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Transatlantic Enforcers Working Group on Pharmaceutical Mergers: Reimagining Innovation May Have Side Effects

BY DESMA POLYDOROU, GEORGE ZACHARODIMOS, AND BILL BATCHELOR

IT MAY SEEM ODD THAT THE QUESTION OF pharmaceutical industry innovation has resurfaced in 2021. The industry's response to the COVID-19 pandemic has seen highly effective vaccines developed and commercialized in record time, leveraging powerful pairings of big pharmaceutical companies and small research start-ups, including Pfizer/BioNTech and AstraZeneca/Oxford. But that is precisely the question occupying a newly formed transatlantic working group of leading antitrust enforcers. The European Commission ("EC"), the U.S. Federal Trade Commission ("FTC"), the Department of Justice Antitrust Division ("DOJ") and Offices of State Attorneys General, the Canadian Competition Bureau, and the UK's Competition and Markets Authority ("CMA") announced in April 2021 a working group that would develop new principles by which to assess "*the full range of a pharmaceutical merger's effects on innovation?*"[1]

Desma Polydorou is Senior Corporate Counsel, Antitrust at Pfizer Inc., Bill Batchelor is a partner and George Zacharodimos is an associate at Skadden, Arps, Slate, Meagher & Flom LLP and Affiliates. *They would like to thank Maria Raptis and Jessica Schneider, also of Skadden, for their help in writing this article. Skadden represented E. I. du Pont de Nemours and Company in its merger-of-equals with The Dow Chemical Company, Sabre Corporation in the proposed acquisition of acquisition of FareLogix Inc, Applied Materials, Inc. on aspects of its proposed, but terminated, merger-of-equals with Tokyo Electron Limited, and PayPal, Inc. in its acquisition of iZettle AB and Adevinta ASA in its acquisition of eBay Classifieds Group from eBay Inc. The opinions in this paper are, however, the authors' sole responsibility.*

As we examine, the answer is far from clear. We chart the sometimes-conflicting cases and approaches from both sides of the Atlantic that will feature in the working group's consideration and explore practical issues relating to evidence, counterfactual analysis and remedies. We conclude that clear and administrable principles are essential. This is an industry that spends huge amounts both on internal and external R&D, the latter principally in acquisitions. There is a cost to innovation in creating an uncertain or unadministrable legal framework. In the pharmaceutical industry, time and money may be short to convert breakthroughs into medicines.

Pharmaceutical Industry Innovation

The pharmaceutical industry spends a quarter of its net revenues on R&D,[2] USD 186 billion globally,[3] more than any other knowledge-based industry. R&D spend has increased ten times since 1980 and doubled since 2000. The number of new approved medicines is up by 60% in the last decade (2010-2019) from the decade before. Companies big and small are pursuing new technologies. 70% of products in Phase III clinical trials are from small pharmaceutical companies.[4]

The costs and risks remain daunting. A new drug's estimated average cost is as high as USD 2.6 billion, taking up to ten years to commercialize.[5] A handful of the 10,000 substances synthesized in the laboratory make it to market.[6] Less than 10% of products in Phase I and 30% of products in Phase II are ever approved.[7]

Pharmaceutical companies invest in new technologies through collaboration or acquisition to complement organic efforts. Acquisitions, acquisition options, and reverse mergers continue to rise, reaching 384 completed or active deals in 2020.[8] These can be small scale collaborations, acquisitions of early-stage assets, or transformative deals acquiring a company with a promising portfolio of commercialized and pipeline products. These deals naturally are assessed by antitrust regulators.

Innovation in Theory and Practice

Famously, the debate on innovation and mergers was polarized between thought-leaders of the day, Kenneth Arrow and Joseph Schumpeter. Arrow theorized competition stimulated innovation that a monopolist might be too lazy to pursue. Schumpeter countered with concentration's role in promoting innovation and the prospect of market power and scale spurring innovation.[9]

But until recently, consideration of innovation as a standalone harm in mergers was rare. The decisional practice almost exclusively concerned itself with existing products, or those contemplated in the merging firms' pipelines, not with risks to some abstractly determined area of innovation.

Academic debate was reignited by papers authored by the then-EC's chief economist team[10] and leading economists

responding to that work.[11] The immediate context of the papers was the EC's investigation of *Dow/Dupont* (2017), in which a standalone innovation theory of harm—independent of current or pipeline products—was part of the EC's merger challenge, leading the merging parties to divest Dupont's global R&D organization.[12]

Innovation hawks posited that in a concentrated market of key innovators, a merger will likely reduce innovation and not be offset by beneficial synergies (or if such exist the burden falls on the merging parties to demonstrate them).[13] Others demonstrated the overall effects of mergers on innovation can be both negative and positive, with neither presumed to predominate.[14] The current EC Chief Economist, writing in a personal capacity, noted mergers with a significant innovative dimension may merit more lenient review than purely "static" transactions.[15]

Efficiencies and changes in investment incentives through mergers may increase innovation. These include innovation knowledge diffusion within the merged entity or changes in investment incentives given that innovations will not "leak" to the target,[16] or use of shared common ("non-rival") proprietary insights or inputs across the merged entity's broader output base[17], e.g., common IP portfolio or knowledge of disease targets. Innovative efforts may also increase post-merger to secure profits from product differentiation, e.g., by focusing on different features, demand niches or customer groups, or from demand expanding innovation, such as next generation or lower cost technologies. The policy implication is that there should be a neutral rather than negative presumption (or burden shifting) for merger innovation effects.

Adding to the debate, Cunningham et al. (2018)'s widely cited *Killer Acquisitions* paper found pharmaceutical companies more frequently cease to develop acquired company R&D projects when the projects competed with the acquirer's existing business.[18] Though as the authors themselves and commentators note, it is not possible to know whether these R&D projects would otherwise have been successful (there may be a degree of "hindsight bias"), and the paper focuses on assets with the same mode of action rather than economic markets.[19] Observed patterns may be explained by optimal project selection rather than "killer" motives. Companies experienced in overlapping drugs may be quicker than companies without that experience, to realize a promising early stage asset has proven to be a false trail.[20] In a competitive market to acquire innovative assets, it is possible that lower-valued R&D assets (falling below the antitrust review thresholds) may reflect the speculative nature of the R&D involved, and consequently, that it had limited prospects of success.[21] Cunningham noted many of the acquisitions it analyzed were valued below the antitrust reportability thresholds.

