and which removed the serious doubts the Commission had regarding the transaction. Accordingly, the Commission waived the commitment to divest the product and the merged entity discontinued the product, while making its trial data and biosamples publicly available to promote R&D. This reflects that pharmaceutical drug development does carry risk, a fact which is reflected in the safeguards adopted by the Commission, and its pragmatic approach to addressing unforeseeable market changes following its decisions.

Finally, it must be noted that while the Commission's practice for remedies in the pharmaceutical sector is well-established, it is essential that each case and proposed remedy be assessed on its own merits. While the time-to-market for pharmaceutical products is long, the pace of medical innovation and new discovery is rapid and investment in the sector is high. As a result, there can be many promising pipelines and shifts in the prospects of treating particular diseases. Proposed remedies must therefore be assessed with care and with specific regard to the prevailing medical and commercial wisdom, in view of the evidence and the feedback provided by informed market participants, to prevent competitive harm. This was well illustrated in the *Illumina/GRAIL* case, where the proposed behavioural remedies (consisting of an attempt to enable upstream entry and provide non-discriminatory treatment for downstream rivals) were found insufficient to address the competition concerns and avoid the competitive harm arising from the transaction, resulting in its prohibition.[49]

5. Jurisdictional aspects in pharma mergers

Undertakings must notify concentrations that meet the EUMR's turnover thresholds to the Commission prior to their implementation. This normally applies to concentrations in the pharmaceutical sector where parties have both marketed drugs generating turnover, in addition to any pipeline developments. However, acquisitions of companies that do not yet have any turnover but may in fact have (potentially competing) pipeline products would not be caught by the turnover-based thresholds, and as such, a potential enforcement gap was identified.

In 2016, the Commission launched an evaluation on the functioning of certain procedural and jurisdictional aspects of EU merger control, covering *inter alia* the effectiveness of the turnover based notification thresholds. The Commission found that while, on the whole, the existing thresholds work well, there has been an increasing phenomenon of concentrations involving firms that generate little or no turnover at the time of the transaction but that already play or may develop into a significant competitive role on the market. These mergers would not be captured by the existing notification thresholds but could have a significant impact on competition. This is particularly relevant for the pharmaceutical sector, where innovation is a key parameter of competition and so targets with promising drug pipelines can have high valuations and significant competitive potential, even if they do not generate any turnover at the time

[45] M.7275 *Novartis/GSK Oncology*, Commission decision of 28 January 2015. The commitments were conditional on Array entering a cooperation agreement with a suitable partner that would assist it to finalise the development and roll out the global marketing of the products in question, otherwise a divestiture trustee would sell the assets to an alternative suitable purchaser.

[46] M.8401 *J&J/Actelion*, Commission decision of 9 June 2017.

[47] See further Commission Remedies Notice, paragraphs 71-76.

[48] M.8955 *Takeda/Shire*, Commission decision of 20 November 2018.

[49] M.10188 *Illumina/GRAIL*, Commission decision of 6 September 2022 (not yet published).

of the transaction and therefore fall below the relevant merger control thresholds.[50]

In light of these findings, the Commission revised its approach to requests for case referrals under Article 22 EUMR. This provision empowers Member States to request that the Commission examine any concentration that lacks an EU dimension and is therefore not directly notifiable to the Commission, provided that it: (i) affects trade between Member States; and (ii) threatens to significantly affect competition within the territory of the Member State making the referral request. Other EU Member States and EEA EFTA States may then join the initial referral request.[51] The Commission's jurisdiction under Article 22 is limited to examining the effects of the transaction in the referring Member States. In the past, the Commission had discouraged Member States from requesting referrals in cases where they do not themselves have jurisdiction, as it was considered, based on experience at the time, that the national thresholds, often turnover-based, captured all transactions that could materially impact the internal market. However, following the results of the evaluation, the Commission considered that referrals by Member States were an appropriate and proportionate tool to capture below-threshold transactions that could give rise to competition issues of the nature identified in the consultation. Accordingly, in September 2020 the Executive Vice-President for Competition announced that the Commission was revising its approach, such that, in appropriate circumstances, the Commission would henceforth encourage Member States to refer certain cases to it even where the transaction was not notifiable to the Member State(s) in question. [52]

Following the publication of its evaluation of procedural and jurisdictional aspects of EU merger control identifying a potential enforcement gap,[53] in March 2021 the Commission adopted a guidance paper introducing a reappraisal of the application of Article 22 to ensure that certain categories of cross-border transactions with potentially significant impact on competition in the internal market are appropriately examined.[54] Under this guidance, the Commission intends to encourage and accept referrals of transactions: (i) over which the referring Member State does not have initial jurisdiction; and (ii) which involve firms that play or may develop into playing a significant competitive role on the market(s) at stake despite generating little or no turnover at the time of the concentration.

