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Antitrust in Life Sciences 2021

#2 Life Science Mergers: Innovation, Exclusion and Killer Acquisitions

Webinar - 23 June 2021*

"In September 2019, nine U.S. senators sent a letter to the Federal Trade Commission Chair urging greater scrutiny of pharmaceutical antitrust."

Thomas Horton

Thomas Horton

Thomas Horton introduced the discussion, referring to the much-discussed paper by Colleen Cunningham, Florian Ederer, and Song Ma. In this paper named "Killer Acquisitions", the authors argue that incumbent firms in pharma may acquire innovative targets solely to discontinue the target's innovation projects and to preempt future competition. They conservatively estimated based on their econometrics that 5.3–7.4 percent of acquisitions in pharma were killer acquisitions. In addition, they found that those acquisitions disproportionately occurred just below the thresholds for antitrust scrutiny. This paper has been much debated, and variations on its themes have emerged. Enforcers and lawmakers have taken steps to investigate the matter. In September 2019, nine U.S. senators sent a letter to the Federal Trade Commission Chair urging greater scrutiny of pharmaceutical antitrust issues and expressing serious concerns about anti-competitive impacts of deals and mergers and acquisitions and collaborations on innovation as well as pricing.

A year later, in September of 2020, the Department of Justice and the U.S. Patent and Trademark Office held two days of formal hearings on innovation and antitrust in the life science sector. All of these events demonstrate how timely issues around innovation competition in life sciences are.

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* Tanguy Laurioz drafted the following synthesis for Concurrences. The views expressed in this presentation are those of the speakers and do not necessarily represent those of the institutions to which they are affiliated.

Pauline Kennedy

> The acquisition may have some positive welfare effect on innovation in the long run in a dynamic setting because the mere fact of being able to be acquired may spur potential innovation."
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> Pauline Kennedy

Pauline Kennedy reflected on the "Killer Acquisitions" paper by Cunningham, Ederer and Ma. In the hypothesis that they describe, the killer acquisition motive is present. In this setting, the target of the acquisition has an innovative project under development. A good example of this would be branded drugs, but the same goes for any sophisticated product that requires important development with an uncertain outcome. Drugs involve years of experiments followed by an *in vitro* test period, then an *in vivo* before clinical trials. In killer acquisitions, the incumbent does not seek to integrate and foster the innovative project into their product portfolio. Rather, the acquirer wants to terminate the innovative project to remove it from the competitive landscape. In this case, competition is harmed, and an innovative product is lost. The authors develop a model that allows us to identify when the killer acquisition motive is the strongest. In particular, it is strong when the innovative project overlaps or substitutes for a product that the incumbent has, and even stronger if that product of the incumbent is more valuable. It is more valuable if the patent is still young and has many monopoly years ahead.

The authors then develop an empirical study based on the acquisitions of branded drugs to determine how likely it is for drug development of a product to be discontinued after acquisition if the incumbent has an overlapping product. They find that nascent drug projects that are acquired by an incumbent where the incumbent has an overlapping drug are 23 percent more likely to be discontinued. As mentioned by Mr Horton, they also find that somewhere between 5 and 7 percent of acquisitions in their sample have killer acquisition motives. Consumers are harmed by these types of acquisitions. They face higher prices because there is less competition, but they are also denied the innovative drug or the innovative product in this case. On the other hand, both the incumbent and the entrepreneur can be made better off by the acquisition. The acquisition may have some positive welfare effect on innovation in the long run in a dynamic setting because the mere fact of being able to be acquired may spur potential innovation. In terms of recent cases, the FTC's challenge of Questcor's acquisition of Synacthen resulted in an important fine, together with an obligation to develop the drug project that allegedly motivated the acquisition.

Noel Watson-Doig

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> Noel Watson-Doig

Noel Watson-Doig focused on policy developments in the European Union that may allow the Commission to review transactions giving rise to innovation concerns, even though national thresholds in the Member States may not be met. Through a new interpretation of Article 22 EUMR, the Commission has changed its policy of discouraging referrals from the Member States where they lacked jurisdiction to stating that they will now encourage references where the Member States do not have domestic jurisdiction. The rationale for this is very much to tackle a perceived enforcement gap in the European Union. Killer acquisition theories –in life sciences and elsewhere- are an important part of those concerns. This is potential of particular concern now that the United Kingdom has left the European Union because it had up to the point of leaving the most flexible jurisdictional regime in the European Union as they were able therefore to capture mergers that other regimes were unable to capture.

This change is a significant development for dealmakers in the European Union. It means that any transaction that can be perceived by national competition authorities or the European Commission as raising competition concerns in that Member State or the European Union could end up being reviewed by the European Commission, no matter how small the target, even after the deal is closed.

The European Commission has now given itself much more latitude and flexibility to work in tandem with national competition authorities to capture transactions that it regards as potentially raising issues about innovation and potentially killer acquisitions.

This is central to the whole life sciences deal structures and the particular candidate cases that will now be potentially reviewable by the Commission but were not previously. The Commission said in its Guidance that third parties may contact the Commission or national competition authorities to suggest a referral. This is encouraging competitors to make references. One should also note that once a referral has been made to the Commission, a suspensory obligation applies, and the deal cannot be closed until it is cleared by the Commission. This change in policy means that pharma deal doers will never be able to completely rule out merger review when they engage in acquisitions. *Illumina/Grail* is an interesting case. Strictly speaking, it is not a killer acquisition, but it is certainly a high-profile deal involving innovation. On this deal, the European Commission has accepted a reference from the several EU Member States under the new Article 22 reference regime from domestic competition authorities. This reference and the acceptance of the reference by the Commission is currently under appeal to the General Court of the European Union.