Merger guidance from the U.S., EU, and UK all highlight innovation competition.[22] But innovation appraisal is complex. The combined undertaking's efforts may enhance, rather than reduce, innovation. And expert regulators have drawn diametrically opposed conclusions on the same transactions. In *Sabre/Farelogix* (2020), the CMA found innovation was harmed by removing an innovation stimulus.[23] Two days before, a U.S. federal judge, ruling on the DOJ's challenge to the acquisition, concluded the same deal would enhance innovation. With access to the acquirer's far larger data sets, the target could use machine learning and artificial intelligence to launch product improvements.[24]

In *Applied Materials/Tokyo Electron* (2015), the DOJ was the innovation skeptic. The DOJ was concerned post-merger that the two firms would not compete to develop equipment to manufacture next generation 450 mm wafer semiconductors (a market where neither firm was then active).[25] The Bundeskartellamt (German Federal Cartel Office) cleared the merger for the opposite reason. Customers indicated the complementary skillsets of the firms could position the combined entity to bring next generation manufacturing technology to market successfully.[26] Conversely, the evidence on harm was insufficient to predict competition harm in the manufacturing of 450 mm wafers.[27]

The fact that innovation can be enhanced by mergers (and retarded by over-intervention) is illustrated by post-merger studies. Acquisitions in the semi-conductor industry have been correlated with stronger innovative output measured by number of patents.[28] In *Unilever/Sara Lee* (2010), overall R&D, as measured by patenting activity, increased post-merger across the industry.[29] Ex-post evaluation of five-to-three concentration in the hard disk drive ("HDD") sector (*Hitachi/Western Digital* (2011) and *Seagate/Samsung* (2011)) showed that the combined *Seagate/Samsung* entity increased R&D intensity, patent activity, and new products launched (while unit costs reduced).[30] One likely reason was the combined patent portfolio enabled the merged entity to innovate more quickly through intra-firm technology sharing. Conversely, in *Hitachi/Western Digital*, innovative efforts were weaker, the ex-post evaluation report found, potentially from the remedies required by authorities to clear the deal.[31]

Regulators' Approaches to Innovation and Pharmaceutical Mergers

United States. Transatlantic regulators have approached innovation mergers in different ways. The FTC's Guidelines acknowledge that competition often spurs firms to innovate, and so the FTC may investigate whether a merger is likely to diminish innovation competition and curtail the merged entity's innovative efforts.[32] The FTC's historic practice is typically to look only at more advanced Phase III pipeline products when considering remedies.[33] But it may also examine overlaps between the merging parties' products and products in the FDA pipeline, which can include pre-clinical research areas.

Several FTC decisions illustrate the challenges of weighing pro-innovation effects of mergers. In *Ciba-Geigy/Sandoz* (1997), for example, the FTC identified a relevant market as the "*research and development of gene therapies*" using viral vectors for certain oncology, transplant, and hemophilia treatments. Though neither had a commercialized product, the parties allegedly led the field with gene therapies "*in . . . or near clinical development.*"[34] In a decision that split the FTC, the majority endorsed allowing the parties to combine their early stage gene therapy R&D to avoid a "*divestiture's potentially disruptive effects on the parties' ongoing research*" while requiring a patent license on reasonable terms to alleviate competition concerns.[35]

In *Genzyme/Novazyme* (2004), the two companies researching Pompe disease (a fatal condition affecting young children) were engaged in pre-clinical investigatory work. The FTC majority accepted that the merger was likely to stimulate innovation. FTC Chairman Muris stated,

> The Commission also investigated whether the merger has made it more likely that the Genzyme program or the Novazyme program will produce a successful therapy, or will do so sooner. The merger made possible comparative experiments and provided information that enabled the Novazyme program to avoid drilling dry holes. By accelerating the Novazyme program, the merger may have increased its odds of success. Moreover, the merger made possible synergies that will help avoid a delay in the Novazyme program.[36]

But recent dissents, by then-Acting FTC Chair, Slaughter, and fellow former Democratic Commissioner, Chopra, have echoed the transatlantic working group's press release in calling for innovation activism.[37] In *Pfizer/Mylan* (2020), Commissioners Chopra and Slaughter stated, "*. . . the status quo approach of seeking settlements through divestitures of individual products is myopic and misses some of the fundamental elements of how firms compete in this industry.*"[38] Commissioner Chopra called on the Commissioners to "*dramatically increase rigor and supervision of innovation-merger investigations, enhance the analytical capabilities when assessing prospective divestiture buyers and when crafting remedies for anticompetitive mergers and conduct.*"[39] In *BMS/Celgene* (2019), Commissioner Chopra also noted that the current framework would not allow the FTC to assess whether the merger would facilitate a capital structure that magnifies incentives to engage in anticompetitive conduct or abuse of intellectual property, or whether it would deter formation of biotechnology firms that fuel industry innovation.[40] These dissents, worded in strong language as they are, did not, however, identify an evidential basis or alternative analytical framework to describe how these concerns might be addressed and, if appropriate, corrected.

European Union. Historically, the EC largely followed the "traditional" U.S. approach. Its analysis focused on specific product markets or advanced pipeline products.[41] For example, in *Pfizer/Hospira* (2015), the EC required divestiture of Pfizer's Phase III pipeline infliximab biosimilar to remove overlaps with Hospira's commercialized biosimilar.[42]

Two cases—the first in pharmaceuticals (*Novartis/GlaxoSmithKline Oncology Business* (2015)),[43] the second in crop protection (*Dow/Dupont*[44])—saw the EC expand not just further back into the pipeline, but to consider as-yet-unidentified potential innovations. In *Novartis/GlaxoSmithKline Oncology Business*, rather than limiting itself to marketed or pipeline products the EC analyzed the parties' clinical research programs in MEK and B-Raf inhibitors more generally.[45] These were based on the same mechanisms of action and were expected to address similar unmet medical needs.[46] Apart from the merging parties, only Roche had B-Raf and MEK inhibitor assets and was alleged not to exert sufficient competitive pressure on the merged entity. Novartis's overlapping R&D programs were divested to maintain an independent B-Raf and MEK inhibitor pole of innovation.[47]

The EC took its analysis one stage further in *Dow/Dupont*, introducing the concept of harm to competition in "innovation spaces". This considered the threat a merger might pose to innovation across a sector as a whole, rather than focusing only on particular pipeline products or specific product markets.[48] The EC alleged the merger would also have restricted competition because of its adverse effects on future efforts to innovate.[49] The EC asserted this was the case, even though it was not yet possible to specify on which markets the effects would ultimately manifest themselves.[50] Those R&D efforts may target existing product markets or take place upstream of actual product markets.[51] *Bayer/Monsanto* (2018) followed the same approach and required far reaching remedies to address innovation concerns.[52]

Post *Novartis/GlaxoSmithKline Oncology Business* and *Dow/Dupont*, the EC has codified its approach as a four-level assessment*:*

(a) overlaps between existing (marketed) products;
(b) overlaps (i) between existing (marketed) and pipeline products at advanced stages of development and (ii) between pipeline products at advanced stages of development. For pharmaceutical products, the EC "*in principle considers programmes in Phase II and III clinical trials as being at an advanced stage of development*" [53];
(c) loss of innovation competition resulting from the discontinuation, delay, or redirection of one party's early stage pipeline products/projects overlapping with the other party's existing products or advanced or early stage pipeline products/projects; and
(d) loss of innovation competition resulting from a structural reduction of the overall level of innovation.[54]

The EC has also recently changed its standing practice to broaden its reach to review otherwise non-notifiable mergers under its new Article 22 EU Merger Regulation ("EUMR") Guidance,[55] including those that might have "killer acquisition" characteristics.[56]

United Kingdom. In contrast to the EC and the FTC, the CMA has tended to adopt a more flexible, expansive analytical framework. Even if products are not, or may never be, in the same product market, it examines the potential for innovation concerns.

