RECAPTURING THE BUSINESS SIDE OF INNOVATION IN ANTITRUST MERGER ANALYSIS

BY KENT BERNARD[1]

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Recapturing the Business Side of Innovation in Antitrust Merger Analysis

By Kent Bernard

The antitrust laws were not passed as an academic exercise. They were passed to break up the great Trusts, and to preserve competition. These were and are business issues. Our current debate over the impact of mergers on innovation seems to have left that business purpose and dimension out of the discussion. It is time to bring business reality back into the antitrust analysis. Innovation drives progress, and is a key factor in determining the success or failure of a business, an industry, and society overall. Innovation also is a concept with a rich heritage in business and social science. But our current legal discussions focus on only a part of what makes innovation important. We have set up a distinction between the idea of an innovation and the development of that idea into a successful product, and then downgraded or ignored that second part. But the transition from idea to product is a critical step in the process. After reviewing the ways in which innovation has been defined in the legal literature, we propose a definition arising out of the business world that captures the full meaning of innovation. It turns out that the current approach to evaluating the impact of mergers on innovation doesn't really have much to do with innovation at all.

I. INTELLECTUAL ANTITRUST MEETS BUSINESS REALITY

The antitrust laws were not passed as an academic exercise. They were passed to break up the great Trusts, and to preserve competition. These were and are business issues. Our current debate over the impact of mergers on innovation seems to have left that business purpose and dimension by the side of the road. It is time to bring business back into the antitrust innovation debate.

We all seem to recognize that innovation is a key factor in determining the success or failure of a business, an industry, and society overall. Innovation drives progress. An antitrust policy that focused only on prices today but ignored a possible reduction in the rate of innovation "would be a calamity."[2]

Recently there has been considerable legal academic writing on whether and how mergers impact innovation.[3] But our current legal discussions focus on only a part of what makes innovation important. What we are omitting is exactly what we should be striving to protect and encourage. Innovation has a rich heritage in business and social science, a heritage that we are ignoring in our legal analysis.

Traditionally, we have looked to the impact of product overlaps in horizontal mergers; actual and potential competition. But the analysis now is going beyond products or even potential products. The argument is being made that a merger of two companies in the same market (or doing research in the same market) reduces "innovation" without regard to any product or even any potential product. In its strongest form, the thesis asserts that horizontal mergers *per se* always reduce innovation.[4] But to get to that point requires us to understand what "innovation" actually means, and what it requires. It turns out that what we have been measuring (and arguing about) doesn't actually correspond to innovation at all. The legal literature may be making a case over protecting some forms of competition, but it is not about protecting innovation, because we have been using a critically deficient definition of innovation.

We have set up a distinction between the idea of an innovation and the development of that idea into a successful product, and then set aside that second part. But the transition from idea to product is a critical step in the process. It is the result, the end product, that supports the importance of innovation and that we should be trying to protect. The current approach to evaluating the impact of mergers on innovation doesn't really have much to do with innovation at all.

2 Frank Easterbrook, Ignorance and Antitrust, in Antitrust, Innovation, and Competitiveness 119, 122 (1992). See also Bernard and Tom, Antitrust Treatment of Pharmaceutical Patent Settlements, 15 Fed. Cir. Bar J. 617, 623 (2006).

3 See e.g. Federico, Giulio and Langus, Gregor and Valletti, Tommaso M., A Simple Model of Mergers and Innovation (June 29, 2017). CESifo Working Paper Series No. 6539. Available at SSRN: https://ssrn.com/abstract=3005163; Ioannis Kokkoris & Tommaso Valletti, Innovation Considerations in Horizontal Merger Control, *Journal of Competition Law & Economics* 1 (April 15, 2020); Mario Todino, Geoffroy van de Walle & Lucia Stoican, EU Merger Control and Harm to Innovation – A Long Walk to Freedom (from the Chains of Causation), The Antitrust Bulletin 1 (2018), available at https://www.jonesday.com/en/insights/2018/12/eu-merger-control-and-harm-to-innovationa-long-wal; L.I.M Suijkerbuijk, Innovation Competition In EU Merger Control, (2018), available at http://arno.uvt.nl/show.cgi?fid=145944.

4 Frederico et al., *supra* note 3; Justus Haucap & Joel Stiebale, Research: Innovation Suffers When Drug Companies Merge, Harvard Business Review, August 3, 2016.

II. WHAT IS INNOVATION?

One striking feature of the legal literature concerning the impact of mergers on innovation is that we confidently set out ways to measure innovation, without ever stopping to consider whether innovation actually is what we are measuring. Scholars outside of the legal field recognize that defining innovation presents some serious problems. After an overview of the literature, Baregheh, Rowley and Sambrook conclude that "there is no clear and authoritative definition of innovation."[5] Some legal scholars have made the same point. As Richard Gilbert noted, "[w]e remain far from a general theory of innovation competition."[6] But if we can't specify what innovation is with some confidence, how can we be confident that some action has an adverse (or a beneficial) impact on that innovation?

