GCR NEWS

More aggressive scrutiny of life science deals – but is there a problem that needs solving?

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Competition authorities on either side of the Atlantic and beyond are signalling greater scrutiny of pharmaceutical mergers, with a view to protecting innovation. Baker McKenzie attorneys ***Fiona Carlin****,* ***Anthony Gamble****,* ***Dan Graulich*** *and* ***Yana Ermak*** *consider the justifications for this tougher approach and explore the potential chilling effect it might have.*

In March 2021, the US Federal Trade Commission proclaimed the need for tougher scrutiny of pharmaceutical mergers, announcing the formation of a dedicated multilateral merger task force comprising it, the Department of Justice and multiple state attorneys general, together with Canada's Competition Bureau, the

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European Commission and the UK's Competition and Markets Authority. One year on, the task force has yet to reveal its cards. Although the focus is on pharmaceutical transactions, the underlying concerns extend to other sectors of the economy, including medical devices and tech markets more generally. The main triggers have been a variety of macro-economic and political concerns about market concentration levels, increasing healthcare costs aggravated by the pandemic, specific instances of bad behaviour as epitomised by convicted felon, Martin Shkreli, and broader systemic failures across the US healthcare system.

Much of the debate has focused on the ability of merger control laws to identify and prevent so-called “killer acquisitions” – transactions that have as their object or effect the discontinuation of overlapping R&D projects. But the debate is widening to include acquisitions in a broader economic sense, including perceived attempts to circumvent merger control by structuring transactions as patent acquisitions or exclusive patent licensing.

President Biden’s *Executive Order on Competition in the American Economy* in July 2021 called for a “whole of government” response to the rising power of large corporations, including closer scrutiny of “serial mergers” and the acquisition of “nascent competitors”. The new German coalition government also flagged in its manifesto that it will encourage European level measures to prevent strategic acquisitions of potential competitors that hinder innovation. Protecting innovation and inclusive growth has become a common cause.

Yet, ironically, pharmaceutical innovation is thriving, thanks to rapid advances in cell and gene technologies and other scientific breakthroughs – as the rapid development of Covid-19 vaccines amply demonstrate. It was a record breaking year in 2020 for investment according to IQVIA’s Report on Global Trends in R&D (2021), with total spend and output each at record levels – and innovation activity highly dispersed across a wide ecosystem. There

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are an estimated 9,000 products in the pipeline, an expansion of more than 40% since 2015.

More recent industry data show a one-third decline in the number of biopharmaceutical deals in 2021 compared to 2020 despite a banner year for M&A generally. Headlines attributing that decline to threats of increased regulatory deal scrutiny are premature, but they are a reminder that competition authorities should be wary of the potential chilling effects of their pronouncements across dynamic sectors of the economy.

There is no compelling evidence that current merger control laws and analytical tools are not up to the task of preserving competition and innovation. Predictions as to the death of megadeals and a waning appetite for smaller acquisitions of innovative start-ups are overly pessimistic. Nonetheless, for the foreseeable future, companies both large and small must plan for increased deal uncertainty and be ready to clearly articulate the pro-competitive factors driving their investment, development and acquisition decisions.

“Given the high volume of these mergers that we’re seeing, skyrocketing drug prices and ongoing concerns about anticompetitive conduct in the pharma industry, it’s imperative that we rethink our approach towards pharmaceutical merger review… We need to ensure that our investigations fully capture the potential impact on prices, quality, access, drug supply chain resilience, capital market investment, and innovation for new drugs…”

— FTC acting chair Rebecca Kelly Slaughter, 16 March 2021

Increased political attention

An IMF staff working paper penned in March 2021 triggered a high level political debate on the correlation between market consolidation and rising mark-ups and profits on the one hand, and declining business dynamism on the other. But the picture is

nuanced. A policy brief by the European Commission in November 2021 concluded that increasing concentration and profit trends merit continued vigorous enforcement, but recognised that even the most disaggregated industry definitions are typically larger than relevant antitrust markets. Others argue that, despite a rise in industry concentration, product market concentration has been decreasing.