For example, the CMA challenged *Illumina/PacBio* (2019)[57] on the basis of a company's R&D efforts, examining the loss for future competition between technologies traditionally viewed as poor substitutes, Illumina's long read sequencing technology, and PacBio's short read sequencing technologies.[58] The CMA concluded that these technologies would come to compete at some indeterminate future point but without a specific time frame. Illumina was researching long read technologies and PacBio would likely invest in research where it would compete with Illumina's instruments. The CMA alleged the merger would incentivize PacBio and Illumina to re-focus R&D towards complementary, rather than competing, use cases.

In the same vein, in *Roche/Spark* (2019), the CMA considered competitive interaction over a long time horizon between two hemophilia therapies—Roche's recently launched Hemlibra, a novel, but non-gene therapy, treatment with minimal UK share and Spark's gene therapy, then in Phase II. Despite very different modes of action and potential target groups, the CMA predicted Hemlibra might gain as much as 60% market share in the UK within five years and that Spark would successfully launch and represent a competitive constraint.[59] Ultimately, however, it concluded that proximate entry by other gene and non-gene treatments would mean no loss of competition.

The CMA's revised 2021 merger guidelines codify the CMA's approach to innovation.[60] The CMA will assess whether a merger will reduce dynamic competition by (i) reducing an existing supplier's current efforts to protect against the impact of future market entry; or (ii) by reducing the incentives of a dynamic competitor to innovate because it will no longer have an incentive to "steal" profits which will now be captured by the merged firm. The guidelines show the CMA unfazed by the future-divining capabilities this might require. The CMA, the guidelines state, will not be deterred by the uncertain outcome of investments and innovation efforts which frequently do not reach the market. Instead, it will consider the economic value of the likelihood that new innovations or products could reach the market—even where entry is "*unlikely and may ultimately be unsuccessful.*"[61] When specific product overlaps are not identifiable, the CMA may consider the broader pattern of dynamic competition, such as between merging pharmaceutical companies engaging in research programs that are likely to treat the same illnesses.[62]

Transatlantic Divergence or Consensus. Though the UK, EU, and U.S. have nominally different approaches, the practical differences may be more imagined than real. The UK's enforcement practice in pharmaceutical innovation cases is nascent. Its initial forays appear more flexible, and less predictable, than U.S. and EU peers. That is partly a feature of a more free-form statutory framework and limited judicial constraints upon the UK merger process. But it remains to be seen whether the CMA's decisional practice will develop, and become more settled, with its expanding post-Brexit case load, taking independent jurisdiction over global deals formally filed only with the EU.

The EC's expansive approach has created extensive debate amongst academics and practitioners as to whether it presents the correct analytical framework for innovation competition. The complexity of pro- and anti-innovation consequences of mergers do not easily lend themselves to this level of simplification, as cases such as *Genzyme/Novazyme* illustrate, as well as the conflicting results in *Sabre/Farelogix* and *Applied Materials/Tokyo Electron*.

But as a practical matter the EC has never found a risk of an "innovation space" harm in pharmaceutical mergers. The generally competitive nature of the industry across all areas of research has been evident on even a cursory examination.[63] For example, in *BMS/Celgene*, the EC found that the merger did not give rise to competition concerns regarding innovation spaces "*given the very large number of R&D organisations competing at global level (e.g., pharmaceutical and biotechnology companies, university research programmes) in the overlapping therapeutic spaces, which are characterised by intensive R&D.*"[64] Rather, its decisional output has been broadly consistent with that of the FTC. It has never found a "pure" innovation concern in a pharmaceutical merger. As the industry's innovative output suggests, this is for good reasons.

Practical Issues: Evidence

Quite aside from the challenges of an appropriate analytical framework, the transatlantic working group will also consider more bread-and-butter practice issues.

At its most extreme, an innovation-harm theory may seek to assess lost innovation for products as yet undeveloped. It becomes impossible to use tools such as market shares (no product or pipeline asset yet exists) and it is challenging to judge which firms are potential innovation rivals. Since the new innovation is unknown, it is difficult to judge who might potentially enter.

To assess innovative potential, in *Dow/Dupont* and *Bayer/Monsanto*, the EC used both shares of past product launches and patents (weighted by subsequent citations) in the "innovation space" as a measure of innovation potential.[65] Similarly, in *GE/Baker Hughes* (2017), regulators considered which firms had led product innovations, and which had followed, over a 10-year period.[66]

But both are inherently backwards looking measures. By definition they plot only *past* product launches and *past* patented inventions. Patent and citation-based indexes might not be informative for nascent/early-stage products and may not constitute appropriate innovation proxies. Similarly, they are unidirectional innovation proxies.[67] Adding HDD

patent shares in *Seagate/Samsung* might have revealed high shares, but it would have missed the point that precisely the broader patent portfolio enabled the combined entity to innovate *more* successfully.

The CMA has recently considered allegedly outsized valuations may be evidence the deal is anticompetitive. In *PayPal/iZettle* (2019), the CMA considered whether the USD 2.2 billion valuation, higher than the target's expected IPO valuation of USD 1.1 billion, might be suspect. However, it concluded that "*the consideration appeared justified by commercial valuations and calculations of synergies*"[68] and there was "*no evidence that PayPal intended to shut iZettle or increase prices post-Merger.*"[69] Conversely, the EU Court has given short shrift to valuation evidence, holding that "*the applicants cannot overcome the shortcomings of their arguments relating to the harm to competition . . . by referring to the purchase price of USD 8.5 billion*." [70]

For want of objective metrics, regulators frequently use internal documents on innovative intentions. In *Roche/Spark*, documents in which Roche tracked Spark's progress in gene therapy was treated as evidence of competitive innovative rivalry, despite the very different hemophilia treatment types.[71] In *Dow/Dupont*, documents suggesting post-merger R&D streamlining were also cited.[72] Build, buy or partner business case documents are also commonly perused as intent evidence of entry by the acquirer into the target's business.

Internal documents should be treated with caution, however. The seniority/knowledge of author and the objective of a document is key. Are these individuals engaged in blue sky thinking or at the company's R&D coalface? Documents may be created by people without the necessary knowledge or authority to implement the ideas they contain, may represent early thinking that was quickly rejected, or may have been created to "sell" a certain view of the world to a specific audience (for example, to potential investors). In *Servier*, the EU Court faulted the EC's reliance on Servier's promotional documents to allege market power. These extolled the Servier ACE-inhibitor's virtues over rivals. But this was to discount health authority prescriber guidelines, a more neutral evidential source. These stated that there was little to distinguish the many competing products.[73]

Past documents or past innovation success may be particularly unreliable in fast-moving dynamic industries. In *Sabre/Farelogix*, the DOJ focused on internal documents that evidence at trial showed reflected a dated and inaccurate "rearview mirror" of the industry.[74] In the pharmaceutical market in particular, internal views of, or strategies for, products can change significantly and quickly. A company may have a potentially strong pipeline product, but the product misses its primary endpoint or causes significant adverse events, and so the development strategy for that product necessarily changes, too.