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Niels Ersbøll

Niels Ersbøll also discussed the new Article 22 policy. On its scope, it is not limited to killer acquisitions. The terms of the Guidance are not so narrow that they only would capture acquisitions by a large incumbent of an innovative startup to remove that potential competitor from the market. In a contribution to the OECD, the Commission explained that concerns about discontinuation or killing of innovative projects are not necessarily characteristic only to the acquisition of startups, but may arise also in the context of mergers of established companies. In its Working Paper on the new policy, the Commission also made the point that it has in the past raised substantive innovation concerns in transactions where the concern related to global markets with little or no revenue in Europe, and which triggered the EU thresholds only because the parties had sufficient European revenue in other unrelated markets.

On timing, uncertainty is a real problem about Article 22. To refer a transaction to the Commission under the new regime, the Member State needs to assess whether the transaction has an impact on interstate trade, whether it threatens to significantly affect competition within its territory, and it has fifteen working days to do that. Those fifteen working days only start from when the Member State has "sufficient information" to carry out a preliminary assessment against the referral criteria. It is likely that, in reality, consideration of possible referrals only will start once either customers or competitors might submit a complaint or once other agencies decide to support the referral. Agencies may hunt in packs. In the *Illumina/Grail* merger, the FTC tried to obtain interim relief to stop the parties from closing. Then the European Commission encouraged France to request a referral and accepted it. As the standstill obligation arose, the FTC no longer needed to get interim relief in court.

On substance, there is a risk that pharma deals that get referred under Article 22 will be drawn into a lengthy and potentially less focused investigation based on theories of harm that are still fragile. As the debate on killer acquisitions has been almost singularly focused on digital markets and pharmaceutical markets, one can fear that agencies might be slightly biased. The Multilateral Working Group stated an intention to explore what it calls "refreshed" or even "new" theories of harm when it comes to pharmaceutical mergers. Those theories may go beyond killer acquisitions into *terra incognita*. What to do to mitigate associated risks? First, counsels will have to wonder whether their deal is a candidate for scrutiny. The reality may be that it is hard to get enough comfort by looking at existing guidance and practice. Taking the initiative and asking the Commission for guidance may be the solution if this discussion does not turn into a quasi-investigation. The CMA may be a good source of inspiration. Its policy is to provide informal views but it has a strict five-page limit on the brief that one can submit to get guidance. It forces both the regulator and the parties to keep things simple. In case of a referral, counsels will have to address possible theories of harm as early as possible.

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>
> Niels Ersbøll

Norbert Maier

Norbert Maier explained that there is still uncertainty on how efficiently these referrals will help minimize false negatives. It is true that the issue of notification for acquisitions involving targets with low turnover needed to be addressed in one way or another. Until now, the Commission had focused on some very narrowly defined theories of harm of reduction of innovation by the merger. However, the basic killer acquisition theory does not capture all the effects of a young firm acquisition, far from it. Synergies and spillovers can be expected from acquisition, contributing to incentivize innovation. It is not as simple as a gross reduction of innovation. It will also be important to spend time on counterfactuals and merger specificity. The paper by Colleen Cunningham and others did not describe at length this aspect. It, therefore, overlooked the fact that discontinuing an activity can happen in many ways. Many small pharma companies that have a patented drug use acquisitions as an exit route. Quite often, they simply do not have the means and the resources to develop or to perform Phase III clinical testing. They do not have access to patients. Their access to capital, which is quite substantial at that stage, is more expensive. It follows that the counterfactual should show that if a small pharma company is not bought by a company, it could be bought by another, possibly a bigger one. Various theories of harm should therefore be tested and discussed.

In the vertical setting, acquiring a unique supplier of an important input could allow foreclosure of competitors downstream. The question is whether these competitors will be severely incapacitated or not. A recent example was the acquisition of the leading oncology clinical data

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platform Flatiron by Roche in 2018. This was examined by neither the Commission nor the FTC. The outcome was that Roche did not block access to Flatiron's data for its competitors. In conclusion, one should remain vigilant. In pharma mergers, including when innovative players are involved, it will stay necessary to examine and discuss a variety of theories of harm, and not to neglect counterfactuals.

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Michael Cowie

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Michael Cowie pointed that the FTC recently asked for public comment on the subjects at hand. The FTC has not committed to publishing a report or issuing new guidance. It did indicate it may hold public workshops. On potential competition, the US Merger Guidelines only focuses on whether the evidence supports a conclusion that a firm is committed and capable of entering in the near term. In nascent competition cases, it is unclear whether this standard is applied. In *Questcor/Mallinckrodt*, the FTC identified significant uncertainty on whether the development program would ever get approved. In *Illumina/PacBio*, on the contrary, the FTC argued that the research program was “poised to succeed”. Merging parties may state that a company is likely to enter their market–and therefore enforces competitive constraints on their conduct-. But, if the FTC or Justice Department sees significant uncertainties, they are going to discount that. They will examine all relevant assets to decide whether the potential competitor is indeed likely to enter. The FTC and DOJ have issued a very good guidance to the business community on these points: the need for experienced management, IP, business plan and other attributes. These are concrete criteria to use –as good conclusions cannot come from speculating on whether a very early-stage research program might succeed in some years. ■

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