HIGHER SCHOOL OF ECONOMICS
NATIONAL RESEARCH UNIVERSITY

Björn Lundqvist

KILLER ACQUISITIONS AND OTHER FORMS OF ANTICOMPETITIVE COLLABORATIONS IN TIME OF CORONA

PART II

Working Paper WP22/2022/01
Series WP22
BRICS Competition Law and Policy Series

Moscow
2022

Editors of the Series WP22
"BRICS Competition Law and Policy Series"
A. Ivanov, E. Voinikanis, S. Avdasheva

Lundqvist, Björn.

Killer Acquisitions and Other Forms of Anticompetitive Collaborations in Time of Corona. Part 2 [Electronic resource]: Working Paper WP22/2022/01 / B. Lundqvist; National Research University Higher School of Economics. – Electronic text data (600 Kb). – Moscow: HSE Publishing House, 2022. – (Series WP22 "BRICS Competition Law and Policy Series"). – 38 p.

In this two-part paper, we analyse so-called 'killer acquisitions' and other detrimental collaborations. We thus view an acquisition as a form of collaboration between the seller and the purchaser, and between management and owner. In the first paper (part 1) we analyse various forms of collaborations, including strategic R&D alliances, which represent collaborations rather than clear cut change of control of businesses and assets. We conclude that society would benefit from a more intense competition law scrutiny of mergers and strategic R&D alliances, especially when these forms of collaboration originate from the pharmaceutical industry.

In this second paper (Part II) we analyse the merger rules and whether they can identify and capture the problematic cases identified in paper I. After concluding that this is not the case, we present a proposal that we believe would benefit competition and innovation in the pharmaceutical industry. We suggest that certain firms in the pharmaceutical sector should be obliged to notify all collaborations that imply change of control over research, research assets or research results, and that the focus under the merger rules should be on innovation and innovation results. A notification system should thus be put into place also for strategic alliances including license agreements and R&D collaborations in which the control over promising research or research capabilities is transferred to a large pharmaceutical firm. Such transfer is conducted through the covenants and restrictions of an R&D start-up and its key employees, even though there are no formal change of control of the start-up as such. We furthermore suggest that that ancillary agreements to such collaborations including shareholding agreements and option programmes that imply that leading researchers are locked-in by explicit or implicit non-compete and other forms of covenants should be scrutinized more intensely. Indeed, both the threshold requirements and the substantial tests that are needed to be developed will be discussed and presented. A BRICS or developing country perspective will be taken, where indeed, a new methodology for 'killer acquisitions' and 'shelving collaborations' is presented.

Key words: mergers, strategic alliances, competition law, killer acquisitions, pharmaceutical, BRICS

Björn Lundqvist, Higher School of Economics, BRICS Competition Law and Policy Centre, Leading Researcher, and the University of Stockholm, Professor; E-mail: blundqvist@hse.ru

Table of Content

1. Introduction

The label 'killer acquisitions', now universally recognized and commonly used both in academic literature and documents of international organizations,[1] was introduced by Yale School of Management's Song Ma and Florian Ederer and LBS's Colleen Cunningham in their paper "Killer Acquisitions" of 2018.[2] Cunningham et al describe a killer acquisition as a case in which the acquiring firm's strategy is "to discontinue the development of the targets' innovation projects and pre-empt future competition".[3] Their findings show that in the pharmaceutical industry, there are as many as 50 killer acquisitions every year in which incumbent firms acquire innovative start-ups solely to discontinue their research projects and to preempt future competition.

Start-ups, as a key source of new ideas and products, as well as disruptive innovation, play a vital role in the pharmaceutical markets. A number of recent empirical studies show that most of the innovative drugs registered on the horizon from 2009 to 2018 were invented not at all by pharmaceutical giants, but by small and medium (in terms of capitalization) biopharmaceutical companies. Moreover, the dynamics of such companies' shares in the R&D of innovative drugs shows a steady upward trend, which is especially illustrative in case of small biopharmaceutical companies and

[1] See, e.g.: OECD. Start-ups, Killer Acquisitions and Merger Control – Background Note; materials for the Meeting of the Competition Committee on 10-12 June 2020, available at: http://www.oecd.org/officialdocuments/publicdisplaydocumentpdf/?cote=DAF/COMP(2020)5&docLanguage=En

[2] Cunningham, Colleen and Ederer, Florian and Ma, Song, Killer Acquisitions. The version revised as of April 22, 2020 is available at: https://papers.ssrn.com/sol3/papers.cfm?abstract_id=3241707

[3] Cunningham et al. Op. cit. P. 1.

start-ups – if in 2009 they registered about 31% of new drugs (which is comparable to the share of Big Pharma for the same year), in 2018 already 63% of newly registered drugs came out of the laboratories of small biopharmaceutical companies, while Big Pharma registered only 16% of the total number of new drugs in the same year.[4]

Thus, start-ups, developing disruptive technologies are often purchased by larger firms providing the investment and knowledge to develop the promising R&D result into drugs. However, the start-ups might pose a competitive threat to Big Pharma's blockbusters and internally developed drugs, and hence may become targets for killer acquisitions. Indeed, the acquiring firm might find it more profitable to buy and shut down a start-up's innovative molecule, rather than suffering the loss of revenue that it expects to occur when this molecule matures, or buying and continuing to develop this molecule under the risk of affecting its own sales.

Alternatively, the acquirer might kill-off its own internal efforts to develop a competing product in order to remove a potential risk to the newly acquired product. Active M&A strategies of Big Pharma divert resources from their own R&D, as the companies spend millions of dollars annually on acquisition of competitive start-ups instead of investing them into development of innovative drugs.

It can be suggested that M&A activities in the pharma and biotech sector have several negative effects on innovation. Recent empirical research of M&A activities on the pharmaceutical markets lead to a conclusion that the concept of 'killer acquisition' might only be the tip of the iceberg, a small part of a larger problem. Big Pharma engages not only into share or asset deals on acquisition of biopharmaceutical start-ups' with the strategy to either of dismantling a future competitive threat or internally dismantle its own internal effort to the same effect, but that also larger pharma mergers and collaborations historically seem to lead to less innovation and to higher prizes and the lock-in of talents and entrepreneurs.

Though there is none direct evidence as of today that killer acquisitions have held back vaccines for COVID-19, there are some concerns that certain acquisitions have restraint the availability of certain important medical devices important in the treatment of COVID-19 patients. Certain News Outlets have claimed that the Covidien's $108 million acquisition of Newport in 2012 was a killer acquisition that reduced the availability of ventilators, the most effective treatment against some of the most severe COVID-19 symptoms, in the US.[5]

One merger that was terminated just days in the initial outbreak of Covid-19, was Illumina, a leading biotechnology firm active in sequencing technology proposed purchase of rival Pacific

[4] HIM. New Drug Approval Report Analysis of FDA. New Drug Approvals in 2018 (and Multi-Year Trends), p. 17, available at: https://www.hbmpartners.com/media/docs/industry-reports/Analysis-of-FDA-Approvals-2018-and-Previous-Years.pdf

[5] See NYTimes. https://www.nytimes.com/2020/03/29/business/coronavirus-us-ventilator-shortage.html. See also OECD. Start-ups, Killer Acquisitions and Merger Control – Background Note; materials for the Meeting of the Competition Committee on 10-12 June 2020, available at: http://www.oecd.org/officialdocuments/publicdisplaydocumentpdf/?cote=DAF/COMP(2020)5&docLanguage=En

Biosciences (PacBio). The US FTC had only weeks before alleged that Illumina had sought to "unlawfully maintain its monopoly in the U.S. market for next-generation DNA sequencing (NGS) systems by extinguishing PacBio as a nascent competitive threat"[6]. The UK watchdog CMA considered the merger would result in a substantial lessening of competition in the supply of DNA sequencing systems before the Illumina offer was withdrawn. PacBio research focus is inter alia COVID-19 DNA sequencing.

CMA noted that Illumina had approximately 80% market share of NGS systems worldwide and 90% in the UK. Through analysis of internal documents and customer feedback, the CMA found that the parties saw each other as competitive threat on a day-to-day level, but foremost on a strategic level. "There is also clear evidence that this market is dynamic and that the competitive overlap and closeness of competition between the Parties is likely to increase in the future as R&D is devoted to improving each Party's technology to address a wider range of use cases, applications and/or projects."[7] The CMA noted that in the highly concentrated market, other small players in the sector would not exert a competitive constraint on the merged entity.

There are several firms and collaborations that are pursuing to obtain a vaccine to end the COVID-19 pandemic. A Russian vaccine is already on the market. A number of other firms are in advanced clinical (phase III) testing, yet it is likely that no vaccine will have general efficacy on COVID-19. It seems that we will have several vaccines, with various level of effectiveness vis-à-vis different segments in the market (i.e. various risk groups, general public, the younger population etc.). Certain groups of individuals might need to take several doses on a continuing basis to be able to withstand being infected by COVID-19. Possibly, we will have different sorts of vaccine originating from different sources be it unilateral research conducted by university connected research centres, biotech or pharmaceutical firms, and collaboration with such centres. This might open up also for killer acquisitions in reference to vaccine producers, and a more thorough research would perhaps reveal such cases in the pharmaceutical sector, where treatments may have been lost due to so-called "killer acquisitions" or where the research efforts have been shelved due to two or more firms have agreed to collaborate to pursue a unilateral research effort. Moreover, to protect a vibrant competition between COVID-19 vaccine producers, the under enforcement of competition law in reference to the human medicine industry needs to be addressed.

Historically, antitrust authorities have been rather reluctant to consider explicitly long-run effects of mergers on innovation, though the nascent practice of innovator acquisitions can affect the industry dramatically. Though there has been a significant amount of merger activity involving Big Pharma firms buying highly valued biopharmaceutical start-ups in recent years, such transactions commonly do not come under the radar of competition authorities. Start-ups, in the early stages of their development, tend to have low turnover, as their business models concentrate on carrying out

[6] FTC Challenges Illumina's Proposed Acquisition of PacBio, December 17, 2019
See https://www.ftc.gov/news-events/press-releases/2019/12/ftc-challenges-illuminas-proposed-acquisition-pacbio
[7] CMA, Anticipated acquisition by Illumina, Inc (Illumina) of Pacific Biosciences of California, Inc. (PacBio) Summary of Provisional findings, para. 37 https://assets.publishing.service.gov.uk/media/5db1685940f0b609bdf449fc/Summary_of_the_provisional_findings.pdf

R&D before seeking to register drug and launched its production and marketing. The result is that such acquisitions may not come to the attention of competition authorities that focus upon turnover, despite the potential for them to have anti-competitive effects.

The issue of (under-)enforcement of competition law in reference to killer acquisitions is however not unique. Collaborations between pharmaceutical companies where de-facto the control of the R&D result of the target is transferred to a larger Big Pharma firm can take several forms. In essence it can be conducted by the exclusive technology transfer (licensing) between the firms, through an R&D collaboration or assignments of the patent and connected know-how. Such collaborations do not necessarily fall under the merger rules because they do not reflect a change of control of the start-up as such. Often, such collaborations should be self-regulated by the parties and are analysed under the prohibition against anticompetitive agreements or even under the abuse of dominance prohibition.

It should be acknowledged that also collaborations in the pharmaceutical industry not triggering the merger threshold have been treated leniently from the standpoint of antitrust regulation in certain jurisdictions (including, the US and the EU). These activities, due to practical difficulty to predict their successfulness and potential further anti-competitive effects, are not subject to notification and analysis of competition agencies, and are often even exempted under the antitrust rules. Introducing merger control over killer acquisitions could moreover lead to increase of the popularity of licensing and R&D collaborations which in some stances can be as anti-competitive as a killer acquisition because they also open up for the possibility for the larger firm to 'kill off' the potential competing alternative. Indeed, looser forms of collaboration, not reaching the threshold for merger control should benefit from a heighten antitrust scrutiny.