The ways in which the courts and agencies have tried to define innovation for the purposes of analyzing the impact of a merger, fall into a fairly consistent pattern. The analysis is done based on one or more research related factors that we can count on day one. We then assume or assert that what we have counted is "innovation" or determines innovation. But just because we can count something doesn't mean that it is the right, or the only, thing to count.

If we take a broader view, the importance of innovation lies in the fact that it merges two separate actions. We measure the number or amount of inputs into the process - such things as the dollar amount invested in research, the number of compounds advanced in the FDA approval process - and in some cases (such as patents) the number of intermediate outputs from the process. But if we stop there, we are making a serious mistake. There also is an output dimension that links the idea and the execution of that idea into a successful product.

It is that execution component of innovation that is missing in our legal analyses, although it is a major point in the business and social science scholarship. *Innovation is important because it has real world effects* – better products, cures for diseases, explanations of natural phenomena. Meeting market needs (in the broad sense in which scientific advancement can be treated as part of the market) is a key parameter in determining whether something is a successful innovation, rather than simply an ingenious idea.

The Oslo Manual[7] published by the OECD, defines innovation as follows:"An innovation is the implementation of a new or significantly improved product (good or service), or process…."[8] That definition encompasses both the idea and the successful actualization of that idea. It is more than just R&D.[9]

"Successful innovation requires the coupling of the technical and the economic in ways that can be accommodated by the organization while also meeting market needs, and this implies close coupling and cooperating among many activities in the marketing, R&D, and production functions."[10]

The models used in the legal literature analyzing the impact of mergers on innovation never reach the question of meeting market needs. Partly, this may simply be a concession to the nature of models and the need to limit the number of variables at play at any one time. But the variable that is being excluded is a key one: the execution of the idea that takes it from just an idea to a successful product or process. This is what business cares about, and why antitrust is important. Business not only looks for that actualization of the idea, it measures it.[11] Our analysis has been simplified by eliminating perhaps the most important factor.

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5 Anahita Baregheh, Jennifer Rowley, Sally Sambrook, Towards a multidisciplinary definition of Innovation, Management Decision Vol.47 No.8 (2009) page 1323, 1324. Available at https://www.emerald.com/insight/content/doi/10.1108/00251740910984578/full/html?queryID=2%2F5414905.

6 Richard Gilbert, Looking for Mr. Schumpeter: Where are we in the Competition-Innovation Debate, 6 Innovation Policy and the Economy 159, 206 (2006).

7 The Oslo Manual is an internationally recognized methodology for collecting and using innovation statistics, assembled by the Organization for Economic Co-Operation and Development (the "OECD"). The Third Edition specifically treats the innovation process in some depth. Guidelines for Collecting and Interpreting Innovation Data (2005 Edition), available at https://ec.europa.eu/eurostat/web/products-manuals-and-guidelines/-/OSLO?inheritRedirect=true; see also https://unstats.un.org/unsd/EconStatKB/KnowledgebaseArticle10270.aspx.

8 Oslo Manual, Paragraph 146 (emphasis supplied).

9 Stephen J. Kline and Nathan Rosenberg, An Overview of Innovation, Studies on Science and the Innovation Process: Selected Works of Nathan Rosenberg, Chapter 9, pages 173-203 (2009), available at http://dec.ec.unipg.it/~fabrizio.pompei/KlineRosenberg(1986).pdf (pages 275 – 305).

10 *Id.* Pages 301-302 (emphasis supplied).

11 Nick Paul Taylor, Pfizer reports big jump in clinical trial success rate, Fierce Biotech February 2, 2021, available at https://www.fiercebiotech.com/biotech/pfizer-reports-big-jump-clinical-trial-success-rate (counting the compounds that that started out being tested in humans and ended up being approved for commercial sale).

This concept of actualization – whether a good idea can be taken to a successful product, is enormously important. When one company is evaluating another as an acquisition candidate it looks at both the quantity and the value of the other company's research. Are there projects that the acquirer believes can succeed both in terms of being technically feasible, and being a success on the market? Those questions – technical feasibility and market value - drive decision making. Unless a proposed product is considered to be both something that both can be brought to market, and which is likely to earn back more than what it costs to bring it to market and to sell it, that proposed product is likely to be scrapped.[12]

III. INPUT QUANTITY MEASUREMENTS AND THE AMOUNT OF INNOVATION

Most of the legal analyses of impact on innovation start by measuring inputs. Measures of such "innovation inputs" that have been used or proposed in this context include the number of companies doing R&D in a given market,[13] the number of R&D projects in that market, the amount of R&D Assets, the R&D capabilities of the parties,[14] the total R&D expenditures, and the amount of patenting that takes place.

With the exception of the number of patents, which will be discussed separately, these quantity measures share one key characteristic: they all assume that measuring inputs into the innovative process is the right way to measure innovation. That assumes not only that inputs alone can define innovation, but also that that a greater quantity of inputs into the innovation process correlates to greater innovation outputs. This second step is often glossed over as being obvious. But at the end of the day what is important is what comes out of the process, rather than what went into it. Inputs are simply tools to get us to the outputs that we desire. Input metrics measure if you are doing enough of the right activities. Output metrics measure whether you actually have achieved your goals.[15]

With those factors in mind, let us take a look at the various measures that have been proposed to determine if a merger has an adverse impact on innovation, and see if they capture both the conceptual and the actualization sides of innovation.