Moreover, there is a risk of selective reliance. If one document expresses a view that seems at odds with the rest of the record, the first question should be just that. Is this document an outlier that does not reflect the company's overall business intent? In *Steris/Synergy* (2015),[75] the FTC sued to block the merger, claiming the merger would end Synergy's plans to enter the U.S. market. The FTC relied on select emails from executives at Synergy stating Synergy's U.S. x-ray project was approved. The FTC did not give weight to other documents that highlighted how difficult this entrance would be. Synergy did not have the financial resources nor the customer demand to enter into the U.S. Synergy ultimately decided not to enter into the U.S. for business reasons independent of the Steris transaction. But those facts were not captured by the FTC's cherry-picked documents.

This is even more the case if internal documents are being used to support speculative theories of harm in relation to which there is little or conflicting evidence (including "killer acquisition cases"). In *Dow/DuPont*, alleged innovation concerns derived from internal documents (redacted from the decision) were only supported by a minority of the respondents in the EC's market investigation, primarily the parties' rivals.[76]

Practical Issues: Counterfactual/Standard of Proof

As theories of harm move beyond commercialized products, inevitably, outcomes become more challenging to predict. The ability of a competition authority to predict future anticompetitive effects sharply decreases the further into the future that those effects would take place. This is even more so regarding innovation in the pharmaceutical industry where there is no consistent pattern of events or trajectory. This can involve the counterfactual, i.e., would a small target with a promising clinical asset, about to reach the limits of its funding, really have commercialized a product without the help of its new acquirer?

Recent cases have seen authorities look increasingly into the future, and sometimes the pace of innovation can overtake the antitrust outcomes. The CMA takes an expansive, long-time horizon approach to the counterfactual. In addition to the forward looking assessment in *Illumina/PacBio*,[77] in *Amazon/Deliveroo* (2020), the CMA considered that Amazon was likely to re-enter the supply of online restaurant platforms in the UK in the short-to-medium term (i.e., within five years), despite having exited that market in 2018.[78] In *Adevinta/eBay* (2021), the CMA considered that Adevinta's Shpock, and eBay's Gumtree and eBay Marketplace, competed closely and required the divestiture of Adevinta's Shpock *and* eBay's Gumtree as the CMA found eBay would have sold its classified assets to a non-competing buyer absent the Adevinta sale.[79]

By contrast, the EC is more constrained in its evaluation of the counterfactual and the EU Courts' case law sets out the required evidential standard for more complex theories of harm. The EC generally does not consider anticompetitive effects beyond a three-year time horizon.[80] The EU

Courts have also held the EC to a high standard of proof when seeking to demonstrate complex theories of harm. In its landmark *CK Hutchison* dictum, the EU General Court stated of complex merger theories:

> [T]he more a theory of harm advanced is complex or uncertain, or stems from a cause-and-effect relationship which is difficult to establish, the more demanding the Courts of the European Union must be as regards the specific examination of the evidence submitted by the Commission in this respect.[81]

The risks of making too many forward assumptions are well illustrated in *Shire/Takeda* (2019). As a condition of its approval of the proposed transaction, the EC required the parties to divest Shire's IBD pipeline product. However, poor IBD clinical trial results and swift emergence of IL-23s as a more effective treatment meant Shire's pipeline product was unsaleable. The parties were unable to find a buyer for the product after fourteen months of searching and sixty potential buyers.[82] Ultimately, the EC released Takeda from the obligation to divest this pipeline product. Market dynamics had shown the remedy's predicate theory of harm was incorrect.

Enforcement authorities should have strong evidence for diverging from the pre-merger conditions as the counterfactual. That is particularly so in this industry. The competitive landscape in pharmaceuticals is constantly changing as new products enter the market and the industry's understanding of therapy efficacy evolves: expansion of gene-editing and gene-therapy technologies, especially ex-vivo; use of viral vectors and mRNA to deliver therapies (e.g., COVID-19 vaccines); and, particularly in the oncology area, the discovery that combination treatments are more effective than standalone therapies.

Against this context, regulators should be slow to identify early-stage technologies as nascent rivals. The target will commonly need the additional resources, capital, and reach of the acquirer to bring the technology to commercial development. Absent evidence those challenges could be independently overcome or there was certain to be an alternative investor, this should not be considered a potential competitor. In particular, it is far too speculative to treat pre-clinical or Phase I projects as nascent rivals because only 10% of Phase I projects ever reach the market.

Practical Issues: Remedies

In pharmaceutical deals, identifying overlaps and suitable remedies is straightforward for discrete overlaps (product/Phase III pipeline versus product/Phase III pipeline). However, as regulators look further into the future at pre-commercial assets and "undirected" (i.e., not product specific) research, the established approach might not be effective.

There are particular challenges in remedy design for broader innovation theories in the pharmaceutical sector. Broader innovation theories may implicate the wider organization in a remedy, such as the management of incentives to ensure pipeline divested drugs come to market (e.g., structuring divestitures of in-development BRAF and MEK inhibitor drugs developed by the Novartis/GlaxoSmithKline Oncology Business[83] to ensure development of the BRAF and MEK inhibitors continues), patent licenses (i.e., *Illumina/PacBio*,[84] *Elanco/Bayer* (2021),[85] and *Ciba-Geigy/Sandoz*[86]), and R&D capabilities (divestment of research teams as in *Dow/DuPont*[87]). However, the impact of the remedial action on the merging firms' incentives to invest and innovate should be taken into account. As the ex-post evaluation report stated of the different fates of *Samsung/Seagate* and *Hitachi/Western Digital*, remedies can sometimes prevent the merged entity from realizing pro-innovation synergies. In the pharmaceutical sector, a (broad) divestiture may disrupt innovation in another (non-overlapping) disease area, or disrupt potential future plans for marketed products, e.g., label expansion and combination studies.

Most recent decisional practice shows that although regulators typically required the divestiture of pipeline products, the decision of the divested product may rely on broader factors. For example, in *BMS/Celgene* the merging parties divested Celgene's Otezla's (marketed product) to preserve BMS's incentive to continue developing its own oral product for treating moderate-to-severe psoriasis.[88] In *AbbVie/Allergan* (2020),[89] the competitive innovation risk was that there were only a small group of companies selling or developing IL-23 inhibitor treatments for ulcerative colitis and Crohn's disease. In this case, Allergen's Brazikumab, an IL-23 inhibitor in Phase II/III, was divested to AstraZeneca, from whom Allergan had licensed the drug, and kept Abbvie's Skyrizi, which was its IL-23 inhibitor in late-stage development.