Within the discussed category of start-ups takeovers, the killer acquisition theory of harm is one that might apply, but it is only one among others. Alternative theories of harm might include vertical theories of harm in which the acquired product might grow into a key input that allows input foreclosure in downstream markets. They might also include conglomerate theories of harm in which the acquired product might grow into a complement that might be bundled or tied to the incumbent's product in order to exclude rivals. Finally, and closely related to the concern in a killer acquisition theory of harm, is the nascent potential competitor theory of harm. The concern here is that the acquired product might grow into a rival product, and hence that controlling that product (but not killing it), removes the competitive threat that it poses. [8]

The rapidly growing pharmaceutical markets of the BRICS countries are becoming increasingly attractive to Big Pharma companies. The dynamics of annual increase in the population of most BRICS countries, large public investments in health care and the annual increase in the number of chronic diseases in these countries stimulate a constant demand for medicines. Moreover, biopharmaceutical start-up firms with promising molecules or antidotes may very well originate from BRICS countries and gain the interest of Big Pharma. The wave-like nature of mergers and

[8] See: OECD. Op. cit. P. 7.

acquisitions in the pharmaceutical market is determined by the expiration of patents for blockbuster drugs, the evolvement of new illnesses, and the approximation of which encourages Big Pharma companies to acquire generic manufacturers.

At the same time, global pharmaceutical companies build their strategies around geographical regions, and certain reshaping of such regions (in economic sense) can be seen nowadays. This encourages countries to cooperate more with trade unions, for instance inside of the Eurasian Economic Union. On the other hand, it supports some doubtful marketing strategies of Big Pharma, such as pricing segmentation based on nominal classification of countries on developed and developing. Indeed, the market for pharmaceuticals is far from being global when taking into consideration there is now global exhaustion of patent rights, or intellectual property rights in general. When scrutinizing a merger between a promising start-up originating in a BRICS country and a large Big Pharma firm, also these parameters need to be taken into consideration.

The paper aims to address the problem of so-called killer acquisitions broadly in time of the Corona pandemic. It shall analyse the current trends of merger control and M&A transactions in the pharmaceutical industry and the effectiveness of the existing regime for considering the M&A transactions not only from the standpoint of economic concentration, but also from the view of their harm to innovation in the industry as a whole. Different theories of harm will be analysed on their applicability to support the merger regulation in the BRICS pharmaceutical markets. We plan to develop suggestions on policy response that might be required to address the issues that arise from killer acquisitions and other forms of collaboration that may trigger the same or similar anticompetitive effect on innovation.

Several proposals have already been put forward in different jurisdictions in order to change the merger notification regime. One of them would be to lower the existing notification thresholds. However, doing so in the context of a mandatory notification system would inevitably result in large numbers of low turnover transactions being notified. This option has therefore not been adopted, but several jurisdictions have introduced, or propose to introduce, additional or complementary thresholds or criteria, notably value-based thresholds or a system where the Competition Authority may require certain parties to notify the merger irrespectively of whether the merger meet the thresholds, or not. The propositions would enable high value low turnover transactions that might pose a threat to potential competition to be investigated. As an example, Germany in 2017 amended its Competition Act (GWB), specifically, Section 35 (Scope of Application of the Control of Concentrations), introducing a size of transaction threshold alongside its turnover threshold.[9]

Another option is to single out a specific industry to whom a special regime should apply. An approach that is also discussed is to acknowledge the uncertainty of killer acquisitions, take a cautious and permissive ex-ante approach and then to intervene ex-post if necessary. A number of

[9] OECD. Op. cit. P. 40.

countries have some sort of ex-post review powers, including Hungary, Ireland, Sweden and Lithuania.

Both threshold requirements and substantive tests that need to be developed will be discussed and presented. The papers will address threshold requirements and substantive tests and their relevance for the BRICS countries. We also plan to consider other possible solutions, including those that are provided not by legal instruments but rather by providing alternative source of investment and service to provide the necessary development work including the clinical tests. It could be imagined that if the competition authority would find a risk for a killer acquisition, a right to first refusal in certain situations will be triggered. That a biotech and pharma venture capital fund/investor would be available and be given a right to invest in the target (R&D start-up) on the same terms as the larger pharma firm, so to eliminate risk of allowing for a killer acquisition.

Part I starts with an analysis of the pharmaceutical industry from both an innovation economics and empirical perspective[10]. Here in part II, the competition law challenges in reference to killer acquisition and other forms of collaborations are presented. Both threshold requirements and the substantial tests that are needed to be developed will be discussed and presented. A BRICS or developing country perspective will also be taken, where indeed, a new methodology for 'killer acquisitions' and 'shelving collaborations' is presented. Finally, we conclude.

2. Challenges for Competition Authorities to review anticompetitive mergers and collaborations in the pharma and biotech sectors

a. Thresholds

Mandatory notification for mergers is present in most jurisdictions with competition law systems. However, a number of countries, such as Australia, New Zealand and the United Kingdom have adopted voluntary notification systems. Generally, in several jurisdictions globally, a merger within the meaning of the Competition Law arises when (i) two or more previously independent companies legally merge under corporate law, or, more common, (ii) one or more companies acquire by purchase of securities or assets, by contract or by any other means, direct, indirect or partly control of the whole or parts of one or more companies (target(s)).

The creation of a joint venture which on a lasting basis fulfils all the functions of an autonomous economic entity or reflects an integrated collaboration between competitors may constitute a merger within the meaning of point (ii) in certain jurisdictions, while also (iii) contractual collaborations that reach the level of joint ventures may be required to be notified in some jurisdictions.[11]

[10] Lundqvist B. Killer Acquisitions and other forms of anticompetitive collaborations in time of Corona. Part 1. Working Paper WP22/2021/01 Series WP22 BRICS Competition Law and Policy Series. National Research University Higher School of Economics. URL: https://wp.hse.ru/data/2021/12/13/1776219519/WP22_2021_01_____.pdf (accessed 15 January 2022г.)

[11] [See for example the Russian, Brazil and Ukranian merger law.]

Several countries, also require the parties to notify acquisitions of minority stakes in competitors or firms active down or upstream from the purchaser without the purchaser acquiring control in the formal meaning of the merger rules.[12]

For the parties to be required to notify the merger often certain turnover, asset or market share thresholds need to be met. Generally, a concentration is required to be notified to the relevant Competition Authority under a two-prong test:

(1) the global combined aggregate turnover and/or assets of the undertakings concerned in the preceding financial year exceeds a certain number or value, while (2) at least two of the undertakings concerned had a turnover or assets in the jurisdiction of the Competition Authority the preceding financial year which each exceeds a certain smaller amount or value for each of the undertakings concerned.

Some jurisdictions may require the merging parties to reach certain levels of market presence or share of supply for the parties to be obliged to notify. Under, for example, UK merger law there is a share of supply test to the detect the market presence vertically between the merging firms. The test enables the CMA to review a transaction if the parties to a merger have a share of supply exceeding 25 % and the transaction would lead to any increase in that share.[13]

Some jurisdictions have notably transactions test to complement the turn-over test. Under the US Hart-Scott-Rodino Act certain high valued transactions are required to be notified. Germany together with Austria also recently introduced a transaction value test. In the US, the Hart-Scott-Rodino Act (HSR Act) specifies thresholds whereby filing is mandatory (size of transaction and size of person thresholds)

However, both the EU and the US merger regimes are flexible since they allow for the investigation and challenge of mergers and acquisitions if the transaction would violate the relevant antitrust provisions, namely section 7 of the Clayton Act, Section 5 of the FTC Act and Sections 1 and 2 of the Sherman Act, in reference to the US, and Arts. 101 or 102 TFEU in the EU. Therefore, the both the EU and US competition authorities can take action, even if the transaction has already been concluded and even if the transaction does not meet the relevant

mandatory notification thresholds.[14]

[12][See Indian, Russian and USA merger law.]

[13] This can mean that in the case of a 'nascent' acquisition, such as Roche/Spark the test was fulfilled on the basis that the share of employees supplying the particular service in question exceeded 25% (since while the target had little turnover it did have employees). While the share of employees might be very relevant to a monopsony theory of harm, this does demonstrate the flexibility of the test, which can be used to ensure that nascent acquisitions can be reviewed. See OECD Ops it, p. 14.

[14] The US authorities make use of this possibility to a larger extent than the EU authorities.
For example, the FTC has recently used its powers to undertake ex-post assessments of past mergers to request information on hundreds of acquisitions made by Google, Apple, Facebook, Amazon and Microsoft over a 10-year period. In doing so, it has noted the possibility that this might lead to ex-post merger enforcement action. Indeed, this follows past cases in which the US has re-examined and remedied completed hospital mergers. See OECD, op. cit, p. 15.

Moreover, in some jurisdictions there exist a possibility for the authority to issue an injunction to notify even for mergers which do not meet the requirements or thresholds stated above. Such possibility exists in Sweden, Hungary, Ireland, Latvia and the UK. Also, Norway has a merger control system including a possibility to issue an injunction to notify a transaction. Furthermore, at least Finland and France have recently been considering empowering their competition authorities with such a power.[15] The main concern for the countries considering giving the competition authority an injunction power seem to be concerned with 'killer acquisitions'. France, for example, has recently announced that there have been mergers that they would have liked to review but could not as the thresholds for mandatory notification were too high.[16]

The rules regarding when a competition authority can issue an injunction are different, but one way to try to catch larger firms acquiring smaller competitors can be to set up a rule where if the aggregate turnover requirement according to point 1 is fulfilled, but the individual turnover of the target does not exceed what is laid down in point 2, the Authority may require a party to a concentration to notify the concentration where particular grounds exist for doing so, while such a rule can be supplemented with the right to notify. A party and other participants in a concentration always have the right to voluntarily notify a concentration, where the turnover requirement as laid down in point 1 is fulfilled.

The undertakings concerned are normally the merging undertakings or the undertaking acquiring control and the target over which control is being acquired. The notification shall normally be made by the merging parties or the party or parties acquiring control of the target.

From the date of receipt of a complete notification, the Competition Authority regularly has a number of (working) days in which to decide whether to clear the merger or initiate a special investigation.[17] This period is called the stand-still period where the parties are not allowed to conduct acts that would advance the merger.

A concentration that must be notified or has been voluntarily notified can be prohibited if the concentration is liable to (significantly) restrict or impede the existence or development of effective competition in the jurisdiction, as a whole, or a substantial part thereof, and if a prohibition can be issued without significantly setting aside national security or essential supply interests. The competition test in several jurisdictions globally corresponds to the generally used SIEC test, while many competition authorities focus on the market share of the merged entity and aim to prevent the creation of monopoly or dominant position.

Undertakings may also voluntarily make commitments to the Competition Authority and the commitments may be made subject to a penalty of a fine.

---

[15] Katia Duncker, Päivi Tammilehto. Overlooked Issues in Merger Control, 05-2020, https://www.twobirds.com/en/news/articles/2020/global/overlooked-issues-in-merger-control (accessed 15 January 2022).

[16] OECD op. cit., p. 13.

[17] If an undertaking offers commitments during this period with a view to having the merger cleared by the Competition Authority, the time limit is often increased with 10-20 working days.

To the extent that the creation of a joint venture, which constitutes a concentration has the aim or effect of co-ordinating of the competitive behaviour of the undertakings which remain independent, such co-ordination shall be appraised in accordance with the cartels rules, in conjunction with the SIEC test.

b. Killer acquisitions – getting them inside the door

Several jurisdictions have or are considering the introduction of transaction value-based thresholds for deals in which the target company does not yet generate sufficient revenues to meet turnover thresholds. Such thresholds would allow the Competition Authority to assess deals where a large firm acquires a smaller innovative target in order to prevent its rise as a competitor in the future, a start-up in the pharma sector (sometimes referred to as "killer acquisitions").

Some large jurisdictions have notably introduced transactions tests to complement their general turn-over tests. Germany, for example, recently introduced a transaction value test, where the filing thresholds where complemented with a new EUR 400 million size-of-transaction test. The new German rules can hence be concluded as:

- all parties to the transaction together had global turnover of more than EUR 500 million;
- at least one party had turnover in Germany of more than EUR 25 million; and
- the value of the consideration for the transaction exceeds EUR 400 million and the target company has significant activities in Germany.

The new threshold consists of two limbs: (i) the transaction value; and (ii) the local nexus test, and applies only if the EUR 5 million threshold mentioned above is not met. The German de minimis exemption does not apply to transactions that meet the new size-of-transaction threshold.