A. Companies in the Innovation Space

This is perhaps the highest level attempt to measure the impact of a merger on innovation – how many companies are doing something in your chosen field (broadly defined)? On this level, what we are looking for is what the European Commission in its 2010 Guidelines on Horizontal Cooperation called a "sufficient" number of R&D poles.[16] In the United States, the 2000 Antitrust Guidelines for Collaboration Among Competitors, at Section 4.3 state:

> "Absent extraordinary circumstances, the Agencies do not challenge a competitor collaboration on the basis of effects on competition in an innovation market where three or more independently controlled research efforts in addition to those of the collaboration possess the required specialized assets or characteristics and the incentive to engage in R&D that is a close substitute for the R&D activity of the collaboration."[17]

So how many companies or research poles is truly enough? In some innovation areas there are fewer than four players at the start of the relevant time. Does that mean that the parties should never be allowed to merge or collaborate? Should we simply ignore the Genzyme acquisition of Novazyme in 2001, bringing together the only two companies doing research into a treatment for Pompe disease, a rare and often

12 This analysis and cull is done totally apart from any considerations of the structure of the acquisition or the status of the acquirer. It is simply part of the process of trying to be successful.

13 Petit, Innovation Competition, Unilateral Effects, and Merger Policy, 82 Antitrust Law Journal 873, 875 (2019). There is recognition that given the uncertainty that surrounds early research, the exit of one of the parties from an innovation space does not necessarily entail a loss of innovation output. *Id.* at note 113.

14 *Id.* page 874, citing cases.

15 Julia Kylliainen, Measuring Innovation – The Definitive Guide to Innovation Management KPIs (June 29, 2018), https://www.viima.com/blog/how-to-measure-innovation-kpis.

16 See the discussion in Bernard, Innovation Market Theory and Practice: An Analysis and Proposal for Reform, Competition Policy International, Spring 2011, Vol. 7, No.1 (2011), at text accompanying notes 105 and 106 and sources cited therein.

17 Available at https://www.ftc.gov/sites/default/files/documents/public_events/joint-venture-hearings-antitrust-guidelines-collaboration-among-competitors/ftcdojguidelines-2.pdf . But cf. Antitrust Guidelines for the Licensing of Intellectual Property (2017) at Section 4.3 stating that you need four or more independently controlled technologies in addition to the technologies controlled by the parties; https://www.justice.gov/atr/IPguidelines/download.

fatal disease affecting infants and children for which there was no effective therapy at the time.[18] The question was which path promised to get an effective cure for Pompe disease approved and on the market faster – keeping the projects of the two companies separate, or allowing them to join forces?[19] The parties did merge and product did get developed and launched. Are we comfortable adopting an approach that tells us that the merger harmed innovation, despite its success in getting a treatment launched, because it led to one of the two projects being "killed"? Or did the merger increase innovation, by combining operations of the companies with the most knowledge in the field?[20] This would seem to be a highly fact dependent question. We can't support a broad claim that fewer companies in an innovation space means less innovation in that space. In Genzyme, the merger pretty clearly helped actualize the idea into a product.

B. R&D Spending

The impact of the merger on combined R&D spending appears to be the most common way that we try to measure the impact of mergers on innovation.[21] The analysis usually proceeds based on two premises. First, if you put the two organizations together, the combined research and development spend will be less than the sum of the individual spends pre-merger. This is something that can be looked at and measured. Second, the less money spent on R&D equates to less innovation.[22] This is much more problematic.

The merged company may have substantial savings from combining facilities and streamlining the management structure. No one would seriously assert that either of those actions would have an adverse impact on innovation. In addition, as a matter of normal business practice, organizations rank research projects to determine funding and priority. When you combine two organizations, you can expect that there will be a review of the combined research pipeline. The result of that review may well be that some projects are discontinued. Some of the savings may be reallocated to more promising projects. How do those moves impact the amount of innovation? There is no a priori way to tell.

The use of R&D spending as a measure really just gives us our starting assumption (R&D spend equals innovation) enshrined in more complicated mathematical formulae. Reducing spending does not necessarily entail a reduction in innovation. You have to go much deeper into the specific details of the projects that were discontinued before you can establish that assertion. Would the project have succeeded in leading to a viable and profitable product but for the merger?

Furthermore, when you look beyond the legal literature, there is a substantial case that the whole argument rests on an unsound premise. Although it may seem counterintuitive, there is substantial evidence that the amount of R&D spending does not correlate with the amount of innovation very well, if at all.[23]

"Strategy & Business," a business unit within PriceWaterhouseCoopers, has been publishing an annual report of the top 1000 most innovative companies in the world for over 12 years now. In that time, it has found no statistically significant relationship between R&D spending and sustained financial performance. Its findings apply to total R&D spend, as well as R&D spending as a percent of revenues. Spending on R&D is not related to growth in sales or profits, increases in market capitalization or shareholder returns. In every single annual report that Strategy& has published, the top 10 most innovative companies are rarely the top 10 spenders on R&D."[24]

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18 FTC Closes its Investigation of Genzyme Corporation's Acquisition of Novazyme Pharmaceuticals, Inc. (2004); available at http://www.ftc.gov/opa/2004/01/genzyme.htm.