A number of studies posit that mergers in research-intensive sectors not only reduce the merged entities' innovation efforts, but also negatively impact rivals' innovation spend and efforts. The study by Colleen Cunningham, Florian Ederer and Song Ma has attracted most attention by coining the term "killer acquisitions". After analysing 16,000 drug development projects over a 25 year period, it estimated that between 5.3% and 7.4% of pharmaceutical acquisitions were designed to eradicate a potential future competitive threat, noting that the phenomenon was most pronounced when deal value was priced just below the US Hart-Scott-Rodino merger filing threshold. The authors concluded that projects were 23.4% less likely to be continued where the parties' activities overlapped, with a 20.7% lower development probability compared to projects where the acquirer had no overlap.

This has spawned a new lexicon: "hard" killers, where the target is shut down with no or negative synergies; "soft" killers, where the target is shut down with limited synergies accruing to the acquirer; "reverse" killers, where the target's projects are continued but the acquirer's projects and products are eliminated; and "nascent" acquisitions of early stage research that are a speculative future threat, but where regulators do not have enough empirical evidence to substantiate a "killer" theory of harm.

Other commentators recognise that whilst killer acquisitions are a valid concern, their likely prevalence does not justify over-enforcement or changes to the law. Perhaps the clearest example that the rules work is the FTC's intervention in 2017 to claim $100 million in restitution and disgorgement after Questcor Pharmaceuticals acquired in 2013 the US rights to Synacthen, a new

drug that threatened its US monopoly for a certain class of specialty drug used to treat infantile spasms. Competing unsuccessful bidders had planned to develop Synacthen to compete against Questcor at a significantly lower price. The FTC found that Questcor had increased prices of its product from $40 per vial in 2001 to $34,000 in 2017, an increase of 85,000%. Such conduct is regrettable but not sufficiently common to merit any radical departure from the existing rule-book. In addition to paying the restitution, Questcor's new owner, Mallinckrodt, was required to license Synacthen to another company in order to promote competition and protect against future abuse. Past studies have found that large pharmaceutical mergers are associated with statistically significant increases in R&D productivity pointing to depth of scientific information and objectivity of decision-making based on that information as instrumental factors, both of which could be expected to increase because of a merger. A more recent study on the dynamic merger effects on R&D spend and drug development provides more empirical evidence of M&A being broadly positive.

Yet another study for the European Commission on the impact of M&A on innovation in the pharmaceutical sector somewhat tentatively concluded that acquisitions have mixed effects on average and suggested that deal rationale can impact innovation. Nonetheless, it and other papers urge competition authorities to be bold. They urge agencies to proactively track the industry press; to improve the data relied on; to assess whether new thresholds and investigative tools are required; and to push the boundaries of the legal tests and burden of proof constraints rather than defaulting to caution and inaction where evidence is uncertain.
“When faced with uncertainty, it is therefore important that competition agencies are willing to challenge the presumption often promoted by merging firms and their advisers that mergers are generally efficiency-enhancing and should only be restrained where there is certainty that serious detriment will result.”

— Joint statement by the Australian Competition and Consumer Commission, the CMA and Germany’s Federal Cartel Office, April 2021

Fanning the flames

At the centre of the debate on both sides of the Atlantic, is the pending and controversial *Illumina/Grail* case, which involves neither pharmaceuticals nor a killer theory of harm, but that seems to have innovation concerns at its core.
The FTC challenged the deal in March 2021 on the basis that Illumina could engage in vertical input foreclosure strategies, blocking future potential Grail competitors from accessing Illumina's next generation sequencing system. The challenge proceeded despite Illumina making an irrevocable offer to continue supplying genomic sequencing platforms to other companies developing their own cancer screening tests post-transaction. This is an example of the FTC following the EU's footsteps in terms of its willingness to challenge deals involving early stage products and in taking a tougher approach to suitable remedies. The US litigation is still pending.