Lastly, the suitability of potential buyers and their ability to compete in innovation should be fairly and objectively assessed. For example, in *Abbvie/Allergan*,[90] Nestlé Health Science (Nestlé's medical nutrition business) acquired Zenpep. The FTC majority view was that the acquired divestitures were highly complementary with Nestlé Health Science's existing product line. Both treat gastrointestinal conditions that hinder the body's ability to extract nutrients from food, and this was an opportunity for Nestlé to enter the pharmaceutical space. Commissioner Chopra, in his dissent, criticized Nestlé as a divestiture buyer due to lack of experience as a pharmaceutical company.[91]

Conclusion

The transatlantic working group asked whether a revised approach to innovation is appropriate. As respondents to its consultation noted, departing from accepted antitrust principles requires caution.[92] Assessing effects on innovation is a complex and multifaceted analysis. There should be no presumption (or burden-shifting) against mergers in innovative sectors, such as the pharmaceutical industry. Effects on innovation should be assessed in the round based on theories of harm anchored to product or developed pipelines. Theories such as the EC's "innovation space" theory

rest on uncertain academic foundations, with risks that pro-competitive mergers are unfairly condemned or negatively weighted.

The benefits of pooling R&D must also be considered. The spillovers from R&D teams may be as likely to speed up development rather than to delay it, and this should be weighed in the assessment. The assessment of positive pooled innovation effects should not be relegated to an impossible-to-prove efficiency defense.[93]

Pharmaceutical innovation must also be considered in the market context. The development timelines, regulatory framework, and commercialization lifecycle—from initial invention, through commercialized patented medicine through to launch of generics/biosimilars—is entirely different to other knowledge-based innovative industries, such as the IT industry, and the same analytical framework is not appropriate. [94]

This is an industry that depends heavily upon external investments, through acquisition or collaboration, to invest in promising new therapies. Those naturally require proper antitrust scrutiny. A major asset of the U.S. review process is the FTC staff's experience and sectoral knowledge. This provides for expert engagement with the facts against a robust, predictable legal framework. Conversely, an uncertain legal environment and the protracted, exploratory notification review periods observed in novel innovation-theory cases may harm early-stage innovation incentives of start-ups as well as investment by major pharmaceutical companies to assist in the next stages of development through to commercialization.[95] These are important considerations for a successful competition policy.

So, pharmaceutical companies and antitrust practitioners alike welcome and encourage the transatlantic working group to deliver, above all, a transparent and predictable process based on clear principles. There is heavy competition for these assets. The stakes are high and the pace of innovation unrelenting. An uncertain legal environment risks harming investment and jeopardizes achieving the tangible results the world has come to expect from pharmaceutical companies in the race to develop breakthrough medicines and better patient outcomes. ■

[1] FTC, *Federal Trade Comm'n Multilateral Pharmaceutical Merger Task Force Seeks Public Input* (May 11, 2021), https://www.ftc.gov/news-events/press-releases/2021/05/multilateral-pharmaceutical-merger-task-force-seeks-public-input (last visited Oct. 7, 2021). The FTC's press release describes the group's remit in refreshing and expanding potential theories of harm, particularly as to innovation, examining effective remedies, and asking whether remedies might address non-merger specific conduct, such as, quote price fixing, reverse payments, and regulatory abuses.

[2] Cong. Budget Off., Research and Development in the Pharmaceutical Industry 1 (Apr. 2021) [hereinafter "CBO Report"], https://www.cbo.gov/system/files/2021-04/57025-Rx-RnD.pdf.

[3] Matej Mikulic, *Total Global Pharmaceutical R&D Spending 2012-2026*, Statista (Aug. 27, 2021), https://www.statista.com/statistics/309466/global-r-and-d-expenditure-for-pharmaceuticals.

[4] CBO Report, *supra* note 2, at 4.

[5] Mikulic, *supra* note 3.

[6] IQVIA, EFPIA Pipeline Review 2021 Update (Feb. 2021), https://www.efpia.eu/media/602564/iqvia_efpia_pipeline-review_final.pdf.

[7] Biotechnical Innovation Org. et al., Clinical Development Success Rates and Contributing Factors 2011-2020, at 3 (Feb. 2021), https://pharmaintelligence.informa.com/~/media/informa-shop-window/pharma/2021/files/reports/2021-clinical-development-success-rates-2011-2020-v17.pdf.

[8] Marie Daghlian, *Biotech and Pharma M&A in 2020*, DealForma (Feb. 17, 2021), https://blog.dealforma.com/biotech-and-pharma-mergers-and-acquisitions-in-2020/. The industry is unconcentrated, growing through entry faster than it contracts via acquisitions. In 2001, there were ~1,200 pharmaceutical companies with active R&D pipelines, and this number rose to ~4,300 in 2019 and was expected to increase up to over 4,800 during 2020. *See* Matej Mikulic, *Pharma companies worldwide with active R&D pipelines 2001-2021* (May 20, 2021), https://www.statista.com/statistics/791340/pharmaceutical-companies-number-with-active-pipeline/

[9] *See* Kenneth J. Arrow, *Economic Welfare and the Allocation of Resources for Invention*, *in* The Rate and Direction of Inventive Activity: Economic and Social Factors 609 (1962); Joseph A. Schumpeter, Capitalism, Socialism and Democracy (1942).

[10] *See* Giulio Federico, *Horizontal Mergers, Innovation and the Competitive Process*, 8 Journal of European Competition Law and Practice 668, 668-77 (2017); Giulio Federico, Gregor Langus & Tommaso Valletti, *Horizontal Mergers and Product Innovation*, 59 International Journal of Industrial Organization 1, 1-23 (2018).

[11] Vincenzo Denicolò & Michele Polo, *The Innovation Theory of Harm: An Appraisal*, (Bocconi University Working Paper N. 103, 2018); Bruno Jullien & Yassine Lefouili, *Horizontal Mergers and Innovation*, 14 Journal of Competition Law and Economics 364 (2018); Pierre Régibeau & Katharine E. Rockett, *Mergers and Innovation*, 64 Antitrust Bulletin 31, 31-53 (2019), https://journals.sagepub.com/doi/pdf/10.1177/0003603X18822576.

[12] Case M.7932, Dow/DuPont, Comm'n Decision (Summary), 2017 OJ C 353, para. 4023–4044, https://ec.europa.eu/competition/mergers/cases/decisions/m7932_13668_3.pdf.

[13] Ioannis Kokkoris & Tommaso Valletti, *Innovation Considerations in Horizontal Merger Control*, 16 Journal of Competition Law & Economics, 220 (2020); Shapiro et al., *Antitrust and Innovation: Welcoming and Protecting Disruption*, 20 Innovation Policy and the Economy 125 (May 2019), https://papers.ssrn.com/sol3/papers.cfm?abstract_id=3393911.

[14] Regibeau & Rockett, *supra* note 11.

[15] *Id.* at 44.

[16] *Id.* at 39.

[17] Denicolò & Polo, *supra* note 11.

[18] *See* Colleen Cunningham, Florian Ederer, & Song Ma, *Killer Acquisitions*, 3 Journal of Political Economy 649 (Mar. 2021).