19 Bernard, *supra* note 16, page 178.

20 See Grise, Burns & Giodano, The No Kill Zone: The Other Side of Pharma Acquisitions, CPI Antitrust Chronicle May 2020.

21 See e.g. Petit, *supra* note 13, page 874 and sources cited therein.

22 Kokkoris & Valletti, *supra* note 3, page 14; Haucap & Stiebale, *supra* note 4 (using money spent and R&D and number of patents produced as the measures of innovation).

23 The question is the effective use of resources resulting in a successful product, not just spending.

24 Tendayi Viki, Why R&D Spending Is Not A Measure Of Innovation (Forbes 2016), available at https://www.forbes.com/sites/tendayiviki/2016/08/21/why-rd-spending-is-not-a-measure-of-innovation/#2e2d5b4dc77d . The Strategy & report cited to is even more direct: "There is no long-term correlation between the amount of money a company spends on its innovation efforts and its overall financial performance." Jaruzelski, Chwalik, Goehle, What the Top Innovators Get Right, Strategy + Business Issue 93, Winter 2018 (October 30, 2018), available at https://www.strategyand.pwc.com/gx/en/insights/innovation1000.html; https://www.strategy-business.com/feature/What-the-Top-Innovators-Get-Right?gko=e7cf9.

Financial performance is not the same as innovation *per se*. Still, one would expect the most innovative companies to show financial gains from that innovation. But these data argue that even if you show a reduction in R&D spending post-merger, the impact on innovation is unknown.[25] And as will be discussed further below, even a horizontal merger with actual overlapping programs does not necessarily entail that one or more of those programs will be killed. Before we can predict what will happen to a given research program we have to investigate patent protection, patent life, and the potential for successful product differentiation between the programs. You can't reliably predict the outcome without knowing the facts.

In light of this evidence, it is puzzling to see the European Commission concluding that if a horizontal merger will reduce spending on R&D, it therefore will reduce innovation. Innovation would seem to depend more on the effective use of R&D assets, rather than just the amount spent. And if we are looking for effective use of assets, sometimes a party already working in a field can better advance the work being done by the other party, than could someone outside the field.[26] Knowledge in a field learned on one project, can be used on another project. Rather than reducing innovation, a horizontal acquisition may actually increase the chances of a successful result.

A case study of this "use of knowledge" hypothesis was explored by the FTC in the matter of Genzyme's acquisition of Novazyme,[27] mentioned earlier. Only two companies were working in the field. The disease at issue affects a small number of people (i.e. the potential market for any end product is small), and the research was at the time preliminary, risky, and expensive. At the time of the case, there was no treatment for Pompe disease.[28] There was no evidence that anyone else was planning to enter into research on the treatment of the disease.

The issue for FTC Chairman Muris was whether the merger was likely to slow or reduce the progress towards and effective treatment for Pompe disease or whether it was likely to give the merged firm a greater ability to innovate and get an effective product launched more quickly. Two R&D programs had already failed. Genzyme and Novazyme had the remaining two programs. Both compounds were in the early pre-clinical stage. For drugs entered in Phase I testing (the first stage in which the drugs are given to people in the clinic); the failure rate is between about 75-85 percent.[29] The compounds in this case were not yet even in the clinic. It was by no means likely that either of these projects would make it to the finished drug stage at this point. Collaboration seemed scientifically the best way to get a

But what if two companies are both doing research that is more likely than not going to result in the near term in products that will directly compete? If they merge, will the merged company kill off one of those projects?[30] All we can say with any confidence is "perhaps."

The issue in that case isn't impact on *innovation*. It is a straight potential competition case, and can and should be analyzed that way.[31] It is a very different situation if the potential products are far from the market, or if we try to cut innovation from away from products entirely. If we are measuring whether or not drug compounds are likely to be advanced in the FDA approval process, without regard to whether they are more or less likely to reach the market (much less earn back their cost of capital), we have simply redefined innovation to be the number of drug compounds advanced one step in the approval process, regardless of whether the compounds ever became products. But in so doing we have hollowed out the definition of innovation. From a business and over all societal perspective, simply having candidates advance and fail at a higher step in the approval process cannot be the measure of innovation.

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25 This failure of proof has nothing to do with merger structure. If a private equity firm buys an operating company, we can expect cuts in R&D spending as part of an overall strategy to boost short term value and enable a resale of the company. See Bernard, Private Equity Meets Antitrust – Complications Ensue, CPI Antitrust Chronicle, January 2018.

26 Grise, Burns & Giodano, *supra* note 20, page 20.

27 FTC Closes its Investigation of Genzyme Corporation's 2001Acquisition of Novazyme Pharmaceuticals, Inc.(2004); https://www.ftc.gov/news-events/press-releases/2004/01/ftc-closes-its-investigation-genzyme-corporations-2001 What we had in that case was a debate over the decision to close (in 2004) the investigation of the merger which took place in 2001.