In April 2021, the European Commission controversially asserted jurisdiction despite the deal not triggering notifications anywhere in the EU. In a policy U-turn, the commission encouraged national competition authorities to refer the case to it on the basis of Article 22 of the EU Merger Regulation, which allows cases to be referred that are likely to affect trade within the EU single market and that threaten to significantly affect competition within the territory of the state making the referral. The French and Italian competition authorities obliged with a referral request followed by those in Belgium, Greece, Iceland, the Netherlands and Norway. At least some national authorities were reluctant to join, querying whether they were empowered to refer a case to Brussels where their domestic merger control laws did not confer jurisdiction on them in the first place.

Illumina's challenges to the abrupt change in policy before the French and Dutch courts were unsuccessful. An appeal to the EU General Court is pending on the question of whether the commission has legitimate jurisdiction to review the case.

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Adding fuel to the fire, Illumina controversially proceeded to close the deal, an aggressive move that immediately triggered EU infringement proceedings for gun-jumping that are likely to result in a fine as high as 10% of Illumina's worldwide revenues. Interim orders require Illumina to hold the Grail business separate until the commission concludes its assessment. Whilst Illumina has offered behavioural commitments to obtain approval, it is unclear whether these will suffice and the deal may yet be abandoned.

Stronger, Together… the Multilateral Pharmaceutical Merger Task Force

The avowed goal of the multilateral pharmaceutical merger task force is to enhance deal scrutiny by developing more detailed and aligned analytical approaches and expanded and refreshed theories of harm. Their first step was to launch a public consultation inviting responses to seven questions.

1. What theories of harm should enforcement agencies consider when evaluating pharmaceutical mergers, including theories of harm beyond those currently considered?

2. What is the full range of a pharmaceutical merger's effects on innovation? What challenges arise when mergers involve proprietary drug discovery and manufacturing platforms?

3. In pharmaceutical merger review, how should we consider the risks or effects of conduct such as price setting practices, reverse payments, and other ways in which pharmaceutical companies respond to or rely on regulatory processes?

4. How should we approach market definition in pharmaceutical mergers, and how is that implicated by new or evolving theories of harm?

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5. What evidence may be relevant or necessary to assess, and if applicable, challenge a pharmaceutical merger based on any new or expanded theories of harm?

6. What types of remedies would work in the cases to which those theories are applied?

7. What factors, such as the scope of assets and characteristics of divestiture buyers, influence the likelihood and success of pharmaceutical divestitures to resolve competitive concerns?

Out of 45 responses from industry, think tanks, other competition agencies and academics, a handful provide neutral observations, with the remainder more or less evenly split between the view that the current tools suffice versus the need for more radical intervention. Many in the interventionist camp are motivated by market failures across the US healthcare system, problems that require specific regulatory solutions rather than stricter merger control enforcement.
What form any merger task force roadmap will take following the consultation remains to be seen - there has been no follow-up as yet to the consultation exercise – but a reshaping of the regulatory landscape can be discerned from developments in the participating jurisdictions.

Testing the boundaries

Brussels

The European Commission's Directorate-General for Competition is a key part of the larger EU policy machine that is pursuing a broad policy reform agenda to promote a fairer, greener more resilient European economy.

To bolster its position after boldly asserting jurisdiction in *Illumina/Grail*, the Commission issued new guidance on Article 22

referrals in April 2021. Henceforth, it will permit the referral of transactions to it, even if the deal falls below national filing thresholds, and even if the deal has since closed. Although this policy shift is not sector-specific, the commission has made clear that likely candidate deals for referrals will focus on the pharmaceutical, biotech and technology sectors, broadly targeting: acquisitions of start-ups or recent market entrants with significant competitive potential that have yet to generate any revenues; innovators conducting potentially important research; and any entity that constitutes an actual or potential important competitive force. This new approach creates deal uncertainty in terms of both procedure and substance.

Procedural uncertainty stems from the ability of any national authority to make a referral request within 15 working days from the date on which the transaction is "made known to it", which is interpreted rather open-endedly as "implying sufficient information to make a preliminary assessment" as to the deal's likely effects on trade and competition in the EU single market.