This approach has been confirmed by the EU General Court concerning the *Illumina/GRAIL* decision [55] by which the Commission accepted Article 22 referrals from six EEA States [56] regarding a concentration that was not notifiable at national level in any EEA State.[57] The General Court's judgment is under appeal before the European Court of Justice.[58] Even when a referral request fulfils the substantive and procedural[59] conditions of Article 22, the Commission has discretion to accept or reject the referral request. The Commission exercises this discretion based on the principles of the Referral Notice[60] and the more recent Article 22 Guidance.[61]

As explained in the Commission's Referral Notice, when considering whether to accept a referral request, the Commission will consider, e.g., the need to ensure effective protection of competition in all markets affected by the concentration.

The Article 22 Guidance complements the Referral Notice and adds a new category of cases generally deemed most appropriate for an Article 22 referral. These are concentrations where the turnover of at least one of the undertakings concerned does not reflect its actual or future competitive potential, for instance because the target is a start-up or recent entrant with significant competitive potential or an important innovator or has access to competitive significant assets such as raw materials, infrastructure, data or intellectual property rights.[62] The Guidance foresees that the recalibrated approach to Article 22 could be of particular relevance to the pharmaceutical sector, due to the importance of innovation as a parameter of competition. Accordingly, the Guidance provides hypothetical examples of transactions that could be considered as suitable candidates for

[50] See Communication from the Commission - Guidance on the application of the referral mechanism set out in Article 22 of the EU Merger Regulation to certain categories of cases, 26 March 2022, C(2021) 1959 final, paragraphs 9-12.

[51] According to Article 6(3) of Protocol 24 of the EEA Agreement, one or more EEA EFTA States (i.e., Iceland, Liechtenstein and Norway) may join a request for referral made by a Member State under Article 22 if the concentration affects trade between one or more EU Member States and one or more EEA EFTA States and threatens to significantly affect competition within the territory of the EEA ETFA State joining the request.

[52] See Speech by EVP Vestager, "*The future of EU merger control*", 11 September 2020, SPEECH/20/2884.

[53] Evaluation of procedural and jurisdictional aspects of EU merger control, SWD(2021) 66 final, 26.3.2021.

[54] Guidance on the application of the referral mechanism set out in Article 22 of the Merger Regulation to certain categories of cases (2021/C 113/01), ("Article 22 Guidance" or "Guidance").

[55] Case T-227/21 *Illumina v Commission,* EU:T:2022:447, judgment of 13 July 2022, paragraphs 85-184. Appeal of the judgment is pending before the European Court of Justice, Case C-611/22 P *Illumina v Commission*.

[56] While only EU Member States can make the initial referral request under Article 22 EUMR, EEA EFTA States may join the initial request. See footnote 51 above.

[57] M.10188 *Illumina/GRAIL*, Commission decisions of 19 April 2021 pursuant to Article 22(3) (not yet published). The initial referral by France was joined by Belgium, Greece, Iceland, the Netherlands, and Norway.

[58] Case C-611/22 P, *Illumina v Commission*.

[59] Referral requests are to be submitted within a period of 15 working days of the date on which the concentration was either notified; or if it was not notifiable nationally, otherwise made known to the Member State concerned. In *Illumina/GRAIL*, the General Court confirmed the Commission approach that "made known" should be understood to imply an "active transmission of information" to the Member State concerned to enable a preliminary assessment as to the existence of the criteria relevant for the assessment of the referral. See Case T-227/21 *Illumina v Commission*, paragraphs 200-213.

[60] Commission Notice on Case Referral in respect of concentrations (2005/C 56/02) ("Referral Notice").

[61] See fn. [54] above.

[62] Article 22 Guidance, paragraphs 19-20. See also Practical information on implementation of the "Guidance on the application of the referral mechanism set out in Article 22 of the Merger Regulation to certain categories of cases", Frequently Asked Questions and Answers (Q&A), available on the Commission's website at: https://competition-policy.ec.europa.eu/system/files/2022-12/article22_recalibrated_approach_QandA.pdf.

an Article 22 referral. These include an acquisition by an active pharmaceutical player of an innovative pharmaceutical company with no actual revenues but an advanced pipeline project which could target the same disease and have a comparable mode of action as an already commercialised drug of the acquirer.[63]

Other factors that the Commission may consider under the recalibrated approach to Article 22 include whether the consideration paid by the purchaser is particularly high compared to the target's current turnover – which could indicate that it does not reflect its actual or future competitive potential; potential ongoing/parallel reviews by Member States – which may undermine the 'one-stop-shop' principle; and potential period of time elapsed since the implementation of the transaction.[64]

The Commission applied this approach for the first time to the *Illumina/GRAIL* transaction which, due to the target being a start-up, did not trigger a notification anywhere in the EEA. The Commission accepted an initial referral request from France and joining referrals from five other EU/EEA countries, none of which had jurisdiction to review the transaction based on their national legislation.[65] In addition to finding that the referrals met the legal criteria of Article 22, the Commission considered a set of additional factors in favour of accepting the referrals. These included: (i) the fact that the value of the deal was particularly high compared to the turnover of the target at the time of the transaction; (ii) the fact that, while the target did not generate revenues from the sale of products, one of its products in development was expected to capture a significant share of the addressable market; and (iii) the consideration that an EU-level coordination of investigative efforts was desirable given that the transaction concerned cancer detection, a priority of the Commission in the area of health.[66]