28 In 2006 the FDA approved the first such treatment, Genzyme's Myozyme. See https://www.biospace.com/article/releases/fda-approves-genzyme-corporation-s-myozyme-r-for-all-patients-with-pompe-disease-drug-to-carry-warning-/ (May 1, 2006).

29 Abrantes-Metz, Adams & Metz, Empirical Facts and Innovation Markets: Analysis of the Pharmaceutical Industry, The Antitrust Source, March 2005.

30 This is the premise behind Cunningham, Colleen and Ederer, Florian and Ma, Song, Killer Acquisitions (April 19, 2020). Available at SSRN: https://ssrn.com/abstract=3241707 or http://dx.doi.org/10.2139/ssrn.3241707 . The article makes predictions based on overall review of transactions and what products were advanced in the FDA approval process (but not necessarily reaching the market). The problem is that there is no factual analysis as to why a given compound failed, or was not developed further. Was there an Intellectual Property issue, a timing question, a royalty obligation, was the product simply a "me too" with minimal commercial prospects? Did the compound fail in clinical tests? All of these are key considerations, and ones that a company with a similar product in its own pipeline likely has more information about. We need to know what percentage of the "killed" products never really had good odds to reach the market at all. Otherwise we may be dealing with potential competition, but we are not dealing with innovation.

31 See Bernard, *supra* note 16, page 170 and notes 41 and 42.

In *Dow/DuPont*,[32] the European Commission took a leap of faith into the unknown. The Commission gave us two separate analyses. The first is a classical one, looking at competition in markets for existing pesticides. The second is that the merger would reduce innovation. What is intriguing is that the Commission says that the merger would remove the parties' incentives to pursue ongoing parallel innovation efforts, without specifying what those efforts were.[33] Indeed, it could not really identify which projects, or even which lines of research, were likely to be discontinued.[34]

It is one thing to have a theory. It is quite another to say that your theory allows you to avoid identifying where there will be harm. The Commission's rationale is straightforward:

> "The merger between A and B will result in internalization by each merging party of the adverse effect of the R&D projects on the net revenues of the product lines of the other merging party; hence, in what this Annex called a merger-induced reduction in innovation competition, it will reduce investment in the competing R&D projects. The innovation competition effect follows the basic logic of unilateral effects, which is equally applicable to product market competition and to innovation competition."[35]

There is no real definition of innovation or innovation competition. And why the theory of unilateral effects should automatically apply to innovation competition, is left unsupported. But besides the theoretical problems it raises, the Commission's approach seems to be out of sync with what actually happens in many mergers. Where there are two paths, the merged company may well pursue both of them, especially if they take different approaches or could lead to differentiable products,[36] or have different levels of patent protection. We see this clearly with certain prescription drugs (e.g. Glaxo has Imitrex and Amerge, both are triptans indicated to treat migraine headaches. One is quick onset and strong, the other is slow acting but longer acting.).[37]

Only about 1 in about 4000 drugs proposed in preclinical testing actually ever makes it to market.[38] Once the drug gets to Phase I clinical trials, the probability of success increases substantially. Data show that about 26 percent of Phase I drugs eventually are launched on the market. For drugs that reach Phase II, the probability that the drug will get to market increases somewhat to 33 percent. For drugs that reach Phase III, the probability of success is 57 percent. But to predict the probability of success of an R&D project that has not yet entered clinical trials at all is just wild speculation.[39] And if it is too early to determine whether a pipeline product will ever become a marketed product, it seems unreasonable for the competition law agencies to intervene on the speculative ground that this potential overlap somehow harms innovation.[40] The analogy used is requiring a high school track coach to bless (or not) the engagement of a couple that may – one day – have a child, who may take to athletics and may become a champion sprinter.[41]

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32 Case M.7932 – Dow/DuPont, Comm'n Decision Paragraph 145 (March 27, 2017), non-confidential version available at https://ec.europa.eu/competition/mergers/cases/decisions/m7932_13668_3.pdf.

33 The EU Press Release makes this clear; Mergers: Commission clears merger between Dow and DuPont, subject to conditions 27 March 2017, available at https://ec.europa.eu/commission/presscorner/detail/en/IP_17_772.

34 See Petit, Innovation Competition and Merger Policy: New? Not Sure. Robust? Not Quite! (2018) available at https://medium.com/@CompetitionProf/innovation-competition-and-merger-policy-new-not-sure-robust-not-quite-19c8cec35494, page 4.

35 Case M.7932 – Dow/DuPont, Comm'n Decision, Paragraph 145 (March 27, 2017), non-confidential version available at https://ec.europa.eu/competition/mergers/cases/decisions/m7932_13668_3.pdf.

36 See Denicolo and Polo, The innovation Theory of Harm: An Appraisal, 82 Antitrust Law Journal 921, 924 (2019).

37 See, e.g., Oliver & Taylor, Choosing the Right Triptan, Practical Pain Management, Volume 20, Issue 3 (forthcoming 2020), available at https://www.practicalpainmanagement.com/pain/headache/migraine/choosing-right-triptan.