The bar was already low in relation to the commission's ability to intervene substantively. It traditionally focused on market-to-pipeline or pipeline-to-pipeline overlaps in late stage development close to launch, such as in *Covidien/Medtronic* in 2014, but soon began asking for data on early stage pipeline products. In *Novartis/GSK Oncology* in 2015, it recognised that early pipeline products face higher uncertainty as to their future clinical use than products at more advanced stages, but nonetheless concluded that "whatever the level of uncertainty might be, a reduction in the efforts invested to bring forward a clinical research program can reasonably be expected to reduce its probability of success".
The commission went further in *Dow/DuPont* in 2017, examining the parties' incentives to continue overlapping lines of basic research in "innovation spaces not markets". It relied on a broad set of indicators: the merging parties' relative R&D spend; R&D headcount; sophistication of research facilities; citation-weighted patent shares; internal documents; and even an observed relationship between

past consolidation and innovation levels in the sector. This far-reaching approach was also deployed in *Bayer/Monsanto* in 2018, generating considerable controversy at the time, but the approach has not been widely replicated in subsequent cases.
In more recent decisions, such as *BMS/Celgene* and *AbbVie/Allergan*, the commission did not identify any specific harm to overall levels of innovation given the large number of R&D organisations competing at global level in fields such as autoimmune diseases, fibrotic diseases and oncology. It declined to look in-depth at overlap products at early stages of development where there were a large number of potential competitors, recognising that they were many years away from a hypothetical and highly uncertain launch on the market. In the animal health sector, it found that innovation barriers to entry are high, but concluded that Elanco's acquisition of Bayer's animal health division would not harm innovation, since three other large players spent more on R&D than the parties, Bayer had not been an active innovator for some time, and medium-sized companies were able to develop new products including through partnerships with third parties.

Innovation is now firmly part of the mainstream merger analysis in a framework that specifically looks at: potential competition between existing and pipeline products, or between pipeline products at an advanced development stage (Phase II or III clinical trials); innovation competition, where there is a risk of discontinuation, delay or redirection of overlapping pipeline products (including those at an early stage); and innovation competition in terms of the risk of a structural reduction of the overall level of competition in "innovation spaces".

Since the new approach to Article 22 referrals effectively allows the commission to cherry-pick any transaction it chooses without the need to legislate to introduce a deal-value or other triggering threshold, the outcome of the *Illumina/Grail* appeal on the referral policy's legitimacy is eagerly awaited. The commission appears confident that it will prevail. In the interim, it has refrained from widespread recourse to referrals based on innovation concerns.

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It is however in the process of awarding a €500,000 tender for a study on killer acquisitions in the pharmaceutical sector to be completed by the end of 2023. The study is intended to enable the authorities to detect the most suitable referral candidates by identifying past discontinuations of overlapping R&D projects that were likely caused by a previous acquisition rather than by intrinsic technical or commercial reasons. The authors will study not just deals that fall within the EU Merger Regulation, but acquisitions in the wider economic sense, including collaborative – or non-full function – joint ventures, IP acquisitions and licensing deals.

The economic studies referred to above, and recent experience from regulators in Europe that have expanded their toolbox to review acquisitions of start-ups based on deal value, suggest that there is little evidence to justify any radical new approach. Since 2017, Germany has had a requirement to notify the acquisitions of nascent companies where deal value exceeds €400 million provided the target has sufficient nexus in Germany. Austria enacted a similar system with a lower threshold. These changes have triggered a handful of notifications annually but have not as yet unearthed a single instance of a "killer acquisition".

Nonetheless, the new commission study will no doubt contribute to a continued reflection on the adequacy of the competition rules in tackling innovation theories of harm, including the question of whether acquisitions of IP assets can be brought within the scope of the EU merger rules. The study will no doubt influence the reflections of the multilateral phamaceutical merger task force and other agencies around the globe. The implications could potentially be far-reaching.