The problem that the new thresholds is trying to address is 'killer acquisitions', i.e. when market leading companies are able to fully integrate an emerging competitor or its assets into its own business by acquiring it in the early stage of its development and change or discontinue the original activities of the acquired company, or, on the other hand, terminate its own in-house competing effort and develop the acquired alternative instead. From a competition policy perspective, such acquisitions may require a preventive competition law investigation, especially with regard to protecting innovation potential and innovation competition in human medicine or similar industries.[18]

[18] Bundeskartellamt, Guidance on Transaction Value Thresholds for Mandatory Pre-merger Notification (Section 35 (1a) GWB and Section 9 (4) KartG). URL: https://www.bundeskartellamt.de/SharedDocs/Publikation/EN/Leitfaden/Leitfaden_Transaktionsschwelle.pdf?__blob=publicationFile&v=2 (accessed 15 January 2022)

Technically such a change of the merger rules in reference to the thresholds is not difficult to conduct. A supplementary test can be drafted focusing on the transaction value, like the German example above, while a way to enclose more firms in the scope is to change the second prong of the general used test (cf above) from "at least two of the undertakings concerned had a turnover… for each of the undertakings" to "at least ***one*** of the undertakings concerned had a turnover…." Indeed, this enable the Competition Authority to catch several more mergers where one party with a large turnover is purchasing smaller target(s), and could be accompanied with a de minimis rule focusing on transaction value, e.g. while concentration with a deal-value of less than XX are not required to be notified to the competition authority. The de minimis rules could also exclude certain minority stakes, where the control of the target is not transferred and the investment is pure financial rather than strategic.

However, to stipulate a new test based on only transaction value is difficult because no one really knows the difference between the transaction value of a 'killer acquisition' compared to the transaction value of other forms of acquisitions. Moreover, the transaction value can be difficult to calculate should it include several parts where remuneration is paid out in different milestones in the form of options, shares or even salary. These milestones can moreover be connected to active participation of the sellers and innovators, as part of the management or the scientific board of the target, ex post the merger.[19] Moreover, thresholds may very well push down prices, where firms with killer acquisition intention seek "cheap" targets. "Cheap" targets in the biotech and pharmaceutical industries imply going after the start-ups when they are conducting early research, which imply that the research has not reached the maturity where the promising research has gained value due to the perceived uncertainty of its benefits. Indeed, a way to prevent this is to oblige pharma and biotech firms with a special status to notify all of their acquisitions.[20]

Moreover, when a merger is at hand, the ancillary agreements in reference to key individuals should be included in the analysis. Are they required to enter into option programmes or to purchase options or shares in the firm, which imply that they are locked-in for a certain period of time, or otherwise risk the personal investment made in the share and option programme. When entering such agreements, the individuals can be encompassed with non-compete and confidentiality covenants also for a period of time after the termination of the relationship with the firm. The idea is that the individual should be offered a lucrative programme that will be paid out after a certain period of time (or in miles stones) when the molecule or drug is proven successful, while still the

[19] European Commission, Replies to the consultation, https://ec.europa.eu/competition/consultations/2016_merger_control/index_en.html; CMA contribution to the Evaluation of procedural and jurisdictional aspects of EU Merger Control, 13 January 2017 https://ec.europa.eu/competition/consultations/2016_merger_control/united_kingdom_competition_and_markets_authority_en.pdf. One way to identify. A transaction value is to require the filing party the net present value as of closing of highest remuneration that can be paid out under the transfer agreement. According to the German/Austrian Guidelines for establishing a transaction value "the value of a consideration that includes earn-out payments or other uncertain components or components whose value fluctuates can be validated more easily if not only the buyer but also the seller14, independently of one another, describe and explain how each of them calculated the consideration value." Ibid, para. 21.

[20] Furman et al. (2019)

individual also makes a substantial personal investment. The package of agreements making up the transaction need to be scrutinized since key individuals should be regarded as R&D capabilities and may be locked-in, which can be detrimental to innovation.

A strategic purchaser may however very well try to circumvent even the new transaction notification obligations and try to create a looser contractual collaboration to fulfil the aim of killing or shelving the active ingredient, while trying to escape the merger review. The control of the active ingredient (molecule) in reference to biotech innovative start-ups can be transferred taking into consideration the terms and conditions of the license agreement or R&D collaboration agreement without the transaction tests are being triggered.

c. Alternative solutions – looking at the collaboration or conduct as a trigger

With the aim to catch the agreements which revolve around the issue of control of the active ingredient or molecule, and to address the collaborations which works as a veil for the killing or shelving of the competitive alternative molecule or compounds, the effort could be to focus on certain agreements that imply a closer collaboration between large pharma companies and a R&D start-ups.

In reference to the agreements in the pharmaceutical industry, agreements that include collaborative parts such as setting up a scientific board, identifying certain personal to be available for the collaboration or including non-compete covenants including the obligation not to conduct incremental R&D in the area for the collaboration ex post the termination of the agreement should trigger a need for notification because they may very well hide a collaboration that may kill off or shelve an important promising research in a similar fashion as a killer acquisition. The should thus benefit from a higher level of scrutiny.

Some jurisdictions are utilizing notion of 'full-function' joint ventures, or make a distinguish between cooperative and concentrative joint ventures when identifying what collaborations should be notified and under what rules they should be scrutinized. However, collaboration in the pharmaceutical industry may not necessarily imply that such assets are transferred or that such full-functioning organisation is set-up, and will hence not be triggering a notification requirement.

A way to have these mergers and collaborations screened is to require that they are notified, and to find an easy test to distinguish the problematic vis-à-vis the unproblematic. To identify the potential problematic collaboration is best done by reference to the covenants stipulated in the collaboration agreement.

Generally, a difference could be made between collaborations that is purely financial in character, while collaborations with a strategic aim, where a larger pharma firms acquires the right to use and develop a research result by or in collaboration with a R&D start-up should be required to be notified by the parties to the collaboration irrespectively whether the collaboration amount to a

merger, or not.[21] Indeed, require mergers and collaborations which including certain covenants to be notified. Should the collaboration agreement, for example, (i) imply exclusive transfer of a license to use a patent covering a molecule or antidote, (ii) stipulate the setting up of a scientific board with the aim to collaborate or transfer relevant know-how from Target to Big Pharma, and also include (iii) non-compete obligations or that only the larger firm will post termination of the collaboration be selling the drug, while (iv) Big Pharma will conduct incremental innovations and the start-up R&D focused firm is allowed to only conduct basic research and exist the market after the end of the collaboration, then such collaboration should be required to be notified, even though the collaboration is neither full-functioning nor concentrative.[22]

These collaborations should be notified and screened under a SIEC test. However, other frameworks may also be relevant to suspected killer or shelving collaborations. The competition authorities could examine the acquisition not as a concentration, but as a potentially unlawful collusion or as an act to maintain of monopoly power, or as an abuse of dominance offence.[23] For example, the US Illumina/PacBio merger discussed infra was challenged by the US FTC as violation of the prohibition of maintain of monopoly power.

---

[21] The US code for R&D collaboration can be used to identify the R&D collaborations: The NCRPA defines "joint ventures" widely, as a group of activities engaged in by two or more legal persons for the purpose of:

(i) theoretical analysis, experimentation, or systematic study of phenomena or observable facts;
(ii) the development or testing of basic engineering techniques;
(iii) the extension of investigative findings or theory of a scientific or technical nature into practical application for experimental and demonstration purposes, including the experimental production and testing of models, prototypes, equipment, materials, and processes;
(iv) the production of a product, process, or services;
(v) the testing in connection with the production of a product, process, or services by such venture;
(vi) the collection, exchange, and analysis of research or production information; or
(vii) any combination of the purposes specified in the paragraphs above, and may include the establishment and operation of facilities for the conducting of such a venture, the conducting of such a venture on a protected and proprietary basis, and the prosecution of applications for patents and the granting of licenses for the results of such ventures.

Also, the EU definition of R&D collaboration may be used:

(i) joint research and development of contract products or contract technologies and joint exploitation of the results of that research and development;
(ii) joint exploitation of the results of research and development of contract products or contract technologies jointly carried out pursuant to a prior agreement between the same parties;
(iii) joint research and development of contract products or contract technologies excluding joint exploitation of the results;
(iv) paid-for research and development of contract products or contract technologies and joint exploitation of the results of that research and development;
(v) joint exploitation of the results of paid-for research and development of contract products or contract technologies pursuant to a prior agreement between the same parties; or
(vi) paid-for research and development of contract products or contract technologies.

[22] It should be acknowledged that this is often the case, and the research ventures require the smaller R&D driven firm to exit the research area often ex post the collaboration. Interestingly, many economists have not yet recognised this. See Shapiro etc stating "An RJV would be less anticompetitive than a full merger because it would preserve price competition in the current and future product market." Giulio Federico, Fiona Scott Morton and Carl Shapiro, Antitrust and Innovation: Welcoming and Protecting Disruption, Innovation Policy and the Economy, National Bureau of Economic Research.

[23] This is suggested by the OECD in op. cit., 37 et seq.

Given the above, parties entering into a license agreement or a collaboration in the pharmaceutical sector could be obliged to notify the collaboration under the antitrust framework, and not under the merger rules if the jurisdiction in question would like to save the merger legal system for notifying transactions which imply a transfer of control. While the assessed evidence might not differ substantively between assessing the case as a merger case or as a collusion or monopolisation case, the implications of the different legal framework may be different. However, in the end, the collaboration which is discussed here centres around a transfer of exclusive rights under patents for a promising molecule or antidote from a start-up to a Big Pharma, and to 'break up' such a collaboration would not imply much needed administrative or management attention. Indeed, breaking up a merger or a collaboration between a R&D start-up and Big Pharma is very different from a detangling a merger of equals between two industry players. This would imply that the collaboration discussed here could be notified pre-implementation, while the legal framework could do without a stand-still period. That the parties should notify and they can set-up the collaboration, while risking that the competition authority requires the parties to break up the collaboration should it be considering violating the relevant rules within a certain period of time.

However, this is only to have the mergers and collaborations inside the door of the competition authority. An equally important issue is for the competition authority to use a test that would identify the mergers or collaboration where the effect or aim is to neutralise a (future) competing alternative.

d. SIEC test under merger rules and the test under the cartel rules should include a more innovation focused analysis?

Research conducted by Cunningham *et al*, based om empirical data, shows that 6 % of all mergers in the pharma industry are 'killer acquisitions', where a larger pharma firm purchase a R&D intensive smaller start-up with promising research to close the research in order to terminate a possible future competing drug to reach the market. Likewise, we can suspect that there are R&D ventures, where the large pharma company by acquiring an exclusive right to control the development of that molecule into a drug, may kill or at least shelve the molecule for future development. Indeed, theoretical economic research supports this suspicion.[24]

The idea that R&D collaborations may also provide the possibility for 'killer acquisitions' of possible future competing drugs to reach the market is not new. Considering that the research institution generally may agree to far reaching non-compete covenants and often becomes foreclosed to

[24] In the literature on R&D joint ventures, absent spillovers, cooperation between rivals leads to lower innovative efforts because it internalizes the business-stealing effects on innovation. See, for example, d'Aspremont, Claude, and Alexis Jacquemin. 1988. "Cooperative and Noncooperative R&D in Duopoly with Spillovers." American Economic Review 78 (5): 1133–7. and López, Ángel L., and Xavier Vives. 2019. "Overlapping Ownership, R&D Spillovers, and Antitrust Policy." Journal of Political Economy 127, no. 5 (October): 2394–437. (2019).

third parties after entering an R&D agreement, *de lege ferenda,* these collaborations should be included when discussing killer acquisitions.[25] Anecdotal evidence in academia have flourished that smaller innovative firms originating from university environments may have been foreclosed by larger firms under R&D agreements in the pharmaceutical sector, yet the Cunningham *et al* study was the first to empirical show that killing acquisitions exist.[26] The R&D start-up firms originating from academia are often research-driven without the possibility of developing promising molecules or antidotes etc. to drugs. The larger firms often trade their development, testing and distribution skills with the start-up. R&D agreements in the pharmaceutical sector have included stipulation that the discovered molecule or antidotes may only be jointly developed or shall exclusively be in the control of Big Pharma under the agreement.[27] Such covenants gives the larger firms veto power regarding developing the drug. Possibly, the larger firms have other incentives than to develop the new drug. Perhaps such development cannibalizes on already marketed drugs and the vertically integrated firm decides to delay the development of the new drug.[28]

Killer acquisitions should be prevented irrespectively whether they are conducted as merger, licensing agreement or as a R&D venture.[29] However, it should be acknowledged that the great majority of mergers and collaborations between smaller R&D specific start-ups and big pharma are not to be considered killer acquisitions or attempts by the larger firms to kill or shelve possibly competing molecules. On the contrary, collaborations between large pharma firms, conducting the development and testing of drugs, and R&D start-ups, often founded by researchers connected to universities, hospitals and academic centres, constitute a mainstream development of new drugs in the current human medicine industry.[30] Smaller R&D intensive firms that have developed promising molecules or treatments that are being purchased or engaged in collaboration with larger pharma companies and where the aim and hope for both parties are that the promising treatment shall prove successful. So, the competition law test needs to work precise so to identify the harmful killer collaborations, while not disturbing the regular mainstream methodology and development for drugs for future illnesses.