38 Abrantes-Metz, *supra* note 29, pp. 3-4.

39 The actual chance of success for any given pre-clinical compound, based on the overall statistics, is 0.025%. That is twenty five one-thousandth of one percent.

40 Waisman and Hevia, Merger Control and Innovation: A Rights-Based Approach, Journal Of Economic Law and Practice (2021), page 3.

41 Id. Page 6 (citing Gavin Bushell, EU Merger Control and the Innovation Theory of Harm: Fake News? (2017) Kluwer Competition Law Blog, available at http://competitionlaw-blog.kluwercompetitionlaw.com/2017/03/03/eu-merger-control-and-the-innovation-theory-of-harm-fake-news/.

A final point is the assumption by some authors that the projected reduction in R&D spending is related to the structure of the transaction as a horizontal merger. But the motivation to reduce spending is inherent in just about every transaction, and is independent of deal structure. Even if the purchaser is a pure financial buyer with no other holding in the field at issue, we can expect cuts in R&D spending as part of an overall strategy to boost short term value and enable a resale of the company.[42]

C. R&D Headcount

The next measure proposed to determine impact on innovation is R&D headcount. But whether more bodies will lead to more innovation is unproven. The R&D headcount measure doesn't distinguish between the skills of the people involved, or how efficiently they operate. Throwing more people at a problem doesn't mean you have the right people, or that they are working on the right approach.[43] The purpose of spending on innovation is to get something valuable out the other end of the tube. Headcount doesn't tell us that. So can we measure innovation by output? And if so, output of what?

IV. OUTPUT QUANTITY MEASUREMENTS AND THE AMOUNT OF INNOVATION

"Innovation really has two parts, and this is what some people miss," [Jon Lauckner, Chief Technology officer, General Motors] explained. "The first part of innovation is the development, invention, patent or some other form of intellectual property. The second piece of innovation is the commercialization of that into products and services. *It's only when you commercialize that intellectual property, that know-how, that you transform an invention into an innovation.*"[44]

The analysis thus far has led us to consider that innovation is something that comes out of the process and that actualizes the invention. That is the "innovation" that we want to protect and nurture. With that caveat, let's look at a couple of measures that have been proposed as quantifying the output of innovation.

A. Patents

Correlating the amount of innovation with the number of patents has a certain intuitive charm. After all, two of the criteria for getting a patent in the United States are that the invention be novel and useful.[45] But assuming that the number of patents is a stable measure of innovation creates its own set of problems. There are a variety of factors that can affect patent counts.[46] People can apply for lots of patents without actually being very innovative. Other times, an industry can be exceptionally innovative without being patent dependent. That said, some commentators argue that patent numbers are a good measure of innovation,[47] and that patenting is closely related to other measures of innovative activity.[48] One author tried to balance the various factors and arguments:

> "But just how strong is the link between patent activity and innovation in an era of exponential technological progress?

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42 See Bernard, Private Equity Meets Antitrust – Complications Ensue, CPI Antitrust Chronicle, January 2018.

43 See e.g. Collison and Nielsen, Science Is Getting Less Bang for Its Buck, The Atlantic, November 16, 2018, available at https://www.theatlantic.com/science/archive/2018/11/diminishing-returns-science/575665/.

44 Joann Muller, How GM Lost – And Found The Path to Innovation, Forbes.Com (January 13, 2013) available at https://www.forbes.com/sites/joannmuller/2013/01/13/how-gm-lost-and-found-the-path-to-innovation/#554f4e584740 (emphasis supplied).

45 35 U.S.C. Section 101. See also https://www.justia.com/intellectual-property/patents/patentability-requirements/ .

46 Bronwyn H. Hall, Using Patent Data as Indicators, (2013), available at https://eml.berkeley.edu/~bhhall/papers/BHH13_using_patent_data.pdf.;' Erin Brown, Do Patents Invent Innovation?, Knowable Magazine (March 13, 2018), available at https://www.knowablemagazine.org/article/society/2018/do-patents-invent-innovation.

47 Carol Robbins, How Valuable are Patents as a Proxy for Innovation? Science and Engineering Indicators Perspective, Government-University-Industry Research Roundtable June 28, 2017, available at file:///C:/Users/Kent/Downloads/ecrobbinsjune%20guirr%20presentation_patents%20(5).pdf.; Riitta Katila, Using patent data to measure innovation performance; International Journal of Business Performance Management 2(1) · January 2000. But see Petra Moser, Patents and Innovation in Economic History, Annual Review of Economics, Vol. 8:241-258 (October 2016), available at https://www.annualreviews.org/doi/10.1146/annurev-economics-080315-015136.

48 See Jay Shambaugh, Ryan Nunn, and Becca Portman, Eleven Facts About Innovation and Patents, Brookings Institution, December 13, 2017, available at https://www.brookings.edu/research/eleven-facts-about-innovation-and-patents/.