EU study on killer acquisitions in the pharmaceutical sector: verbatim research questions

1. Which publicly available data would allow the Commission to determine in practice whether a given acquisition has led or might

lead to the discontinuation of significant competing drug R&D projects?

a) What data would be best suited to assess the status of drug R&D projects before and after the acquisition?

b) What data would be best suited to determine the patent status of the drug R&D project?

c) What data would be best suited to assess the potential effects of the acquisition on innovation competition?

d) What open-source intelligence (OSINT) data and tools would be best suited to determine the merging parties' objectives in terms of the development of competing drug R&D projects: official company filings, investor presentations, clinical trial database, trade press, scientific publications, LinkedIn profiles of researchers, etc.?

e) How best to exploit and combine the information obtained from the above data sources, in order to identify past 'killer acquisitions' or determine whether a recently announced acquisition risks being a 'killer acquisition' and therefore deserves scrutiny?

2. On the basis of the investigative methods and data sources discussed under (Q1.) and with the benefit of hindsight regarding the discontinuation of drug R&D projects, which acquisitions in the pharmaceutical industry between 2014 and 2018 most likely led to the discontinuation of one or more significant competing R&D projects (excluding projects that were terminated for objective, scientific reasons)?

3. What are the typical features of the acquisitions identified under (Q2.)?

a) What are typical features of the 'buyers' and their targets?

b) How to describe the typical situation in which a competing drug R&D project (either the target's or the acquirer's project) was discontinued likely because of the acquisition?

c) At what stage(s) in the R&D cycle do 'killer acquisitions' typically take place and at what stage(s) are the drug R&D projects discontinued?

d) What are typical modalities of 'killer acquisitions' (merger transactions within or outside of the scope of the EUMR, an acquisition of intellectual property or a licensing deal; options followed by an exercise of the option; other modalities)?

e) How do buyers and their targets typically communicate about such acquisitions to the public (if at all)? Is the absence of communication to shareholders or the public a possible indicator that the transaction may lead to the discontinuation of an R&D project?

4. In light of the answers to the previous questions, how widespread is the practice of such 'killer acquisitions' in the commercial reality of the pharma industry?

UK

Post-Brexit, and as part of its "Building Back Better" response to the Covid-19 pandemic, the UK government is consulting on wide-ranging reforms to domestic competition and consumer policy. Proposed changes to the merger control regime include a new jurisdictional threshold designed to catch transactions that may remove potential competition from a market, or that facilitate the leveraging of market power across different products or services. Pharmaceuticals and digital markets have been flagged as a high priority under the new regime.

Meanwhile, the CMA is taking an increasingly interventionist approach, positioning itself as one of the leading competition and consumer protection agencies, particularly since it now has jurisdiction to review transactions that would previously have been subject to the exclusive jurisdiction of the European Commission under the EU Merger Regulation "one-stop shop". It has sought to be at the cutting-edge of debates on emerging areas such as digital transactions, and has also entered into a number of co-operation arrangements with other leading authorities (including the multilateral pharmaceutical merger task force).

Reflecting the CMA's ambitions, there have been a number of material changes to its Merger Assessment Guidelines, and its jurisdictional and procedural guidance, over the past year. These changes give the CMA significantly more flexibility, placing less weight on traditional market shares and signaling a broader approach to protecting dynamic competition where the CMA may not be able to identify specific overlaps at the time of its assessment. In the Merger Assessment Guidelines, the CMA cites the example of two pharmaceutical companies engaging in research programmes likely to target the same illness even if they have no readily identifiable overlapping pipeline products in an approach reminiscent of the innovation theory of harm pursued in *Dow/DuPont*.