For a period the issue about identifying the harmful mergers, collaborations or conduct by dominant firms in the research and development stage, i.e. pre-market (pre-competitive stage) has been

[25] It has been shown that specific research institutions do prefer exclusive licensing arrangements so as to be able to extract supra-competitive profits. Cf. S. Scotchmer, Innovation and Incentives (The MIT Press 2004), 236 et seq.
[26] Cf. S. Zain, 'Suppression of Innovation or Collaborative Efficiencies?: An Antitrust Analysis of a Research & Development Collaboration That Led to the Shelving of a Promising Drug', (2006) 5 John Marshall Review of Intellectual Property Law 347, 350 et seq., and D. Hamilton, 'Silent Treatment: How Genetech, Novartis Stifled a Promising Drug', (2005) Wall Street Journal A1, A1
[27] Ibid.
[28] See for example Cunningham, Colleen and Ederer, Florian and Ma, Song, Killer Acquisitions (March 22, 2019). Available at SSRN: https://ssrn.com/abstract=3241707 or http://dx.doi.org/10.2139/ssrn.3241707
[29] Generally, Frederick M. Abbott and Grahamn Dukes Global Pharmaceutical Policy – Ensuring the Medicines for Tomorrow's World. Edward Elgar 2009. See also industry leaders like Garnier, JP. 2008. Rebuilding the R&D engine in big pharma. Harv Bus Rev. 86(5):68-70, 72-6, 128. (Jean-Pierre Garnier (jean-pierre.garnier@gsk.com) was at the time of writing the article, the chief executive officer of GlaxoSmithKline and is based in London and Philadelphia).
[30] Ibid.

conducted by identify 'innovation markets' or with the use other forms of proxies so to establish whether the conducted create dominance that leads to less investment in R&D or otherwise harm the innovation process. The US way to do this was to identify innovation or R&D markets, while the EU authorities have tried to use regular markets (product or service markets) as proxies for evaluating the power of the merging or collaborating parties in the innovation process.[31] The EU also used a separate methodology for biotech, human medicine industry and chemistry industries, where R&D paths and poles could according to the EU Commission and Courts could be identified at an early stage and used so to establish whether there were competing research efforts present.[32]

In 1995 the innovation market concept was introduced by the US Justice Department's Guidelines for licensing and the efforts by the economists Gilbert and Sunshine (hereinafter Licensing Guidelines).[33] Several cases followed where the innovation market was used foremost by the FTC in mergers in the pharmaceutical sector. In the 10–15 cases where it was used during the 1990s, the FTC and the Justice Department focused on clear cases of correlation between identified future markets and innovations, and where the mergers were likely lead to dominance or monopoly positions.[34] There were exemptions, but mostly the antitrust agencies focused on the merger where it seemed that rivalry would be exchanged for monopoly position, and where the innovation efforts would lessen and only one or few innovation efforts would be pursued ex post the merger. The FTC and Justice Department during this period were more ambitious than the EU Commission and several cases which were prohibited by the FTC were cleared by the EU Commission.[35] Generally the test seem to have focused on three questions or prongs: (i) the ability of the merged firm to reduce total market investments in R&D, (ii) the incentive of the merged entity to reduce the innovative effort and (iii) the impact of the merger on the efficiency of the R&D expenditure.[36] The

[31] See for example the R&D block exemption, EU Merger regulation and Horizontal Guidelines

[32] EU Horizontal Guidelines

[33] DOJ/FTC, Antitrust Guidelines for the Licensing of Intellectual Property issued 1995. New Guidelines were issued in 2017, also including a chapter about what is now called research and development markets. The concept has been developed. Two Deputy Assistant Attorneys initiated the discussion in an article, outlining the innovation market concept, see Richard Gilbert & Steven Sunshine, 'Incorporating Dynamic Efficiency Concerns in Merger Analysis: the Use of Innovation Markets ', (1995) 63 Antitrust Law Journal, 569, 574 et seq. Several commentators have commented and criticised their views. See, e.g., Robert Hoerner, 'Innovation Markets: New Wine in Old Bottles?', (1995–1996) 64 Antitrust Law Journal, 49; George Hay, 'Innovations in Antitrust Enforcement', (1995–1996) 64 Antitrust Law Journal, 7; and Richard Rapp, 'The Misapplication of Innovation Market Approach to Merger Analysis', (1995–1996) 64 Antitrust Law Journal, 19. See also Gilbert and Sunshine's reply: Richard Gilbert & Steven Sunshine, 'The Use of Innovation Markets: A Reply to Hay, Rapp, and Hoerner', (1995–1996) 64 Antitrust Law Journal.

[34] The FTC has identified and referred to research and development markets in some cases, see e.g. Complaint, Amgen Inc., 134 F.T.C. 333, 337-39 (2002) (identifying a research and development market for inhibitors of cytokines that promote the inflammation of human tissue); Wright Med. Tech., Inc., Proposed Consent Agreement with Analysis to Aid Public Comment, 60 Fed. Reg. 460, 463 (Jan. 4, 1995) (identifying a research and development market for orthopedic implants for use in human hands); Am. Home Prods. Corp., Proposed Consent Agreement with Analysis to Aid Public Comment, 59 Fed. Reg. 60,807, 60,815 (Nov. 28, 1994) (identifying a research and development market for, among other things, rotavirus vaccines).

[35] Björn Lundqvist, Standardization under EU Competition Rules and US Antitrust Laws – The Rise and the Limits of Self-Regulation (Edward Elgar, 2014).

[36] E. Cefis et al, The Role of Innovation in Merger Policy: Europe's Efficiency Defence versus America's Innovation Markets Approach, Tjalling C. Koopmans Institute, Discussion paper series 07-21.

analysis was hence quite straight forward, focused on the merged firm's ability to profitably decrease investment in research. However, the innovation market concept was not well received in some parts of the academic community.[37] According to some academics innovation markets hence represent an anomaly for the antitrust community. Normally, antitrust authorities focus on encouraging the maximization of the output for a given level of input or on preventing artificial limitation in the output. Under the innovation markets approach, the focus is on the input side, antitrust authorities favouring more R&D investments and/or more research lines.[38]

The effort to make use of the innovation market concept, at least by the FTC and the Justice Department, seems to have been terminated by the 'more economic approach' implemented in the 2004 *Genzyme/Novazyme*[39] case. In the *Genzyme/Novazyme*,[40] where the FTC analysed innovation competition in reference to two firms being the only source of research for a treatment for the rare Pompe disease. While both firms were in pre-clinical testing for a drug/treatment against Pompe disease, the FTC Commissioners were not in agreement and the FTC decision to close the case without remedies was heavily criticised by the dissenting commissioner and abstinent commissioner. The majority pointed to the fact that the FTC could not decline a merger simply based on the number of independent R&D programmes: '[t]he Commission has been cautious in using innovation market analysis,' Chairman Muris stated, because 'economic theory and empirical investigations have not established a general causal relationship between innovation and competition.' Rather, a 'careful, intense factual investigation is necessary' to 'distinguish between pro-competitive and anticompetitive combinations of innovation efforts.' Furthermore, there were substantial efficiencies to be gained by the merger. Perhaps, the FTC did something similar as to what now is stipulated in the US Horizontal Guidelines, while the majority also found great efficiencies in this specific merger.[41] However, the *Genzyme/Novazyme* can also be read as throwing the concept of innovation market over board.[42]

---

[37] R. Hoerner, 'Innovation Markets: New Wine in old Bottles?', (1995-1996) 64 *Antitrust Law Journal* 49, 53.
G. Hay, 'Innovations in Antitrust Enforcement', (1995-1996) 64 *Antitrust Law Journal* 7, 9 *et seq*. R. Rapp, 'The Misapplication of Innovation Market Approach to Merger Analysis', (1995-1996) 64 *Antitrust Law Journal* 19, 21.

[38] Davis, R. W. (2003), Innovation markets and merger enforcement: current practice in perspective, Antitrust Law Journal, 71.

[39] See press release 13 January 2004, FTC Closes its Investigation of Genzyme Corporation's 2001 Acquisition of Novazyme Pharmaceuticals, Inc., http://www.ftc.gov/news-events/press-releases/2004/01/ftc-closes-its-investigation-genzyme-corporations-2001, last visited 12 January 2013. See also In the Matter of Genzyme Corp. Docket c 4126 File no 0410083 (2005).

[40] See press release 13 January 2004, FTC Closes its Investigation of Genzyme Corporation's 2001 Acquisition of Novazyme Pharmaceuticals, Inc., http://www.ftc.gov/news-events/press-releases/2004/01/ftc-closes-its-investigation-genzyme-corporations-2001, last visited 12 January 2013. See also In the Matter of Genzyme Corp. Docket c 4126 File no 0410083 (2005).

[41] Michal A. Carrier, Innovation for the 21st Century: Harnessing the Power of Intellectual Property and Antitrust Law, (Oxford Scholarship Online, 2009), 303 et seq.

[42] The case has been heavily criticized by both lawyers and economists, see for example Carl Shapiro 2012. "Competition and Innovation. Did Arrow Hit the Bull's Eye?" In The Rate and Direction of Inventive Activity Revisited, ed. Josh Lerner and Scott.

Yet, it seems that the innovation market has had somewhat of a revival lately, and the concept has developed to also include a broader perspective under the notion of "research and development markets".[43] Moreover, the even broader method of analysing the general R&D level of the industry without focusing on specific drugs or treatments has been added.

The US Horizontal Merger Guidelines from 2010 stress that mergers that diminish innovation is a problem and the DOJ & FTC Antitrust Guidelines for the Licensing of Intellectual Property from 2017 use the notion of "research and development markets". The Guidelines state:

"(a) research and development market consists of the assets comprising research and development related to the identification of a commercializable product, or directed to particular new or improved goods or processes, and the close substitutes for that research and development. When research and development is directed to particular new or improved goods or processes, the close substitutes may include research and development efforts, technologies, and goods that significantly constrain the exercise of market power with respect to the relevant research and development, for example by limiting the ability and incentive of a hypothetical monopolist to reduce the pace of research and development. The Agencies will delineate a research and development market only when the capabilities to engage in the relevant research and development can be associated with specialized assets or characteristics of specific firms. In assessing the competitive significance of current and potential participants in a research and development market, the Agencies will take into account all relevant evidence. […] The Agencies may base the market shares of participants in a research and development market on their shares of identifiable assets or characteristics upon which innovation depends, for example, on shares of research and development expenditures, or on shares of a related product. When entities have comparable capabilities and incentives to pursue research and development that is a close substitute for the research and development activities of the parties to a licensing arrangement, the Agencies may assign equal market shares to such entities"[44]

The European Commission's Horizontal Merger Guidelines includes as one of the effects to be analysed under merger control, the 'effect on innovation'[45]. According to the Commission's Guidelines, "(i)n markets where innovation is an important competitive force, a merger may increase the firms' ability and incentive to bring new innovations to the market and, thereby, the competitive pressure on rivals to innovate in that market. Alternatively, effective competition may be significantly impeded by a merger between two important innovators, for instance between two companies with "pipeline" products related to a specific product market. Similarly, a firm with a

Stern, 361–404. Chicago: University of Chicago Press. See however Michal A. Carrier, Innovation for the 21st Century: Harnessing the Power of Intellectual Property and Antitrust Law, (Oxford Scholarship Online, 2009), 303 et seq.

[43] Michal A. Carrier, Innovation for the 21st Century: Harnessing the Power of Intellectual Property and Antitrust Law, (Oxford Scholarship Online, 2009), 303 et seq.

[44] DOJ & FTC Antitrust Guidelines for the Licensing of Intellectual Property.

[45] EU Horizontal Merger Guidelines [2004] OJ C31/5, para 8.

relatively small market share may nevertheless be an important competitive force if it has promising pipeline products"[46].