> Just comparing the absolute number of patents on a company-by-company basis is misleading, to say the least. For example, consider the number of patents that companies have received thus far in 2015. According to this metric, IBM and Samsung are far and away the most innovative companies in the world, with 3,059 and 3,052 patents, respectively. Google ranks number five, with 1,083 patents, just ahead of Microsoft (No. 7), with 1,037. Apple, typically considered one of the most innovative companies in the world, comes in at only No. 11, with 780 patents. Facebook doesn't even crack the top 40.
> …
> However, just because you have a lot of highly cited patents … doesn't immediately mean that you can create valuable products from those patents. If you think about innovation as a process from first invention to final product, then patents only measure the front-end of that process — the actual invention — rather than the back-end of innovation: the launch of the commercialized product. If your research and development system is broken, you may be front-loading the system with a lot of patents, without very much to show for it."[49]

Following up on this point, Tim O'Reilly argues that neither patenting nor R&D spending give us a complete handle on innovation; that we need to take into account both the idea and the actualization of the idea into a product.[50]

In *Dow/DuPont*, the Commission actually created a hypothetical market of patent applications in a field, and then a market of the patent shares of companies for patents on herbicide new active ingredients, and then focused on the citations accumulated by a patent as indicative of the patent's innovative strength.[51] Looking at citations as a potential measure of the quality of the patent, is worth exploring, but ultimately doesn't bridge the disconnect between that patent and product that reaches the market. Can the success of a product really be tracked back to one or more specific patents?

Simply counting patents is a very rough way to try to measure innovation in general. But patenting is important, indeed crucial, on a related issue – the attempt to predict post-merger conduct of the parties. Any commercial advantage that may result from patent protection has a defined life and a defined end point. This life span needs to be a key part of any analysis of what parties are likely to do. If you don't have an estimate of how long an existing product will continue to generate significant revenues, how can you possibly predict how the company will treat a research project that may supplement or supplant that first product?[52]

Antitrust models may predict that a company will kill a potential product which threatens to upset its current "monopoly," but that is too blunt an approach to the issue of subsequent products. It is the time factor of revenue destruction that drives the business decisions.[53] Every seller needs either to continue its income stream, or replace it, in order to survive. A product (or compound) with weak patent protection, is less valuable than a product or compound with stronger patent protection.[54] A non-patented product that is not a prescription drug may survive quite well for many years. Listerine brand mouthwash was first launched in 1879 and is still going strong.[55] The models need to take this into account if they are going to give us valid prediction of what the parties are "likely" to do post-merger. Facts need to drive the analysis. Identifying key patents and their expiration dates, needs to be part of the merger analysis on the legal as well as on the business side.

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49 Dominic Basulto, Patents are a Terrible Way to Measure Innovation, Washington Post July 14, 2015, available at https://www.washingtonpost.com/news/innovations/wp/2015/07/14/patents-are-a-terrible-way-to-measure-innovation/ See also Todino et al., *supra* note 3, page 11; Kokkoris, *supra* note 3, page 23.

50 Tim O'Reilly, How Do We Measure Innovation? Radar (March 26, 2010) available at http://radar.oreilly.com/2010/03/how-do-we-measure-innovation.html. He argues that there ought to be a way to measure the introduction of new products, and rank them by novelty and by widespread acceptance, in some way that reflects a more substantial measure of innovation and its impact on the economy.

51 See Suijkerbuijk, *supra* note 3, at text accompanying notes 259 – 271.

52 Cunningham et al., *supra* note 30, do not seem to take this into the analysis of their cannibalization assumption. The so-called replacement effect needs to recognize that a second product with strong patent protection can be very valuable to a company with an existing product whose protection is ending.

53 See Bernard, *supra* note 16 at pages 168-170.

54 This is what drives the strategy knows as "patent hopping," where a drug innovator, whose patent is expiring soon, tries to encourage or force doctors to prescribe a new version of the product that has longer patent protection. The law here is still evolving. I would predict that the general rule is likely to be that persuasion is fine, but coercion (say, by withdrawing the older product before it can be copied by generics) is illegal. See generally Tobin Klusty, A Legal Test for the Pharmaceutical Company Practice of "Product Hopping, (2015) *AMA J Ethics.* 2015;17(8):760-762. available at https://journalofethics.ama-assn.org/article/legal-test-pharmaceutical-company-practice-product-hopping/2015-08.

55 See Johnson & Johnson, History of LISTERINE®: From Surgery Antiseptic to Modern Mouthwash, available at https://www.listerine.com/about.

B. Products

If the point of innovation is to get new or better products, then counting new products could be used to measure innovation. But there is a problem with that approach which mirrors the problem with counting patents. Launching two great products may be much more evidence of innovation than launching 20 mediocre ones. "It's usually not a great idea to sacrifice quality for quantity."[56] It is difficult to strike that balance between quantity and quality. This may have been one of the reasons that the European Commission explicitly cut its analysis of innovation free from any specific product or product line.

The data do not say that we should ignore the potential impact of any one factor. Cuts in R&D spending may or may not have an impact, depending on where the cuts are made and the value of the projects being no longer funded.[57] It all depends on the facts of the specific situation.

But finding, predicting, or assuming that a number of products will be cut does not entail finding that the merger will cause a decrease in innovation. The same critique applies to attempts to tie the amount of innovation to R&D spending, headcount, or patenting. They all give us quantity, but not quality. But there is one approach that deals with both sides of the innovation definition – the idea and the actualization of it.