In *Facebook/Giphy*, the CMA went as far as stating that the elimination of a dynamic competitor that is making efforts towards entry or expansion may lead to concerns "even where entry by that entrant is unlikely and may ultimately be unsuccessful". This is a common occurrence in any pharmaceutical R&D market and the CMA's bold statement is indicative of the broad discretion the authorities are affording themselves to intervene in almost any deal. The CMA has also abandoned safe harbours, such as the rule of thumb that "five to four" mergers, or combined market shares below 40%, do not usually raise concerns. It will look to the internal documents of rivals to assess the likely strategies of the merging firms and the counter-strategies of competitors and customers. It

will closely scrutinise deal valuation evidence to identify explicit intent or economic incentives including financial models and assumptions, projections about future pricing, capacity or other relevant parameters. Outsized valuations will be viewed as an indicative of a strategy to acquire a rival based on reducing future competition.

The CMA's increasingly interventionist decisional practice is also apparent from its willingness to assert jurisdiction. The CMA may review any deal where: the target's annual UK turnover exceeds £70 million; or the merging parties supply or acquire 25% or more of any particular goods or services in the UK as a whole – or in a substantial part of it – where there is an increment as a result of the transaction. It has wide discretion in interpreting this "share of supply" test that is not to be confused with a market share test: the CMA is not required to ensure that the relevant market/segment used for its jurisdictional assessment corresponds to the product markets used for its substantive assessment.

The CMA is aggressively asserting jurisdiction over transactions that have little obvious nexus to the UK, or where there is no overlap in directly marketed products. This was illustrated in the December 2019 decision to call-in Roche's acquisition of Spark Therapeutics. Since Spark's products were still in clinical development, it did not generate any revenues in the UK. Nevertheless, the CMA asserted that Spark should be considered as active in the supply of prophylactic treatments for congenital haemophilia A in the UK based on its R&D activities since that is integral to the eventual supply of pharmaceutical products. It determined that the share of supply test was met as the parties had a combined share of supply of 40-50% with an increment of 5-10% based on the number of UK-based full-time equivalent employees engaged in activities relating to novel gene therapy and non-gene therapy haemophilia A treatments. It also considered that the share of supply test was met on the equally questionable basis of the parties' procurement of patents for haemophilia A in the UK. The CMA has been criticised for finding that R&D is equivalent to supply and for focussing on a very

narrow segment of “novel” treatments. The deal was ultimately cleared after a Phase I review because of the number of anticipated likely new market entrants.

With the government’s proposals for reform and the CMA’s recent changes to policy and enforcement practice, the UK regime will continue to be a source of uncertainty for deals in the pharmaceutical sector. Parties should assume that the CMA will find a way to assert jurisdiction even where there is little UK nexus. For transactions that are notified, or called-in by the CMA, parties are more likely to face novel theories of harm especially where innovation is a major consideration for the deal, and tougher scrutiny than in other jurisdictions where agencies are more constrained by the burden of proof placed upon them by their courts.

US

A host of pending antitrust legislative reforms – most recently from Senator Elizabeth Warren that seeks to allow the US agencies to block mergers valued at more than $5 billion without a preliminary injunction – may not survive this mid-term election year. But they are indicative of some level of bipartisan support to pursue antitrust reforms that will primarily target the pharmaceutical and tech sectors.

FTC chair Lina Khan and assistant attorney general Jonathan Kanter at the DOJ’s antitrust division have political backing to bolster enforcement. The Biden Administration's July 2021 Executive Order advocates for a “whole-of-government" approach to address overconcentration, monopolisation and unfair competition in the US economy. On the day the executive order was released, the FTC and DOJ announced that they would take a hard look to determine whether the existing federal merger guidelines are overly permissive and ensure that any revision guides enforcers to “review mergers with the skepticism the law demands.”

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The FTC has been active on the merger enforcement front. In August 2021, it announced it would begin sending pre-consummation warning letters for deals that it cannot "fully investigate" during the initial HSR waiting period. In September 2021, it rescinded the 2020 vertical merger guidelines and communicated in a blog post that it would seek to ensure that "merger reviews are more comprehensive and analytically rigorous" in sending second requests, looking more closely at a broader range of issues, including acquisitions of nascent competitors, impacts on labour markets, cross-market effects, and how the involvement of investment firms affect incentives to compete. In October 2021, the FTC voted to approve a statement that outlines situations in which it will seek "prior approval provisions" that require settling parties to seek prior review before making certain future transactions.