Furthermore, for example, the Horizontal Guidelines stipulate what constitutes antitrust harm and how to address these cases:

"In the first scenario, which is, for instance, present in the pharmaceutical industry, the process of innovation is structured in such a way that it is possible at an early stage to identify competing R&D poles. Competing R&D poles are R&D efforts directed towards a certain new product or technology, and the substitutes for that R&D, that is to say, R&D aimed at developing substitutable products or technology for those developed by the co-operation and having similar timing. In this case, it can be analysed whether after the agreement there will be a sufficient number of remaining R&D poles. The starting point of the analysis is the R&D of the parties. Then credible competing R&D poles have to be identified. In order to assess the credibility of competing poles, the following aspects have to be taken into account: the nature, scope and size of any other R&D efforts, their access to financial and human resources, know-how/patents, or other specialised assets as well as their timing and their capability to exploit possible results. An R&D pole is not a credible competitor if it cannot be regarded as a close substitute for the parties' R&D effort from the viewpoint of, for instance, access to resources or timing.

Both the US agencies and the European Commission has actively considered innovation effects in a series of recent merger cases, either exploring the possibility that a horizontal merger will lead to a loss of innovation by eliminating pipeline products that would likely have entered existing markets or that would have created entirely new value chains, thus preventing consumers from increased choice and variety[47], horizontal vertical or conglomerate mergers that would have harmed the ability of the merged entity's rivals to innovate.[48]

---

[46] Ibid.

[47] US cases: Complaint, Amgen Inc., 134 F.T.C. 333, 337-39 (2002) (identifying a research and development market for inhibitors of cytokines that promote the inflammation of human tissue); Wright Med. Tech., Inc., Proposed Consent Agreement with Analysis to Aid Public Comment, 60 Fed. Reg. 460, 463 (Jan. 4, 1995) (identifying a research and development market for orthopedic implants for use in human hands); Am. Home Prods. Corp., Proposed Consent Agreement with Analysis to Aid Public Comment, 59 Fed. Reg. 60,807, 60,815 (Nov. 28, 1994) (identifying a research and development market for, among other things, rotavirus vaccines). See also Statement of the Federal Trade Commission in the Matter of Nielsen Holdings N.V. and Arbitron Inc., File No. 131-0058, September 20, 2013; and FTC Press Release, "FTC Puts Conditions on Nielsen's Proposed $1.26 Billion Acquisition of Abritron," September 20, 2013. See DOJ press release of April 27, 2015, available at http://www.justice.gov/opa/pr/applied-materials-inc-and-tokyoelectron-ltd-abandon-merger-plans-after-justice-department. See DOJ Complaint, USA vs Bayer AG and Monsanto Company, May 29, 2018, paragraph 61. EU cases: COMP/M. 5675 – Syngenta/Monsanto's Sunflower Seed Business, Commission decision of 17 November 2010, para. 248 and paras 200 and 207 (finding that farmers would have suffered from reduced choice); COMP/ M.6166 – Deutsche Börse/NYSE Euronext, Commission decision of 1 February 2012, section 11.2.1.3.4, confirmed by Case T-175/12, Deutsche Börse AG v Commission, ECLI:EU:T:2015:148; Case No COMP/ M.7326, Medtronic/Covidien, Commission decision of 28 November 2014; Case No COMP/M.7275, Novartis/GlaxoSmithKline's oncology business, Commission decision of 28 January 2015; Case No COMP/ M.7559, Pfizer/Hospira, Commission decision of 4 August 2015 Case No COMP/ M.7278, General Electric/Alstom (Thermal Power- Renewable Power & Grid Business), Commission decision of 8 September 2015.

[48] BRICS, Global Food Value Chains and Competition Law BRICS Draft Report 571 et seq.

It has been alleged that in several of the new EU cases that the European Commission has proceeded to establish a novel theory of harm, that of a significant impediment to industry innovation, while the Commission should have left the idea of R&D poles (or even innovation or R&D markets), to take a broader viewpoint. It can also be argued that the same development is present in the US cases.[49] Interestingly, this view is supported by recent paper written by current and former chief economists for both the US and EU competition authorities. In a recent paper, Giulio Federico, Fiona Scott Morton and Carl Shapiro divided horizontal pharma merger cases in different groups: (i) product-to-pipeline overlaps, (ii) pipeline-to-pipeline overlaps and (iii) overlap in capabilities, where the last group of cases shows a general approach where the lessening of innovation in the industry as a whole has been scrutinized.[50]

The current or former antitrust agencies economists clarifies the basic competitive concerns related to the pipeline products, irrespectively of whether we are discussing product-to-pipeline or pipeline-to-pipeline overlaps that arise in these cases. First, the merger or collaboration may lower the probability of successful product introduction of the pipeline product. This reduction in innovation harms customers by reducing product variety and, in turn, applying less competitive pressure on other products in the future. Second, the merger or collaboration may delay the launch of the pipeline product, i.e. so-called 'shelving' of the drug or component, which generates the same anti-competitive effects, albeit less dramatically. Third, even if the pipeline product is successfully developed despite the merger, future product market competition may be less intense because the merger has brought competing products under common ownership. Merger in reference to combine R&D can thus lead to higher prices.[51]

The main concerns for the economists Federico *et al* hence revolve around the notion of 'business-stealing' effects that is limited through the merger. The theory is that the purchaser, often being a

[49] See Statement of the Federal Trade Commission in the Matter of Nielsen Holdings N.V. and Arbitron Inc., File No. 131-0058, September 20, 2013; and FTC Press Release, "FTC Puts Conditions on Nielsen's Proposed $1.26 Billion Acquisition of Abritron," September 20, 2013. See DOJ press release of April 27, 2015, available at http://www.justice.gov/opa/pr/applied-materials-inc-and-tokyoelectron-ltd-abandon-merger-plans-after-justice
-department. See DOJ Complaint, USA vs Bayer AG and Monsanto Company, May 29, 2018, paragraph 61. The DOJ was specifically concerned about the loss of innovation competition in the "bundle" of traits and herbicides, recognizing the importance of complementarities across these two areas ("Bayer is motivated to pursue trait research in part because successful commercialization of a trait will generate additional returns through the sale of the associated herbicide, and vice versa," DOJ Competitive Impact Statement, paragraph 22). See also DOJ complaint, paragraph 36 ("Going forward, competition between Bayer and Monsanto to develop next-generation weed-management systems is likely to increase. According to a Bayer strategy document, the company's number one 'Must Win Battle' is to '[e]stablish Liberty Link as a foundation trait for broadacre [row] crops and position Liberty herbicide as the superior weed management tool.' "Liberty is the commercial name for Bayer's herbicide, and Liberty Link is the name for its genetically modified seeds). In expressing these concerns, the DOJ specifically emphasized the role of contestability absent the merger, and of greater cannibalization after the merger: "Absent the merger, Bayer and Monsanto would have each incentive to pursue these competing pipeline projects [in next-generation weed management systems] because any new innovation developed would help win market share from the other. In contrast, the merged firm will have different incentives due to heightened concerns that new innovation would simply cannibalize sales" (DOJ Competitive Impact Statement, paragraph 10).

[50] Giulio Federico, Fiona Scott Morton and Carl Shapiro, Antitrust and Innovation: Welcoming and Protecting Disruption, Innovation Policy and the Economy, National Bureau of Economic Research.

[51] Ibid.

larger pharma firm, purchases the target so to lessen or eliminate the target from stealing business from the sale or future sale of the pharma firm's competing drug. Pipeline-to-pipeline overlaps arise when both merging firms own products that are still in the development pipeline. The theory of harm is similar to the one relating to product-to-pipeline overlaps. The key distinction is that the business-stealing effects apply only to future products not yet on the market.[52] Indeed, the focus has migrated from concern of level of investment in R&D to output concerns, an analysis whether the firms are rivals in a future market. However, it is still the possible closing of research and development effort, 'killing the research', that should be identified. As discussed below, other antitrust harms may be identified.

Interestingly, the "killer or shelving acquisitions" can be expected to occur, according to the economists Federico *et al*, if the net incremental profit from introducing the product before the merger exceeds the (remaining) development cost but drops below that level after the merger due to the internalization of business-stealing effects. A "killer merger" can be mutually profitable for both the buyer and the seller due to the standard monopoly preemption effect.[53] An incumbent's incentive to acquire a pipeline product to shut it down is greatest if the pipeline product is a strong threat to the incumbent. So, in essence the likelihood that the pipeline product will become a competitive threat and the likelihood of the purchaser shutting the research down should be evaluated.

When discussing substitute pipeline product possibility to become a competitive threat, the element of uncertainty needs to be raised. The first and perhaps biggest challenge in investigating acquisitions is to identify the counterfactual. The framework for considering these issues is in some respects the same as any other merger involving more mature firms and should to some extent involve the timeframe of 2-3 years; focusing on the issue of whether the target if it remained independent, be a competitive constraint? For example, would it be able to obtain funding from private investors or investment markets?

Interesting, the general standard employed in reference to an analysis depicted above regarding the probability of a target becoming a competitive threat and for competitive overlap have generally historically resulted possibly in harmful mergers to proceed, especially when the target company is working on a project that is relatively unlikely to succeed but would generate large benefits if it did.[54] Effectively, such an approach would allow an incumbent firm to acquire a bold, risk-taking disruptive project so long as the acquisition is done early enough so the acquired project is still more likely to fail than to succeed.[55] That policy of under-enforcement has not protected competition or consumers, and it would suppress innovation and disruption in the long run. It would therefore appear that there is some emerging evidence of a systematic bias towards under-enforcement against anticompetitive acquisitions of R&D intensive start-up firms in the EU and US. This

[52] Ibid.
[53] Ibid, see also Gilbert, Richard, and David Newbery. 1982. "Preemptive Patenting and the Persistence of Monopoly." American Economic Review 72 (3): 514–26.
[54] OECD, op. cit., 37 et seq.
[55] Ibid.

would suggest that a more vigorous approach should be taken to the assessment of acquisitions in other jurisdictions. Indeed, it would appear that some agencies are already taking a stronger stand on such mergers.[56]

The second broad category of mergers, raising innovation concerns involves mergers between firms with competing R&D capabilities. By this they mean mergers involving firms with a broad set of assets targeted at similar innovation areas or trajectories. These assets may include several elements required for the effective discovery, development, and commercialization of new products and processes. These assets can include: intellectual property; access to technology; human capital, such as skilled scientists or engineers; R&D facilities, such as laboratories and specialized equipment; specialized regulatory, distribution, and commercialization assets; intangible assets such as track record with customers; and access to an installed base of existing customers who can be upgraded to a new technology. These assets often make certain firms especially well-placed to discover and bring to market new and improved products.[57]

The business-stealing harm implies that due to the merger, the two firms with overlapping innovation capabilities would not divert profitable sales from each other by coming up with new, innovative products in similar areas, and by competing in the corresponding product market. A merger between two would internalize the 'business stealing' effects, leading to less substitute competition.[58] It is likely that the overlap in underlying capabilities would manifest itself in one or more product or pipeline overlaps, making the first concerns applicable. However, concerns about a merger of two firms with overlapping innovation capabilities can arise even if those overlaps have not resulted in observable pipeline or product overlaps at the specific time when a particular merger is evaluated. This possibility needs according to the to be assessed on a case-by-case basis. A broad perspective is required according to the economists. The theory of overlap and business-stealing imply both the harm that the promising research will be killed off and that the R&D start-up is prevented from developing into a competitor. These harms borders to a general principle of

[56] For EU cases, see COMP/M. 5675 – Syngenta/Monsanto's Sunflower Seed Business, Commission decision of 17 November 2010, para. 248 and paras 200 and 207 (finding that farmers would have suffered from reduced choice); COMP/ M.6166 – Deutsche Börse/NYSE Euronext, Commission decision of 1 February 2012, section 11.2.1.3.4, confirmed by Case T-175/12, Deutsche Börse AG v Commission, ECLI:EU:T:2015:148; Case No COMP/ M.7326, Medtronic/Covidien, Commission decision of 28 November 2014; Case No COMP/M.7275, Novartis/GlaxoSmithKline's oncology business, Commission decision of 28 January 2015 ; Case No COMP/ M.7559, Pfizer/Hospira, Commission decision of 4 August 2015 Case No COMP/ M.7278, General Electric/Alstom (Thermal Power-Renewable Power & Grid Business), Commission decision of 8 September 2015., moreover note that market definition is not included in this framework.