[19] *See* International Center for Law & Economics, ICLE Final Report on FTC Hearings on Competition & Consumer Protection in the 21st Century: The Weakness of Interventionist Claims (June 2019), https://laweconcenter.org/wp-content/uploads/2019/07/Concluding-Comments-The-Weaknesses-of-Interventionist-Claims-FTC-Hearings-ICLE-Comment-11.pdf.

[20] *See* Jason L. Alberg, *"Killer Acquisitions" in the Pharmaceutical Industry*, Economists Ink 2 (Summer 2021), https://ei.com/economists-ink/summer-2021/killer-acquisitions-in-the-pharmaceutical-industry/.

[21] *See* Amy C. Madl, *Killing Innovation?: Antitrust Implications of Killer Acquisitions*, Yale Journal on Regulation Online Bulletin 28, 31 (Sept. 2020), https://www.yalejreg.com/bulletin/killing-innovation-antitrust-implications-of-killer-acquisitions/.

[22] U.S. DOJ & FTC, Horizontal Merger Guidelines (Aug. 2010), https://www.justice.gov/atr/merger-enforcement; European Comm'n, Guidelines on the Assessment of Horizontal Mergers Under the Council Regulation on the Control of Concentrations Between Undertakings (2004), https://eur-lex.europa.eu/legal-content/EN/ALL/?uri=CELEX%3A52004XC02

05%2802%29; Competition & Markets Authority, Merger Assessment Guidelines (Mar. 2021), https://assets.publishing.service.gov.uk/government/uploads/system/uploads/attachment_data/file/986475/MAGs_for_publication_2021_-.pdf.

[23] Competition & Markets Authority, Anticipated Acquisition by Sabre Corporation of Farelogix Inc.—Final Report (2020), ¶ 11.130, https://assets.publishing.service.gov.uk/media/5e8f17e4d3bf7f4120cb1881/Final_Report_-_Sabre_Farelogix.pdf.

[24] United States v. Sabre Corp., No. 19-1548-LPS, slip op. ¶¶ 272–78 (D. Del. Apr. 7, 2020) (Stark, J.), https://www.ded.uscourts.gov/sites/ded/files/opinions/19-1548_0.pdf.

[25] DOJ, Applied Materials Inc. and Tokyo Electron Ltd. Abandon Merger Plans After Justice Department Rejected Their Proposed Remedy, https://www.justice.gov/opa/pr/applied-materials-inc-and-tokyo-electron-ltd-abandon-merger-plans-after-justice-department.

[26] Bundeskartellamt [Federal Cartel Office], Nov. 12, 2014, B5-138/13, ¶ 330 (Beschluss in dem Verwaltungsverfahren) [Administrative Procedures Decision], https://www.bundeskartellamt.de/SharedDocs/Entscheidung/DE/Entscheidungen/Fusionskontrolle/2014/B5-138-13.pdf?__blob=publicationFile&v=2.

[27] *Id*.

[28] *See* Robin Kleer & Marcus Wagner, *Acquisition through innovation tournaments in high-tech industries: a comparative perspective,* Economics of Innovation and New Technology, 22(1), 73-97 (2013).

[29] *See* Patricia Lorenzo & Nadine Watson, *Impact on Industry Innovation of a Merger Between Close Competitors*, Law & Economics, Concurrences No. 1-2019, ¶ 43, (Febr. 2019) https://www.concurrences.com/IMG/pdf/_04.concurrences_1-2019_law_economics_lorenzo-watson-2.pdf?47959/0a5372bb70ddcd4ef3de96c455f827d3b0c2d09d (“*Post-merger the number of patents in the deodorant market increased by 21%. Over the same period, the number of patents in the hair conditioner market declined by 62%.*”).

[30] Anna Rita Bennato et al., University of East Anglia, Centre for Competition Policy, *Mergers and innovation: Evidence from the Hard Disk Drive market*, CCP Working Paper 2018-04v3 (June 2020), https://papers.ssrn.com/sol3/papers.cfm?abstract_id=3190156; Peter Ormosi et al., European Comm’n, Feasibility Study on the Microeconomic Impact of Enforcement of Competition Policies on Innovation—Final Report (2017), https://ec.europa.eu/competition/publications/reports/kd0417860enn.pdf.

[31] Bennato et al., *supra* note 30, at p. 35.

[32] U.S. DOJ & FTC, Horizontal Merger Guidelines (Aug. 2010), https://www.justice.gov/atr/merger-enforcement.

[33] FTC has only required a remedy with regard to FDA Phase III Pipeline products, but it may consider earlier-stage pipeline products. *See also* CIBA-Geigy Ltd., No. C-3725 (FTC Apr. 8, 1997) (final consent order), https://www.ftc.gov/sites/default/files/documents/cases/1997/04/c3725.do.pdf.

[34] Ciba-Geigy Ltd., No. C-3725, at. 5 (FTC Apr. 8, 1997) (complaint), https://www.ftc.gov/sites/default/files/documents/cases/1997/04/c3725cmp.pdf.

[35] Ciba-Geigy Ltd., No. C-3725, at 1 (FTC Apr. 8, 1997) (separate statement of Chairman Robert Pitofsky, and Commissioners Janet D. Steiger, Roscoe B. Starek, III, and Christine A. Varney), https://www.ftc.gov/system/files/documents/public_statements/417011/970408cibastmt.pdf.

[36] FTC, *Statement of Chairman Timothy J. Muris (FTC) in the Matter of Genzyme Corporation/Novazyme Pharmaceuticals, Inc.*, at 17, https://www.ftc.gov/system/files/attachments/press-releases/ftc-closes-its-investigation-genzyme-corporations-2001-acquisition-novazyme-pharmaceuticals-inc./murisgenzymestmt.pdf; *see also* FTC, *FTC Closes its Investigation of Genzyme Corporation’s 2001 Acquisition of Novazyme Pharmaceuticals, Inc.* (Jan. 13, 2004), https://www.ftc.gov/news-events/press-releases/2004/01/ftc-closes-its-investigation-genzyme-corporations-2001.

[37] Recently, Caroline Holland, attorney adviser to Acting FTC Chair Rebecca Kelly Slaughter, signaled that enforcers can’t be “bound by the past” on potential theories of harm. Jenna Ebersole, *Enforcers Shouldn’t be ‘Bound by Past’ on Theories of Merger Harm, US FTC Official Says in Pharma Discussion*, MLex (Apr. 16, 2021), https://content.mlex.com/#/content/1284495.

[38] FTC, *Statement of Commissioner Rohit Chopra Joined by Commissioner Rebecca Kelly Slaughter, Pfizer Inc./Mylan N.V.*, Comm’n File No. 1910182, at 5 (Oct. 30, 2020), https://www.ftc.gov/system/files/documents/public_statements/1582382/191_0182_pfizer-mylan_-_dissenting_statement_of_commrs_chopra_and_slaughter_1.pdf.