White House competition adviser Tim Wu has recently criticised prior policy that he says unduly favoured monopoly innovation – the notion that monopoly profits are necessary to fund research and innovation by incentivising start-ups by purchasing and incubating them, thereby allowing monopolies to extract too much of the proceeds of the US economy for themselves.

The agencies launched a formal review of the merger guidelines in January 2022.

Canada

Canada's Competition Bureau traditionally keeps pace with its international counterparts and has been increasingly vocal about the need to keep both large technology and pharmaceutical companies in check to ensure consumers are protected and smaller rivals are able to thrive. The Bureau's recent initiatives, including expanding its proactive intelligence gathering efforts to, among other things, increasingly review non-notifiable mergers, are reflective of its heightened enforcement focus in a number of areas, not the least of which is Canada's health sector.

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The Bureau has identified the pharmaceutical industry as a strategic priority and has been flexing its enforcement muscles in this sector. This coincides with the Bureau's extensive activity in unilateral conduct matters, primarily related to the abuse of dominance provisions. Like other agencies, the Bureau has conducted numerous investigations into pharmaceutical industry practices in recent years, including product hopping, reverse settlements, increased rebates to public and private insurers following generic market entry, free or near free supply of products to individuals and hospitals to inhibit biosimilar entry, and refusals to supply samples of brand name drugs to generic manufacturers to enable the bioequivalence testing required to receive regulatory approval. In addition to its participation in the multilateral pharmaceutical merger task force, it has been active in the merger space, imposing broad remedies in 2020 on the acquisition by Elanco of Bayer's animal health business in close cooperation with the FTC, the ACCC and the European Commission.

This activity signals the Bureau's sensitivity to concerns about market concentration levels whether or not arising from mergers. With the federal government's budget pledges in 2021 to enhance the Bureau's enforcement capacity and ensure it is equipped with the necessary digital tools for today's economy, there is every indication the Bureau will continue to proactively monitor both merger and unilateral activity in the pharmaceutical sector.

A need to tread cautiously

It is legitimate for competition authorities to preserve the potential for innovation in keeping markets contestable when reviewing acquisitions. But political debate about the high prices of medicines and other market failures conflates different issues and does not justify any radical departure from current merger enforcement standards.

The recent literature on macro-economic concentration levels is of little relevance to a sector characterised by large numbers of R&D

organisations competing globally in dynamic early stage innovation. The current rules are fit for purpose in allowing the authorities to challenge any occasional outliers.

With pipeline products close to market authorisation stage, the number of actual and potential competitors can readily be identified and remedies imposed where required. Second-guessing investments in early stage areas of overlap invites errors and may lead to sub-optimal resource allocation given the myriad complex scientific and commercial factors that influence decisions on whether to continue such high-risk investments. IQVIA notes that success rates remain low (less than 10% for vaccines, endocrinology, neurology and cardiovascular), and increased regulatory complexity in getting even viable products to market is a dauntingly specialised task. The synergies created by large pharmaceutical companies acquiring biotech start-ups or assets in what amounts to a highly specialised investment ecosystem are well-documented.

Deal valuation says little if anything about intent. Internal documents may provide insights, but one-off ambiguously worded or unhelpful statements should not be taken out of context. The fact is that sellers have multiple ways of contractually maximising the likelihood of their innovations being brought to market successfully, and this reality should be well understood.

Recent experience of deal value thresholds in Germany and Austria have identified no killer acquisitions in the pharmaceutical sector in the last five years. It is hoped that the pending EU study will be sufficiently robust to provide a reliable measure of the prevalence of this phenomenon so that any regulatory response is appropriately calibrated.

Novel theories of harm based on low-bar presumptions, reduced thresholds, or reversals of the burden of proof, would increase transaction costs and have chilling effects without improving consumer welfare. The sheer dynamism of innovation today is such that competition authorities should tread cautiously so as not to

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upset the balance of incentives that encourage high-risk investments into new pharmaceutical and technological innovations on which we all depend.

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