[57] Discussed in length in Björn Lundqvist, 'R&D collaborations under the Competition Rules of the European Union and The Antitrust Laws of the United States' (Edward Elgar monograph, pp. 303, May, 2015. However, also identified in Giulio Federico, Fiona Scott Morton and Carl Shapiro, Antitrust and Innovation: Welcoming and Protecting Disruption, Innovation Policy and the Economy, National Bureau of Economic Research.

[58] Giulio Federico, Fiona Scott Morton and Carl Shapiro, Antitrust and Innovation: Welcoming and Protecting Disruption, Innovation Policy and the Economy, National Bureau of Economic Research.

harm when a potential competitor is terminated, yet the notion of potential competitors is possibly better used when analysing larger pharma mergers (mergers of equals).[59]

There are other forms of harm that may be applicable in reference to a merger or a collaboration. Vertical theories of harm, where the promising research result will become a key input for other firms, and that the loss of competing alternative will drive prices upwards, or even foreclose research result on downstream markets. In reference to Big Pharma purchasing R&D start-ups or entering exclusive licensing agreements with the same, this eliminates the possibility for the R&D start-up firms to engage other firms in case their "partner" refuses to make use of the R&D result, mostly derived from the smaller R&D firm. The merger or collaboration thus eliminates a potential R&D collaborate for other firms, foreclosing the upstream market.[60] There can be conglomerate theories, that the research result will be marketed in a package, where the exclusive drug is tied to other products, and hence foreclose competitors in these tied product markets.

The need to examine overlaps in capabilities is recognized in guide lines by competition agencies in the United States and in Europe. For example, the recently tweaked DOJ/FTC Antitrust Guidelines for the Licensing of Intellectual Property (January 2017) refer to "R&D markets." These guidelines suggest that a joint venture between two firms within the same R&D market (that is, firms with competing innovation capabilities) is unlikely to be anticompetitive if there are at least other four competitors in the relevant R&D market. Indeed, here we see some form of threshold or safe harbour that may be used in the analysis. Should the filing parties show that there are four actual competing efforts that will likely provide affordable drugs for the relevant future market in the relevant jurisdiction, than the merger could be approved.

It should also be pointed out that the definition of overlap R&D centres, R&D joint venture or R&D collaboration in the guidelines do not differentiate between different forms of research and development. By *not* making a distinction between basic and applied research, the agencies grant a wide scope for what constitutes a R&D centre or programme. This imply that overlap in R&D capabilities may with some 'ease' be identified. In reference to biotech and pharma, it seems that all laboratories with sufficiently developed staff and resources, could be interpreted having same capabilities, irrespective of whether the molecule is not identified yet or in phase I, II or III. So, overlap is quite easy to identify. However, it also implies that when conducting a study to identify R&D centres generally a greater number than which is realistic will emerge if such a wide definition of R&D centres is employed. By abandoning the notion of different treatment under the act of basic, applied, and developmental research, the agencies made the guidelines applicable to both basic science and applied design features. It thereby took a step away from the basic idea of linear product development. Previously, for example the US agencies did not want to stipulate a clear market share threshold for when a joint R&D venture should be regarded as becoming dominant or monopolizing the market. The reason for not stipulating a market share threshold was the

[59] See for example the CASE M.7932 – Dow/DuPont, especially annex 4.

[60] A similar theory of harm is used in the COMP/M. 5675 – Syngenta/Monsanto's Sunflower Seed Business, Commission decision of 17 November 2010, para. 248 and paras 200 and 207

conviction that basic research must be judged differently from applied research. Firms conducting basic research in collusion can be pro-competitive and pro-innovation, even though these firms might hold substantial market power on downstream product markets. Correspondingly, jointly conducted applied research, i.e. research close to the end-product, can have extensive effects on the end-product market, e.g., same or similar cost structures and prices, and, hence, reduce competition on the relevant product market even though there exist several other poles of similar research in the market or globally.

Congress, when introducing the US Antitrust collaborate R&D exemption, the NCRA, made the thresholds or safe harbours thereby enacted, available for all R&D efforts equally. In addition, Congress stipulated in the legal history that four venture efforts constituted the threshold for when a venture might raise anticompetitive concerns when enacting the NCRPA. The four venture threshold was later adopted by the antitrust agencies and inserted in, for example, the Justice Department's and FTC's "Antitrust Guidelines for the Licensing of Intellectual Property" from 1995 (hereinafter the IP Guidelines).[61] We see a similar threshold of four R&D ventures in the EU Licensing guidelines, while interestingly, the US Joint Venture Collaboration Guidelines from 2000 stipulate three competing ventures.[62] The four venture safe harbour should presumably be applicable also when looking generally at R&D capabilities.

One can due to the above be somewhat critical to the four competing R&D centre threshold precisely because R&D centres with the same capability can conducted very different R&D. Indeed, as discussed above, the difference between basic research and development close to product market release is very different, and a way to make the test 'crisper' is to limit the threshold to be R&D centres of equal standing, i.e. focusing on R&D with similar innovation areas or trajectories. Moreover, it should also be stressed that the four venture threshold is in reference to the applicability of the safe harbour, while as shown in the case law in reference to R&D collaborations, for the collaboration to be considered having anticompetitive effect on innovation, much less centres should be present.

The four R&D centres threshold can hence be breached by the merging parties, while yet the collaboration is approved if the parties can show that the merger or R&D collaboration creates efficiencies such as lessening spill-over effects, cut cost of R&D and minimise duplicated R&D efforts. Such efficiencies may be quite easy to argue, when the definition of R&D centres is broad.

The US merger case law is a rich source for when pharma mergers should be considered restricting competition in innovation (cf. above). It has also been scrutinised in detail by academia. However, a second source, not so well utilised is the notifications under the NCRPA (National Collaboration Research and Production Act) and under the US Business Review System where parties can notify

[61] DOJ/FTC, Antitrust Guidelines for the Licensing of Intellectual Property (Dep't of Justice & Fed. Trade Comm'n, 1995) (earlier defined as IP Guidelines).

[62] Compare Collaboration Guidelines, 26 et seq. and IP Guidelines, 13, 23, which state four or more independent research efforts in addition to the scrutinized effort.

R&D collaborations that they would like to have scrutinized to the Department of Justice. The letters coming out of this system shows some indication on how R&D collaborations are conducted and should eb conducted to pass the muster for being a benign horizontal collaboration.

The institutional organisation of the scrutinized research efforts differs greatly. However, as mentioned above, there is one striking similarity in several of the joint R&D ventures scrutinized under the US Business Review Letter procedure: apart from the industrial members there is often a public entity, e.g., a department of a university, which supervises the joint venture and is contracted to perform the research by the joint venture. Researchers at the Justice Department have on two occasions analysed R&D agreements which had been filed under the NCRPA so as to enable the participants to gain access to the safe harbour.[63] From data consisting of 142 Joint R&D agreements, Suzanne Majewski concluded that several joint R&D agreements were entered into by on the one hand a product market competitor, i.e. vertically integrated firms, and, on the other, a R&D focused firm. Majewski's research also shows that there is a new sort of firm emerging: the R&D only firms. These R&D exclusive firms often connected to academic institutions tend to cater to product market competitors but conduct their work exclusively in the innovation and technology markets. By assigning R&D to the R&D specific firm, costs were reduced and duplicative efforts were minimised. They also avoided spillover effects and opportunistic problems of having researchers from the firms interacting. However, by avoiding scientists interacting, supposedly welfare-enhancing exchange of ideas (spillover) was minimised. Synergy effects are lost if the parties do not conduct the research jointly. This was also supported by the fact that in only 14 percent of the analysed R&D joint ventures was a scientist allowed to rotate between the participating firms.

It should be noted that FTC has recently utilised the innovation market concept and even a broader industry wide research focus in some merger cases, and some mergers have been challenged. However, interestingly, when analysing Business Review letters from 1968 to 2014 the Justice Department has never – ultimately – rejected any joint R&D collaboration. Moreover, the general approach appears also to be more permissive today than previously. Arguably, this contrasts with the fact that privately funded basic research is becoming less and less common;[64] at least, private parties perform such research with less and less regularity.[65]

Also the EU Commission has historically had a lenient policy towards R&D collaborations, as shown also in early cases such as *Pasteur Mérieux-Merck*[66] In *Pasteur Mérieux-Merck* two leading suppliers of human vaccines with very high market shares in a number of relevant product markets created a joint venture in which they brought together their total European vaccine business relating to the existing vaccines and future vaccines. The joint venture would thus develop new

[63] S. E. Majewski, How Do Consortia Organize Collaborative R&D? Evidence from the National Cooperative Research Act (SSRN 2004), 12 et seq.; S. E. Majewski & D. V. Williamson, Endogenous Spillovers, Strategic Blocking, and the Design of Contracts in Collaborative R&D: Evidence from NCRA filings of R&D Joint Ventures (SSRN 2002), 20 et seq.
[64] See, e.g., the Economist March 3-9, 2007, The Rise and Fall of Corporate R&D, 69 et seq.
[65] Ibid.
[66] Commission decision Pasteur Mérieux-Merck, OJ 1994 L 309/1.

vaccines based on previous knowledge and new research performed by the parents. It would exclusively sell these existing and future vaccines in Europe.[67]

The market was highly concentrated, with three world suppliers: Pasteur Mérieux, Merck and Smith Klein Beecham (SKB). The market had high entry barriers: costly and high risk R&D; production subject to patents, proprietary know-how and national regulatory licenses. Cross-licensing between the major suppliers and different distribution methods in various Member States added to the difficulties to overcome before entering the market. The Commission concluded that the parties were actual or at least potential competitors for a number of existing and future vaccines. The transfer of their businesses including production, patents and research to a combined entity would eliminate competition (rivalry) between the parents. Furthermore, competition in relation to third parties would be eliminated. The agreement limited the possibility for the parents of licensing third parties under the patent transferred to the joint venture. Third parties were therefore effectively foreclosed from the downstream markets, given the strong position the parents had in the technology market, i.e. IP-market.

Interestingly, the Commission also stated that competitors were restricted by the joint venture since their ability to form cooperative arrangements would diminish when two major competitors were no longer eligible for collaboration. Moreover, some ancillary agreements regarding the distribution in France and Germany were considered anticompetitive since they restricted both intra-brand and Interbrand competition. They not only restricted each licensee or distributor in each Member State not to compete with each other, but also foreclosed products and licenses in light of the strong market position of the parent firms.

The joint venture was exempted after extensive rewriting of the agreements. The parties agreed to open up for competition from the distributors and licensees in Germany and France, i.e. making these firms potential competitors. In the light of those changes all four conditions in Art. 85(3) were fulfilled. R&D competition did not seem to have matter and was not taken into consideration. Indeed, no indication of protecting poles of research in the *Pasteur Mérieux-Merck* case, for example. The result of that decision was that the Commission accepted the fact that there would only be two research poles in the world *ex post* the implementation of the joint venture agreement.

That R&D collaboration are treated more lenient than merger is perhaps not surprising. Several economists claim that killer acquisitions may lessen rivalry in innovation yet states that R&D collaborations are less risky because R&D joint ventures still imply that we will have two different competitors emerging on the relevant market with separate products, so even though they will base their products on the same innovation, they will still compete in price.[68]

[67] See Commission, Report on Competition Policy 1994, 108 et seq. See also the Commission decision Pasteur Mérieux-Merck, OJ 1994 L 309/1.

[68] See for example Giulio Federico, Fiona Scott Morton and Carl Shapiro, Antitrust and Innovation: Welcoming and Protecting Disruption, Innovation Policy and the Economy, National Bureau of Economic Research.

From the case law of the antitrust and competition law agencies, US Guidelines and system to notify R&D collaborations under NCRPA and EU Guidelines and block exemption in reference to R&D collaborations[69], we also know that R&D collaborations and licensing agreement with a major collaboration part (e.g. setting up science boards exchanging researchers and assigning them to conduct R&D under the license agreement) are not required to be notified, if they do not fulfil the requirements of being concentrations/mergers.

However, R&D collaborations between more developed pharma companies and R&D start-ups as well as licensing agreement in the pharma sector seem similar to mergers in that they also lead to lesser products are being released on the relevant market. Indeed, pharma licensing agreements as well as R&D collaborations may very well *de facto* imply a concentration in the industry and a loss of a research rival.