V. A PROPOSED WAY TO DEFINE AND MEASURE INNOVATION

This analysis has tried to show that our current attempts to define and measure innovation suffer from a basic mistake. They divorce the idea of innovation from its implementation in a product.

When we look at various business and other non-legal attempts to define innovation, they have a common theme. Innovation can start out as an idea, a product or a process. What takes that initial idea to the level of an innovation is that it fills a perceived market need (taking market in the broadest sense to include the advancement of science). Pure science apart, an innovation needs to have a commercial dimension. It is this commercial dimension that ties the area back to the competition agencies, and to the purposes behind the antitrust laws. If the "innovation" is not commercial in some sense, it is difficult to see why competition law agencies should get involved in it. We need a definition that captures both the idea of a discovery and the subsequent execution of the idea such that it has a real world impact.

One promising approach to combining the quantitative and qualitative aspects of innovation was proposed by Brian Quinn, writing about how large organizations can innovate more effectively. After looking at various possible measures, he concludes that a measure used in business, the "hit rate," lets us measure innovation in a way that reunites the idea and the implementation dimensions.

"That said, measuring the organization's hit rate – the percentage of innovations that create value by returning their cost of capital or other metric – is one I'd recommend in almost any context, and keeping in the measurement system over time."[58]

Research has not revealed any merger cases where either party's hit rate for innovation has been used in the analysis. Looking at this metric would give us a way to compare the innovative effectiveness of the two companies proposing to merge. Without more, it wouldn't tell us the effect of the merger on innovation going forward. But it would be a starting point. We tend to do analyses based on overall R&D spending. But looking at the hit rate gives us an idea of R&D effectiveness, the quality of the innovation, which is much closer to what we should be caring about. Admittedly it is not easy to calculate whether an innovation does return its cost of capital. R&D is expensed, not capitalized into the overall cost of a specific product. Currently, businesses can choose to fully expense the costs of research and development (R&D); that is, they can deduct the costs of R&D from their taxable income in the year that those costs occur.[59]

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56 Julia Kylliainen, *supra* note 15, page 6.

57 This caution also would apply if a single player cut back on a particular line of inquiry. It may not be simple to link the potential harm here to a merger or acquisition.

58 Brian Quinn, Why Measuring Innovation Matters, Forbes.com (November 5, 2015), available at https://www.forbes.com/sites/brianquinn/2015/11/05/why-measuring-innovation-matters/#59810f3e6cd8 (emphasis supplied).

59 Expensing is the proper tax treatment of investment and other business costs, as it prevents a firm's profits from being overstated in real terms. This lowers the cost of investment. Requiring a firm to amortize business costs over a number of years overstates the firm's taxable income, reducing business capital investment.
Starting in 2022, the Tax Cuts and Jobs Act (TCJA) will require companies to amortize their R&D costs over five years, instead of deducting them immediately each year. https://files.taxfoundation.org/20190204170826/Amortizing-Research-and-Development-Expenses-under-the-Tax-Cuts-and-Jobs-Act-FF635.pdf.

But many companies keep track of expenses attributable to individual projects as a management tool, even if such calculations are not used for tax or reporting purposes. A business wants to know which projects generate a net profit. One measure which comes close to capturing the hit rate concept, is the clinical trials success rate: the percentage of compounds that enter clinical trials in people and go on to win approval to be marketed. In other words, ideas that becomes products. Companies are making those calculations right now.[60] It is time for the legal world to catch up.

To get from the clinical trials success rate to the hit rate is simply a matter of tracking the net sales and profits of the products, something that almost every company does routinely. Those data could be reached by a carefully targeted information request or civil investigative demand from a competition agency. These calculations are primarily backward looking, telling us which projects have met the hit rate test as being true innovations. Projecting what will (or is likely to) happen in the future as a result of a merger is difficult, but not impossible.

VI. SOME CONCLUDING THOUGHTS

This article has tried to deal with the problem of defining innovation so that we can more accurately see what kinds of actions or transactions are likely to help, or harm innovation in a real world context, where theory and commerce combine. So far, the legal arguments and analyses have left business on the sideline. It is time to invite it back into the antitrust game. If we are truly going to protect innovation, we need to use the fully loaded definition that includes both the idea and the result. Then we will have a solid foundation to investigate whether the impact of a given merger is likely to help, harm, or simply bypass innovation. Our current approaches don't actually let us determine the impact of mergers on innovation because they use a one-sided definition of innovation, a definition that is recognized as incomplete in business and social science. The hit rate concept provides us with an approach that includes both sides of innovation – idea and product. It is up to us to use it.

60 See e.g. Nick Paul Taylor, Pfizer reports big jump in clinical trial success rate, Fierce Biotech February 2, 2021, available at https://www.fiercebiotech.com/biotech/pfizer-reports-big-jump-clinical-trial-success-rate . A more detailed explanation, showing the success rate by clinical trial phase, and including the end to end success rate, is found in the Pfizer Earnings Report dated February 2, 2021, at page 10, available at https://s21.q4cdn.com/317678438/files/doc_financials/2020/q4/Q4-2020-PFE-Earnings-Release.pdf.

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