[39] FTC, *Dissenting Statement of Commissioner Rohit Chopra, AbbVie, Inc./Allergan plc*, Comm’n File No. 1910169, at 17-18 (May 5, 2020), https://www.ftc.gov/system/files/documents/public_statements/1574583/191-0169_dissenting_statement_of_commissioner_rohit_chopra_in_the_matter_of_abbvie-allergan_redacted.pdf.

[40] FTC, Dissenting Statement of Commissioner Rohit Chopra, Bristol-Myers Squibb/Celgene, Comm’n File No. 1910061, at 3 (Nov. 15, 2019), https://www.ftc.gov/system/files/documents/public_statements/1554293/dissenting_statement_of_commissioner_chopra_in_the_matter_of_bristol-myers-celgene_1910061.pdf.

[41] European Comm’n, *Competition Enforcement in the Pharmaceutical Sector* (2009-2017), Report from the Commission to the Council and the European Parliament, 30 (2019), https://ec.europa.eu/competition/publications/reports/kd0718081enn.pdf.

[42] Case M.7559, Pfizer/Hospira, Comm’n Decision, ¶¶ 292–299 (Aug. 4, 2015), https://ec.europa.eu/competition/mergers/cases/decisions/m7559_20150804_20212_4504355_EN.pdf.

[43] Case M.7275, Novartis/GlaxoSmithKline Oncology Business, Comm’n Decision, ¶ 89 (Jan. 28, 2015), https://ec.europa.eu/competition/mergers/cases/decisions/m7275_20150128_20212_4158734_EN.pdf.

[44] Case M.7932, Dow/DuPont, *supra* note 12.

[45] In Case M.7326, Medtronic/Covidien, Comm’n Decision, (Nov. 28, 2014), https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX%3A32014M7326&qid=1629322436468, there was similar analysis of the pipeline product of Covidien, Stellarex, in Phase III clinical trials, but the prospect of a successful entry was uncertain because of the lack of sufficient clinical data on efficacy. The EC reached the conclusion that Covidien’s pipeline product constituted a credible potential competitor capable of exerting an important constraint, despite very limited feedback from physicians.

[46] Case M.7275, Novartis/GlaxoSmithKline Oncology Business, *supra* note 43, ¶ 91.

[47] *Id. ¶¶* 104-114.

[48] Case M.7932, Dow/DuPont, *supra* note 12.

[49] *Id.* ¶¶ 2363, 3015–3264.

[50] *Id.* ¶ 3025.

[51] *Id.* ¶ 338–348.

[52] Case M.8084, Bayer/Monsanto, Comm’n Decision, ¶¶ 1273, 3320-3322 (Mar. 21, 2018) (Summary at 2018 O.J. C 459), https://eur-lex.europa.eu/legal-content/EN/TXT/HTML/?uri=CELEX:52018M8084(02)&from=EN).

[53] Case M.9461, AbbVie/Allergan, Comm’n Decision, ¶ 19(b), (Jan. 10, 2020), https://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:32020M9461&qid=1629322733002&from=EN.

[54] Case M.9554, Elanco Animal Health/Bayer Animal Health Division, Comm’n Decision, n.118 (June 8, 2020), https://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:32020M9554&qid=1629317265061&from=EN; Case M.7932, Dow/DuPont, *supra* note 12, ¶¶ 272-302; Case M.8084, Bayer/Monsanto, *supra* note 52, ¶¶ 48-54; Case M.9294, BMS/Celgene, Comm’n Decision, ¶ 22 (July 29, 2019), https://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX-:32019M9294&qid=1629321380526&from=EN; Case M.9461, AbbVie/Allergan *supra* note 53, ¶ 19.

[55] European Comm’n, Commission Guidance on the Application of the Referral Mechanism Set Out in Article 22 of the Merger Regulation to Certain Categories of Cases, 1959 C(2021) final 26.3.2021, https://ec.europa.eu/competition/consultations/2021_merger_control/guidance_article_22_referrals.pdf.

[56] *Id.* ¶¶ 9-10.

[57] Illumina/PacBio, CMA, Provisional Findings Report, ¶ 8.334 (Oct. 24, 2019), https://assets.publishing.service.gov.uk/media/5db1b98a40f0b609ba817d38/Illumina_Pacbio_-_ProvFindings.pdf.

[58] *Id.* ¶¶ 7.44–7.47.

[59] Case ME/6831/19, CMA, Decision on Relevant Merger Situation and Substantial Lessening of Competition, ¶¶ 134, 142, 225, 226 (Dec. 16, 2019), https://assets.publishing.service.gov.uk/media/5e3d7c0240f0b6090c63abc8/2020207_-_Roche_Spark_-_non-confidential_Redacted-.pdf.

[60] CMA, *supra* note 22.

[61] *Id.* ¶ 5.23.

[62] *Id.* ¶ 5.21.

[63] Case M.9461, AbbVie/Allergan, *supra* note 53, ¶ 19; Case M.9294, BMS/Celgene, *supra* note 54, ¶ 22; Case M.9554, Elanco Animal Health/Bayer Animal Health Division, *supra* note 54, ¶¶ 36, 152, 315–321.

[64] Case M.9294, BMS/Celgene, *supra* note 54, at n.28.

[65] Case M.7932, Dow/DuPont, *supra* note 12, ¶ 389; Case M.8084, Bayer/Monsanto, *supra* note 52, at 2018.

[66] Case M.8297, GE/Baker Hughes, Comm'n Decision, 2017, https://ec.europa.eu/competition/mergers/cases/decisions/m8297_1485_3.pdf.

[67] A wide range of papers refer to the weakness of patent numbers in measuring the level of innovation. For a review, *see* Richard Gilbert, *Looking for Mr. Schumpeter: Where Are We in the Competition– Innovation Debate?,* Innovation Policy and the Economy 159, 159-215 (2006).

[68] CMA, Completed acquisition by PayPal Holdings, Inc. of iZettle AB Final Report, ¶ 11 (June 2019), https://assets.publishing.service.gov.uk/media/5cffa74440f0b609601d0ffc/PP_iZ_final_report.pdf

[69] *Id.* ¶ 4.14.

[70] Case T-79/12, Cisco Systems and Messagenet v Commission, (December 11, 2013), ECLI:EU:T:2013:635, ¶ 93. The EC merger control powers "*do not enable it, however, to speculate on the price of an acquisition or to substitute its point of view on the value of a transaction for that of the parties concerned, particularly as the reasons underlying that transaction cannot always be explained by purely economic rationale.*"

[71] Case ME/6831/19, CMA, Decision on Relevant Merger Situation and Substantial Lessening of Competition, *supra note 59*, ¶¶ 43.

[72] Case M.7932, Dow/DuPont, *supra* note 12, ¶¶3061-3224.

[73] Case T-691/14, Servier and Others v Commission, ECLI:EU:T:2018:922, (December 12, 2018), ¶¶ 1468-1473.

[74] *See* Jeff Montgomery, *United Exec Brands Sabre-Farelogix Deal Antitrust 'Nightmare'*, Law360 (Jan. 27, 2020), https://www.law360.com/articles/1238048.