From an EU perspective, it is interesting to note that the block exemption for R&D collaborations covers collaborations where the research institutes, academic bodies, or undertakings which supply research and development as a commercial service without normally being active in the exploitation of results may agree to confine their use of the results for the purposes of further research only. As discussed above, several R&D collaborations in the human medicine sector consist of these forms of collaborations, and the exemption would imply that such collaboration with the aim that only the pharma firms should be selling the drug is considered benign and even upfront legally exempted under EU Competition Law as they are encompassed by the block exemption.[70] Furthermore, when a firm outsources previously captive R&D to specialized companies, research institutes or academic bodies, which are not actively exploiting the results, such agreements shall not be regarded as not even be encompassed by Art. 101(1) and thus are *per se* legal.[71] The block exemption for technology transfer (licensing) is similar. Licensors may be restricted under the license agreements to pursue other commercial activities than R&D. Given the fact that the R&D start-ups in the pharma sector often only contains one true asset, the patents covering the molecule, mergers and R&D collaborations, where the relevant covenants imply that the patent and know-how is exclusively transferred to Big Pharma, should from an economic point of view be placed in the same category. They are both as concentrative, and the risk of killer or shelving activities by the larger pharma firm is as relevant for these mergers as well as for the R&D collaborations.

The US perspective is in no way better. Judging from the black lists in the research and development block exemption, the EU Commission is actually somewhat more interested in *ex post* competition. Indeed, the EU block exemption seems to take into consideration that the parties to the joint R&D may start as non-competitors, but when the collaborations end, they will be

[69] For a comprehensive analysis of all Business Review letter from 1968 to 2014 in reference to R&D collaboration see Björn Lundqvist, 'R&D collaborations under the Competition Rules of the European Union and The Antitrust Laws of the United States' (Edward Elgar monograph, pp. 303, May, 2015.
[70] That the R&D specialised firm is allowed to conduct further research is natural. Research normally do not fall inside the scope of the patents and are not and infringement of the patents often transferred to the pharma firm.
[71] Horizontal Guidelines para. 57.

competitors.[72] Indication of this can be seen that, for example, non-access for the parties to the joint R&D to the R&D result is black-listed.[73]

Any comparable rules protecting R&D-intensive firms are missing in the US both when analysing the guidelines and the NCRPA. The US Congress was more concerned with the fact that a joint R&D venture can be used as a vehicle for cartels (cf. the restriction on covenants for transferring information under the joint R&D venture), even though also stating that participants must be free to conduct research unilaterally and in combination with other firms. Competitors are also prevented from dividing the market between them. Nonetheless, the parties under the NCRPA can restrict the use of the result to only one party.[74]

From the above, it seems clear that both killer acquisitions and licensing agreements (including R&D collaborations, or not) have suffered from under enforcement of competition law, and that neither US antitrust agencies nor he EU Commission has sufficiently addressed the innovations concerns raised in these regards.

3. A BRICS and developing Country Perspective

Perhaps the most important proposal that has emerged from the debate over the killer acquisitions has been to reverse the burden of proof and create a rebuttable presumption in reference to merger that trigger the risk of being a killer acquisition. This has been proposed by two former chief economists in the EU in respective paper (Professors Valletti and Motta), in the Crémer report, the Stigler review, and in the ACCC digital review.[75] Moreover, Shapiro and Hovenkamp in 2018 argued that legislation should go further and require 'clear and convincing evidence' from the parties that the merger is not anticompetitive before they are approved.[76] The debate is bordering to the larger discussion regarding structural presumption. The proper role for market structure in merger review usually devolves to the familiar debate over what is called the "structural presumption." This term is shorthand for the belief that mergers beyond certain concentration and/or share thresholds are, with high probability, likely to be anticompetitive, and hence enforcement by the agencies and courts can rely on those thresholds for predicting anticompetitive outcomes from such mergers.[77]

[72] Case COMP/ M.5984 – Intel/McAfee, Commission decision of 26 January 2011; Case COMP/ M.6564 – ARM/GIESECKE & DEVRIENT/GEMALTO JV, Commission decision of 6 November 2012; Case No COMP/M.7688 – Intel/Altera, Commission decision of 14 October 2015

[73] However, in comparison with the 2000 R&D block exemption, non-challenge clauses are not black-listed but grey-listed.

[74] Björn Lundqvist, Standardization under EU Competition Rules and US Antitrust Laws – The Rise and the Limits of Self-Regulation (Edward Elgar, 2014).

[75] See also the OECD op cit, p. 37 et seq.

[76] Ibid.

[77] See generally John Kwoka, The Structural Presumption and the Safe Harbor in Merger Review: False Positives or Unwarranted Concerns?, 81 ANTITRUST L.J. 837, 837-872 (2017) (finding that empirical data from past mergers confirms the presumption that concentration over a certain threshold produces anticompetitive effects). For a

From a BRICS or global perspective, presumption can work well because it can be difficult to obtain relevant information regarding, for example, R&D centres capabilities. A BRICS competition authority could hence make use of a wide notion of R&D centres, R&D capabilities and pipeline research when identifying whether the acquirer and the target are rivals (i) product-to-pipeline overlaps, (ii) pipeline-to-pipeline overlaps or (iii) overlap in capabilities. The first step could be in the hands of the competition authority, where the merger or collaboration after notification should be screened whether it could risk triggering a relevant antitrust harm, inter alia restricting innovation by either creating such an overlap that research is likely to be dismantled, lessen research spending, restrict access to relevant R&D strains, that business-stealing is likely to decrease in future markets or prices would decrease in the same. This analysis could be conducted with a wide scope identifying relevant R&D poles, innovation markets, or even R&D capabilities.

The second step when making the broader analysis whether there are other comparable R&D centres that still will constitute competitive threats to the merged firm or collaborators, the investigation could become more stringent, having the notifying parties bear the burden of identifying such centres. Here the focus and stage of the R&D should be analysed so that, de facto, that the R&D centres identified are rivals conducting similar or same research as the promising research conducted by the target. Indeed, these centres should have pipeline or marketed alternatives to the product being developed by the merging parties. As the economists discussed above stated, to requiring the government to offer precise quantitative evidence of future competition to meet its burden of proof regarding unilateral innovation effects would be tantamount to giving up on merger enforcement relating to the development of future products that are early in the development stage or not. However, to grant the parties a burden of proof for the second prong in the innovation rivalry test sketched above could be regarded as benign even pro-competitive.[78] Indeed, if they are not able to show four or more relevant rivals in R&D, then the presumption would be that the merger or collaboration should be considering violating the relevant competition rules.

A Competition Court in a BRICS country might also take in consideration in reference to the four R&D centre threshold, where the R&D centres are situated and that global exhaustion is not present in the human medicine field. There is no global market for pharmaceuticals and prices can vary substantial between regions, while parallel import and export are restricted. Indeed, the question is whether the search for competing R&D centres should be done globally or in geographic areas that imply that the drug or vaccine in fact will be provided to a price that reflects the right to

comprehensive look at merger retrospectives, see generally JOHN KWOKA, MERGERS, MERGER CONTROL, AND REMEDIES: A RETROSPECTIVE ANALYSIS OF U.S. POLICY (2015).

[78] By reversing the burden of proof in concentrated markets and presume that such mergers will be anticompetitive, and hence should be blocked, absent evidence to the contrary. The EU has a presumption in regular merger law doctrine. In the US the presumption was established in United States v. Philadelphia National Bank, though only recently, Shapiro & Hovenkamp (2018) have recommended strengthening this presumption, by codifying it in a bill that would prevent it from being undermined by the courts.

health for the citizens in the jurisdiction in question.[79] If that is not the case in reference to a R&D centre, then that centre should be disregarded in the analysis.

The failure of the human medicine markets as well as the human rights triggered by the need to obtain medicine to affordable prices, may in fact imply that a competition authority need to take into consideration whether the merged firm will not only lessen innovation, but also the price given to the innovative drug that hopefully emerge from the relevant R&D.[80]

The price level of drugs globally is very different and it is important to predict for what price a drug will be made available to the public. Indeed, if the target is situated in a BRICS country, while the larger pharma firm originates from a country with substantial higher drug prices, implying that the price-level of the drug may very well increase due to the merger and the transfer of the promising molecule to a higher price country, that could also be taken into consideration in the merger or collaboration analysis; indeed, whether the remaining R&D centres are enough to provide cheap and cost efficient drugs for the future also in the BRICS or developing country jurisdiction in question. It seems clear that prices can be excessive in the human medicine industry to a level that competition law is triggered[81], which is also a concern for a merger or joint venture review.

When a collaboration or a merger is notified, the ancillary agreements in reference to key individuals should be included in the analysis. Are they required to enter into option programmes or to purchase options or shares in the firm, which imply that they are locked-in for a certain period of time, or otherwise risk the personal investment (which can be substantial) made in the share and option programme. Are they not only locked-in but also encompassed by non-compete and confidentiality agreements that go beyond what competition law may find efficient, i.e. that these stipulations indeed lessen innovation because they effectively neutralised the perhaps most prominent R&D capability, the researcher. Indeed, in biotech and other areas innovation is connected to individuals to a greater extent than in other areas of pharmaceutical research.

In reference to the test applied or when scrutinizing whether the proposed efficiencies would outweigh the potential anticompetitive effect of the merger identified because there are, for example, fewer the four competing R&D efforts within the relevant industry and geographic area identified,

[79] Carrier argues that the Genzyme/Novazyme case can be interpreted that the FTC took into consideration the great efficiencies the merger created and that the drug reached the market much sooner due to the merger. An argument in the same vein could be to take into consideration that the drug actually reaches the market to a price which is affordable to consumers. Michal A. Carrier, Innovation for the 21st Century: Harnessing the Power of Intellectual Property and Antitrust Law, (Oxford Scholarship Online, 2009), 303 et seq.

[80] It should also be stressed that in the recent cases where innovation where taken into consideration by the EU Commission, limited geographic markets where identified. Cf. CASE M.7932 – Dow/DuPont, and COMP/M. 5675 – Syngenta/Monsanto's Sunflower Seed Business, Commission decision of 17 November 2010, para. 248 and paras 200 and 207

[81] See for example the Aspen saga, https://ec.europa.eu/commission/presscorner/detail/en/QANDA_20_1339. It should be mentioned that Aspen purchased the six cancer medicines from another company in 2009, and no merger rules were triggered at the time.

the question is how they should be evaluated. The burden of providing the proof for efficiencies will be the parties. However, how should these efficiencies be evaluated and against what bench mark? The Furman review advised that there should be a shift from the 'balance of probabilities' test to what it called a 'balance of harms approach' or an 'expected value test'. Such an approach is also proposed in the Stigler report, and has received support from Crémer, Pecman et al (2020), and Motta & Peitz (2020) amongst others.[82] The approach would therefore differ in that it would lead to intervention in circumstances where the risk of harm is lower, but the scale of harm is high, and hence the expected value of the harm is high (probability of harm multiplied by magnitude of harm).

However, irrespective of what test to use, in the end from a competition policy or industry policy perspective, a realistic counterfactual in these cases imply that the R&D start-up has several potential purchasers or firms that provide the service of conducting clinical test and to develop the promising substances to marketed drugs, since it is very likely that the R&D start-up cannot conduct the development work in-house. Or, is the purchaser de facto the only firm willing and able to develop the research further? From a competition law analysis, the merger analysis may need a counterfactual, a benchmark to be evaluated against otherwise, the merger needs to be approved. That the Big Pharma firm is not the only solution for developing drugs. The existence of investors or purchasers that may in theory purchase the promising molecule absent the investment by the Big Pharma company. The contrafactual should be made available also within the competition law analysis, and only then can a contrafactual test or a balancing test be used with more precision. Indeed, in the end the consumer benefits and welfare for having the start-up compete by itself or together with another partner, be weighed against the benefits of the collaboration of merger with the Big Pharma. Because, in the end, the researchers behind the promising molecule are incentivised by the prospect of selling the molecule, and the possibility for them to exit needs to be protected.

4. Conclusion

In this double paper, we have analysed so-called 'killer acquisitions' and other detrimental collaborations. Firstly, by analysing economic doctrine in part I. Secondly, by looking at the practice in the human medicine industry. Thereafter, thirdly, in part II, we analysed the merger rules, and whether they can catch and facilitate the tests to identify the problematic cases and resolve these cases.