Finally, although pharmaceutical mergers are a key target area for the recalibrated application of Article 22, EU Member States retain discretion in deciding what concentrations they may refer to the Commission. The aim of the current approach is to permit EU Member States and the Commission to ensure that transactions that merit review under the EUMR are examined by the Commission, without imposing a notification obligation on transactions that would not warrant such review. In order to achieve this aim, the Commission is actively monitoring transactions in the pharmaceutical sector in order to consider their suitability for referral under Article 22 by sending requests for information to and receiving briefing papers from the parties to transactions that may warrant a review by the Commission on that basis and encouraging companies to actively reach out to request a consultation in case of doubt.

The recalibrated Article 22 policy has proven to be a necessary and effective mechanism, working as a safety net in permitting the Commission to screen concentrations which are likely to significantly impede effective competition in the internal market and which, because the turnover thresholds have not been met, could otherwise escape a review by the Commission and Member States.

More generally, referral mechanisms of the EUMR may be relevant to merger enforcement in the pharmaceutical sector, as the existence of EEA-wide or global markets for pipeline products may speak in favour of a review by the Commission. By way of example, in 2019, the Commission accepted referrals to review the proposed acquisition by J&J of Tachosil, a competing provider of certain haemostatic and tissue sealing products[67]. The Commission's review raised concerns that although Johnson & Johnson did not sell the overlapping products (dual haemostatic patches) in the EEA at the time of the transaction, it had done so until 2017 and at the time of the transaction sold them outside the EEA. The Commission's investigation revealed that absent the transaction, Johnson & Johnson would have had strong incentives to enter EEA markets either with the product it was marketing outside the EEA or with new product that it might have developed absent the transaction. The Commission initiated an in-depth investigation, and the parties abandoned the transaction before the Commission could reach its final decision.[68] More recently, *Pfizer/Seagen* [69] was referred to the Commission under Article 4(5) EUMR.

6. International cooperation

Taking into account the global nature of large pharmaceutical mergers and the fact that innovation markets are often deemed to be global, cooperation between the competition enforcers is of paramount importance when assessing mergers with innovation elements. Such cooperation is conducted on a case-by-case basis for investigations where multiple competition authorities are involved and the merging parties have provided a waiver allowing authorities to discuss confidential information. Allowing for cooperation between the authorities often leads to positive outcomes for the parties as investigations may be more aligned in terms of timing and, where relevant, remedies. In March 2021, at policy level, the Commission, together with the Canadian Competition Bureau, the UK's Competition and Markets Authority, the U.S. Federal Trade Commission (FTC), U.S. Department of Justice, and three U.S. Offices of Attorneys General launched a multilateral working group to analyse the effects of mergers in the pharmaceutical sector. The working group was initiated by the FTC and is in line with close cooperation between national competition authorities.[70] The working group's efforts culminated in a workshop on 14-15 June 2022, in which the participating competition authorities and sector experts contributed their experiences, views and approaches to pharmaceutical merger enforcement, focusing on innovation aspects of pharmaceutical mergers, amongst other issues, such as price competition and remedies.[71]

[63] Practical information on implementation of the "Guidance on the application of the referral mechanism set out in Article 22 of the Merger Regulation to certain categories of cases", Frequently Asked Questions and Answers (Q&A), available on the Commission's website at: https://competition-policy.ec.europa.eu/system/files/2022-12/article22_recalibrated_approach_QandA.pdf.

[64] Article 22 Guidance, paragraphs 21-22.

[65] See fn. [57] above.

[66] *Ibid.*

[67] M.9547 *Johnson & Johnson / Tachosil* (withdrawn on 8 April 2020).

[68] Withdrawal of notification of a concentration (Case M.9547 – Johnson & Johnson/Tachosil) 2020/C 124/01.

[69] M.11177 *Pfizer/Seagen*, Commission decision of 19 October 2023 (not yet published).

[70] See Commission press release: https://ec.europa.eu/commission/presscorner/detail/en/IP_21_1203.

[71] See FTC-DOJ Workshop Summary: The Future of Pharma (ftc.gov).

Conclusion

The pharmaceutical industry is innovative by nature. Accordingly, innovation plays a key role in merger reviews in the pharmaceutical sector, as it is relevant not only for the substantive assessment but is also a relevant parameter when considering jurisdiction.

The Commission has developed its analytical approach to innovation in pharmaceutical cases over time, applying its assessment framework in multiple decisions. This framework gives certainty over the analytical approach the Commission will use, while allowing for the necessary flexibility required to assess complex innovation theories of harm and potentially remedies based on the relevant facts of each case. The work of the multilateral working group focusing on pharma indicates that competition agencies globally are seeking to develop and improve assessment of innovation aspects of pharmaceutical mergers.