[75] Complaint in the Matter of Steris Corporation and Synergy Health PLC, FTC File No. 1510032 (May 28, 2015), https://www.ftc.gov/system/files/documents/cases/150529sterissynergypart3cmpt.pdf.

[76] Case M.7932, Dow/DuPont, *supra* note 12, ¶¶3217.

[77] Illumina/PacBio, *supra* note 57.

[78] CMA, Anticipated acquisition by Amazon of a minority shareholding and certain rights in Deliveroo Final Report, ¶¶ 32, 59 (Aug. 4, 2020), https://assets.publishing.service.gov.uk/media/5f297aa18fa8f57ac287c118/Final_report_pdf_a_version_—.pdf.

[79] Case ME/6897/20, CMA, Anticipated acquisition by Adevinta ASA of eBay Classifieds Group from eBay Inc., and eBay Inc.'s acquisition of a minority stake in Adevinta ASA, Decision on relevant merger situation and substantial lessening of competition, ¶¶ 6, 17 (Feb. 2021), https://assets.publishing.service.gov.uk/media/606de119d3bf7f401046b6ae/210216_-_Adevinta-eCG-eBay_-_FINAL_-_Official-Sensitive_.pdf. "*The CMA considered that the appropriate counterfactual against which to assess the competitive effects of the Merger is the sale by eBay of eCG to an alternative purchaser that does not have overlapping UK activities, which would result in an independent eCG in the UK going forward.*"; "*As noted above, under the more competitive counterfactual that the CMA considers to be applicable, eBay would not control Gumtree. Under the counterfactual, therefore, both Shpock and Gumtree would be free to compete with eBay Marketplace. […] Overall, this suggests that Gumtree in particular has significant potential to constrain eBay Marketplace.*"

[80] Case M.4737, Sabic/GE Plastics, Comm'n Decision, ¶¶ 26, 29 (Feb. 8, 2007) (Summary at 2007 OJ (C 249)), https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX%3A32007M4737&qid=1628672152979; Case M.4402, UCB/Schwarz Pharma, Comm'n Decision, ¶ 11 (2006); Case M.1846, Glaxo Wellcome/Smithkline Beecham, Comm'n Decision, 2000 OJ (C 170) ¶¶ 70, 190, https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX%3A32000M1846&qid=1628672699459.

[81] Case T-399/16, CK Telecoms UK Investments Ltd v. European Commission, EU:T:2020:217, ¶ 111 (May 28, 2020); *see also* Case C12/03 P, Commission v. Tetra Laval, EU:C:2005:87, ¶ 44 (Feb. 15, 2005) ("*That being so, the quality of the evidence produced by the Commission in order to establish that it is necessary to adopt a decision declaring the concentration incompatible with the common market is particularly important, since that evidence must support the Commission's conclusion that, if such a decision were not adopted, the economic development envisaged by it would be plausible.*").

[82] Takeda, *European Commission Releases Takeda from Commitment to Divest Shire's Pipeline Compound SHP647* (May 29, 2020), https://www.takeda.com/newsroom/newsreleases/2020/european-commission-releases-takeda-from-commitment-to-divest--shires-pipeline-compound-shp647/#:~:text=Osaka%2C%20JAPAN%2C%20May%2029%2C,commitment%20that%20was%20provided%20by.

[83] Case M.7275, Novartis/GlaxoSmithKline Oncology Business, *supra* note 43, ¶¶ 283- 314.

[84] CMA, Anticipated acquisition by Illumina, Inc. of Pacific Biosciences of California, Inc., Notice of possible remedies under Rule 12 of the CMA's rules of procedure for merger, market and special reference groups, (Oct. 24, 2019), https://assets.publishing.service.gov.uk/media/5db02682e5274a090e1458a4/Illumina_Pacbio_-_Remedies_Notice.pdf. ¶ 24-33.

[85] Case M.9554, Elanco Animal Health/Bayer Animal Health Division, *supra* note 54, ¶¶ 331-339.

[86] Ciba-Geigy Ltd, No. C-3725 (FTC Apr. 8, 1997) (complaint), https://www.ftc.gov/sites/default/files/documents/cases/1997/04/c3725cmp.pdf.

[87] Case M.7932, Dow/DuPont, *supra* note 12, ¶ 2363.

[88] FTC, *FTC Requires Bristol-Myers Squibb Company and Celgene Corporation to Divest Psoriasis Drug Otezla as a Condition of Acquisition, Otezla divestiture largest ever in a merger enforcement case* (Nov. 15, 2019), https://www.ftc.gov/news-events/press-releases/2019/11/ftc-requires-bristol-myers-squibb-company-celgene-corporation.

[89] AbbVie, Inc./Allergan plc, Comm'n File No. 1910169 (May 5, 2020), https://www.ftc.gov/enforcement/cases-proceedings/191-0169/abbvie-inc-allergan-plc-matter.

[90] *Id.*

[91] FTC, Dissenting Statement of Commissioner Rohit Chopra, AbbVie, Inc./Allergan plc, Comm'n File No. 1910169, at 9 (May 5, 2020), https://www.ftc.gov/system/files/documents/public_statements/1574583/191-0169_dissenting_statement_of_commissioner_rohit_chopra_in_the_matter_of_abbvie-allergan_redacted.pdf.

[92] Many consultation respondents to the FTC's press release highlight the importance of innovation in this industry, observe significant changes are not warranted, and stress the need for clear rules. FTC, *Multilateral Pharmaceutical Merger Task Force Seeks Public Input* (May 10, 2021), Document FTC-2021-0025-0001, https://www.regulations.gov/document/FTC-2021-0025-0001.

[93] EC Chief Economist, Pierre Régibeau said, "*as competition authorities get tougher on predicted price increase . . . , they are required to be honestly open to the merging companies' efficiencies claims*" (i.e., efficiencies specific to the merger under review). Further, US FTC chief economist, Andrew Sweeting recommended that "*merging companies claim efficiencies up front, not after [the FTC] has stated its estimate of anticompetitive effects; and that they be clear about when efficiencies will reduce*

marginal or variable costs, rather than a fixed cost." Pallavi Guniganti, *DG Comp Top Economist: Zero-Price can be Special and Efficiencies Credible*, GCR (Feb. 10, 2020), https://globalcompetitionreview.com/dg-comp-top-economist-zero-price-can-be-special-and-efficiencies-credible.

[94] Jacques Crémer, Yves-Alexandre de Montjoye & Heike Schweitze, *Competition Policy for the Digital Era, Final Report*, 35 (2019), https://ec.europa.eu/competition/publications/reports/kd0419345enn.pdf. (Contrasting the different nature of innovation in pharmaceuticals and the IT sector).

[95] Review periods are already long, with many Phase I cases in the pharmaceutical sector taking (including pre-notification) seven or more months in the EU, and cases dealing with innovation theories of harm, such as *Dow/Dupont* in the EU, taking more than sixteen months (including pre-notification) until clearance. Long review periods divert resources and delay realizing merger benefits that would otherwise be employed in R&D or meeting patient needs.