The problem with 'killer acquisitions', is the following: when market leading companies are able to fully integrate an emerging competitor or its assets into its own business by acquiring it in the early stage of its development and change or discontinue the original activities of the acquired company, or, on the other hand, terminate its own in-house competing effort and develop the

[82] See discussion in OECD, op. cit.

acquired alternative instead. From a competition policy perspective, such acquisitions may require a preventive competition law investigation, especially with regard to protecting innovation potential and innovation competition in human medicine or similar industries even though the target is not precent yet on any relevant product or service market.[83] Several Competition Authorities seem bend on trying to identify these transactions precisely based on the discrepancy. That a purchaser acquires a firm for a substantial remuneration without gaining any turn-over, a transaction value test.

However, to stipulate a new test based on only transaction value is difficult because no one really knows the difference between the transaction value of a 'killer acquisition' compared to the transaction value of other forms of acquisitions. Moreover, the transaction value can be difficult to calculate should it include several parts where remuneration is paid out in different milestones in the form of options, shares or even salary. These milestones can moreover be connected to active participation of the sellers and innovators, as part of the management or the scientific board of the target, ex post the merger.[84] Moreover, thresholds may very well push down prices, where firms with killer acquisition intention seek "cheap" targets. "Cheap" targets in the biotech and pharmaceutical industries imply going after the early R&D start-ups, where they are conducting pre-clinical or even basic research. We suggest that a way to circumvent this is to oblige pharma and biotech firms with a special status (size) to notify all of their acquisitions.[85]

Indeed, the conclusion of this paper is somewhat controversial, yet mirrors suggestions provided in other reports. We suggest (i) that certain firms in the pharmaceutical sector should be obliged to notify all their transactions, (ii) imply that a notification system should be put in place also for license agreements, R&D collaborations and strategic alliances that do not imply change of control of the R&D start-up if the contracts contain certain covenants that restrict the R&D start-up and its key employees and (iii) the test for finding a violation should be based on presumptions and the burden of proof should switch to the parties, while (iv) the dysfunctional parts of the human medicine industry in reference to high price levels of drugs need to be taken into consideration. These points are developed below.

---

[83] Bundeskartellamt, Guidance on Transaction Value Thresholds for Mandatory Pre-merger Notification (Section 35 (1a) GWB and Section 9 (4) Kart G) https://www.bundeskartellamt.de/SharedDocs/Publikation/EN/Leitfaden/Leitfaden_Transaktionsschwelle.pdf?__blob=publicationFile&v=2

[84] European Commission, Replies to the consultation, https://ec.europa.eu/competition/consultations/2016_merger_control/index_en.html; CMA contribution to the Evaluation of procedural and jurisdictional aspects of EU Merger Control, 13 January 2017 https://ec.europa.eu/competition/consultations/2016_merger_control/united_kingdom_competition_and_markets_authority_en.pdf. One way to identify. A transaction value is to require the filing party the net present value as of closing of highest remuneration that can be paid out under the transfer agreement. According to the German/Austrian Guidelines for establishing a transaction value" the value of a consideration that includes earn-out payments or other uncertain components or components whose value fluctuates can be validated more easily if not only the buyer but also the seller14, independently of one another, describe and explain how each of them calculated the consideration value." Ibid, para. 21.

[85] Furman et al. (2019)

However, we also argue that the killing of promising research can be organised under exclusive licensing agreements, R&D collaborations or other strategic alliances. These forms of joint ventures can imply that Big Pharma gain the control of the potential competing substance and the relevant R&D capabilities and can terminate, slow down and lock-in such research efforts to the detriment to competition. We therefore suggest that also these forms of collaborations should be notified.

Generally, a difference could be made between collaborations that is purely financial in character, while collaborations with a strategic aim, where a larger pharma firms acquires the exclusive right to use and develop a research result by or in collaboration with a R&D start-up should be required to be notified by the parties to the collaboration irrespectively whether the collaboration amount to a license or strategic collaboration. Indeed, require agreements originating from the human medicine industry that certain triggering covenants to be notified. Should the collaboration agreement for example imply exclusive transfer of a license to use a patent covering a molecule or antidote, include non-compete obligations or that only the larger firm will *de facto* post termination of the collaboration be selling the drug and conduct incremental innovations, while the start-up R&D focused firm is required to exist the product market after the end of the collaboration, then such collaboration should be required to be notified, even though the collaboration is neither full-functioning nor concentrative.[86]

This would imply that the collaboration should be notified pre-implementation, while not requiring the parties to wait for a decision from the relevant competition authority. That the parties should notify and they can set-up the collaboration, while risking that the competition authority requires the parties to break up the collaboration should it be considering violating the relevant rules within a certain period of time.

Moreover, the ancillary agreements in reference to key individuals should be included in the analysis. Are they encompassed by non-compete obligations and confidential covenants that are beyond reasonable or required to purchase share options in the firm, which imply that they are locked-in for a certain period of time, or otherwise risk the personal investment made in the programme, the anticompetitive effect or lock-in such R&D capability should be scrutinised.

From a BRICS or global perspective, a competition law analysis based structured presumptions can work well for analysing whether the transaction or collaboration is detriment to innovation and competition. That imply finding overlaps in R&D between the merging or collaborating parties and whether there are other competition R&D centres. It can be difficult to obtain relevant information regarding, for example, R&D centres capabilities. A BRICS competition authority could hence make use of a wide notion of R&D centres, R&D capabilities and pipeline research when identifying whether the acquirer and the target are rivals (i) product-to-pipeline, (ii) pipeline-to-

[86] It should be acknowledged that this is often the case, and the research ventures require the smaller R&D driven firm to exit the research area often ex post the collaboration. Interestingly, many economists have not yet recognised this. See Shapiro etc stating" An RJV would be less anticompetitive than a full merger because it would preserve price competition in the current and future product market."

pipeline or (iii) in R&D capabilities. The first step could be in the hands of the competition authority, where the merger or collaboration after notification should be screened whether it could risk triggering a relevant antitrust harm, inter alia restricting innovation by either creating such an overlap that research is likely to be dismantled, lessen research spending, restrict access to relevant R&D strains, that business-stealing is likely to decrease in future markets or prices would decrease in the same. This analysis could be conducted with a wide scope identifying relevant R&D poles, innovation markets, or even R&D capabilities.

The second step when making the broader analysis whether there are other comparable R&D centres that still will constitute competitive threats to the merged firms or collaborators, the investigation could become more stringent, having the notifying parties bear the burden of identifying relevant competing research centre. Here a heighten analysis of the R&D centres identified should be conducted whether they actually constitute a future competitive threat.

From a BRICS or global perspective, there is moreover an interest in reference to where the relevant R&D centres identified in the second step are situated and that global exhaustion is not present in the pharmaceutical industry. When establishing whether there are competing R&D centers to the merger or collaboration the parties should show whether it is likelihood that a new drug form the competitors will reach the market to an affordable price.

Indeed, the question is whether to search for R&D centres globally or in geographic areas that imply that the drug or vaccine in fact will be provided to a price that reflects the right to health for the citizens of the jurisdiction in question. If the target is situated in a BRICS country, while the larger pharma firm originates from a country with substantial higher drug prices, implying that the price-level of the drug may very well increase due to the merger and the transfer of the promising molecule to a higher price country, that could also be taken into consideration in the merger or collaboration analysis; indeed, whether for example a general threshold of four R&D centres are enough to provide cheap and cost efficient drugs for the future also in the jurisdiction in question.

References

Hayek F.A. (ed.) Individualism and Economic Order // University of Chicago Press. 1948. 92.

Grossman G., Shapiro C. Research Joint Ventures: An Antitrust Analysis. P. 315.

Jorde T., Teece D. Innovation and Cooperation: Implications for Competition and Antitrust // Journal of Economic Perspectives. P. 75.

Jorde T., Teece D. Rule of Reason Analysis of Horizontal Arrangements: Agreements Designed to Advance Innovation and Commercialize Technology // Winter Antitrust Law Journal. 1993. P. 579.

Katz M. An Analysis of Cooperative Research and Development // Journal of Economics. 1986. P. 527.

Lerner J., Merges R. The Control of Technology Alliances: An Empirical Analysis of the Bio-technology Industry // Journal of Industrial Economics. 1998. P. 125.

Lundqvist B. Killer Acquisitions and other forms of anticompetitive collaborations in time of Corona. Part 1. Working Paper WP22/2021/01 // Series WP22 BRICS Competition Law and Policy Series.

Martin S., Scott J. The nature of innovation market failure and the design of public support for private innovation // Research Policy. 1999. P. 437.

Schumpeter J. Capitalism, Socialism and Democracy. 1976. P. 82.

Ландквист, Б. Й.

«Убийственные» слияния и поглощения и другие формы антиконкурентного сотрудничества в период пандемии COVID-19. Ч. 2 [Электронный ресурс] : препринт WP22/2022/01 / Б. Й. Ландквист; Нац. исслед. ун-т «Высшая школа экономики». – Электрон. текст. дан. (600 Кб). – М. : Изд. дом Высшей школы экономики, 2022. – (Серия WP22 «Конкурентное право и политика БРИКС»). – 38 с. – На англ. яз.

В препринте, состоящем из двух частей, анализируются так называемые убийственные слияния и поглощения и другие формы антиконкурентного сотрудничества. Утверждается, что «убийственные» слияния и поглощения – явление, которое на практике происходит не только в традиционной форме (в виде слияния, присоединения и иных форм реорганизации компании), но в гораздо более широких и завуалированных формах сотрудничества. В первом препринте проанализированы различные формы сотрудничества, в том числе стратегические альянсы в области НИОКР, которые направлены на удержание ключевых сотрудников и менеджмента приобретаемой компании, а не на традиционную смену контроля над предприятиями и активами компании. Сделан вывод о том, что компетентным органам необходимо осуществлять гораздо более тщательный контроль экономической концентрации: контроль за сделками слияний и поглощений компаний и контроль за соглашениями компаний о проведении совместных научных исследований, особенно в области фармацевтической индустрии.

В данной второй части препринта (Часть II) анализируется вопрос эффективности правового регулирования в области экономической концентрации для решения проблем, обозначенных в первой части препринта (Часть I). Придя к выводу о том, что правовое регулирование в области экономической концентрации несовершенно, автор предлагает пути модернизации правовых норм с целью повышения конкуренции и инновационной составляющей на фармацевтических рынках. В частности, автор предлагает два изменения правового регулирования: во-первых, установить для отдельных фармкомпаний обязанность уведомлять обо всех случаях сотрудничества с компаниями, которые подразумевают изменение контроля над разработками и исследованиями (в том числе исследовательскими активами или результатами исследований). Во-вторых, автор предлагает сделать инновации ключевым показателем при оценке сделок экономической концентрации. По мнению автора, крупные фармкомпании должны уведомлять антимонопольный орган также при создании стратегических союзов, в том числе посредством заключения лицензионных соглашений и соглашений о проведении опытно-конструкторских работ, если контроль над перспективными исследованиями передается этой фармкомпании. Кроме того, автор предлагает тщательнее изучать не только непосредственно соглашения о сотрудничестве, но также иные соглашения между фармкомпаниями и остальными участниками рынка, включая акционерные соглашения, опционные программы, которые подразумевают, что ведущие исследователи связаны явным или неявным соглашением о запрете конкуренции. Предлагаемые изменения правового регулирования рассматриваются автором в контексте стран БРИКС и развивающихся стран.

Ключевые слова: слияния и поглощения, стратегические альянсы, конкурентное право, убийственные слияния и поглощения, фармацевтика, БРИКС

Ландквист Бьерн Йонас, ведущий научный сотрудник Международного центра конкурентного права и политики БРИКС Национального исследовательского университета «Высшая школа экономики»; E-mail: bjorn.lundqvist@juridicum.su.se

Препринты Национального исследовательского университета «Высшая школа экономики» размещаются по адресу: http://www.hse.ru/org/hse/wp

Препринт WP22/2022/01
Серия WP22
«Конкурентное право и политика БРИКС»

Бьерн Йонас Ландквист

«Убийственные» слияния и поглощения и другие формы антиконкурентного сотрудничества в период пандемии COVID-19
Часть 2

(*на английском языке*)

Публикуется в авторской редакции

Изд. № 2590