The Antitrust Bulletin
1-20

DOI: 10.1177/0003603X18816549
journals.sagepub.com/home/abx
SAGE

EU Merger Control and Harm to Innovation—A Long Walk to Freedom (from the Chains of Causation)

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Abstract

In a string of recent merger decisions, culminating in the *Dow/DuPont* case, the European Commission has profoundly revisited its traditional analysis of innovation and, ultimately, introduced what some authors have labeled "a novel theory of harm in EU merger policy." According to this theory, the Commission does not look at harm to innovation on a specific product market in which parties are developing similar pipeline products, but adopts a general assessment of harm to innovation, unrelated to a specific product market and without considering potential anticompetitive effects on this basis. The purpose of this article is to show that over the last few years, the European Commission has been progressively departing from a "traditional" theory of harm in its assessment of mergers affecting innovation. In particular, we argue that the novel theory of harm developed in *Dow/DuPont*, based on a generic prejudice to innovation, is the landing place of a long journey through which the Commission has progressively altered the analytical framework applicable to traditional cases affecting pipeline products/potential competitors. And while this stance may be inspired by a legitimate policy goal, it brings the Commission on a collision route with the principles of causation and symmetry governing European Union merger control analysis.

Keywords

Dow/DuPont, innovation, harm to innovation, novel theory of harm, mergers affecting innovation, SIEC, R&D poles, potential competition, *Johnson & Johnson/Guidant Medtronic/Covidien*, *Novartis/GSK Oncology Business*, innovation spaces, asymmetric approach, double standard, pipeline products, innovation competition

Introduction

The impressive acceleration of technological progress, combined with the ascent of the internet and the digital economy, have put the issue of innovation at the (controversial) center of the current antitrust

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debate. Innovation is increasingly seen by the European Commission as a key parameter of competition, as businesses increasingly compete on research and development of new products or entirely new business models. This has in turn shifted the antitrust enforcement priorities of the enforcer, and it is no wonder that the rhetoric of innovation has become dominant in European Union (EU) merger control analysis.

In a string of recent merger decisions, culminating in the *Dow/DuPont* case,[1] the European Commission has profoundly revisited its traditional analysis of innovation and, ultimately, introduced what some authors have labeled "a novel theory of harm in EU merger policy."[2] According to this theory, the Commission does not look at harm to innovation on a specific product market in which parties are developing similar pipeline products but adopts a general assessment of harm to innovation, unrelated to a specific product market and without considering potential anticompetitive effects on this basis.

The purpose of this article is to show that over the last few years, the European Commission has been progressively departing from a "traditional" theory of harm in its assessment of mergers affecting innovation. In particular, we argue that the novel theory of harm developed in *Dow/DuPont*,[3] based on a generic prejudice to innovation, is the landing place of a long journey through which the Commission has progressively altered the analytical framework applicable to traditional cases affecting pipeline products/potential competitors. And while this stance may be inspired by a legitimate policy goal, it brings the Commission on a collision route with the principles of causation and symmetry governing EU merger control analysis.

This article is structured as follows: (1) In the first section, we set the stage by highlighting the factors that have led innovation to become the center piece of the Commission's merger intervention. (2) In Section II, we briefly describe the traditional analytical framework the Commission has employed to assess innovation in merger control and provide a short overview of some illustrative cases in point. (3) We then describe the Commission's "new" approach in the *Medtronic/Covidien*,[4] *Novartis/Glaxosmithkline Oncology Business [GSK]*,[5] and *Dow/DuPont*[6] cases. (4) In the last section, we explain how certain parameters relevant for the assessment of potential competition in merger cases have been altered and why these developments bear far-reaching implications.

I. Background—Technological Progress and Digital Economy—Innovation as the Antidote to Market Power

A. Innovation Is the Source of Technological Progress

According to a number of distinguished scholars, over the past five decades, the evolution of global markets has been essentially driven by "competition in the market" whereby firms used to compete on traditional parameters (price and quality), while disruptive innovation remained relatively infrequent. Over the last few years, this landscape has completely changed. The rise of the Internet era has tilted

1. Eur. Comm'n, Case M.7932, *Dow/DuPont*, Decision C(2017), http://ec.europa.eu/competition/mergers/cases/decisions/m7932_13668_3.pdf (hereinafter, *Dow/DuPont*).
2. Nicolas Petit, *Significant Impediment to Industry Innovation: A Novel Theory of Harm in EU Merger Control?* SSRN (Feb. 4, 2017), https://ssrn.com/abstract=2911597.
3. *Dow/DuPont, supra note 1*.
4. Eur. Comm'n, Case M.7326, *Medtronic/Covidien*, Decision C(2014)9215, http://ec.europa.eu/competition/mergers/cases/decisions/m7326_20141128_20212_4138173_EN.pdf (hereinafter, *Medtronic/Covidien*).
5. Eur. Comm'n, Case M.7275, *Novartis/Glaxosmithkline Oncology Business*, Decision C(2015)538, http://ec.europa.eu/competition/mergers/cases/decisions/m7275_20150128_20212_4158734_EN.pdf (hereinafter, *Novartis/GSK*).
6. *Dow/DuPont*, *supra* note 1.

this "traditional" market model and has brought forward disruptive innovation.[7] Online markets are characterized by "competition for the market," rather than "competition in the market," such that a dominant platform can easily be overturned by an entrant or rival with better technology, higher quality, or a different business model.[8] Digitalization has generated new business models in many sectors, and rendered previously existing markets obsolete. The rise of tech giants, the "Rockefellers" of our times, is best illustrated through Schumpeter's economic model, whereby competition *for* the market results in near-monopolies until the next disruptive innovation model will be invented.

B. Consolidation Is a Noticeable Trend in Many Industries

Alongside digitalization, industrial consolidation appears to be another irreversible trend of our modern times: 10% of the world's public companies generate 80% of all profits. The annual number of mergers and acquisitions is more than twice of what it was in the 1990s. Figures show that all over the world more firms are dying than being born.[9]

In the United States, over the past decades, many industries have become increasingly concentrated, and a trend towards higher profit margins is clearly emerging.[10] Several economic studies argue that, at least in the United States, the increase in market power is associated with an increase in concentration and with a relatively permissive competition enforcement.[11]

Also in Europe, research indicates that there is a consolidation trend under way, although less pronounced.[12]

C. The Response of Antitrust Enforcers Across the World

Interestingly, the question whether persistent, high market shares and profit margins in the new market economy are detrimental for consumers and innovation has triggered different reactions in the EU as opposed to the United States. While in the United States, certain scholars (dubbed the "neo-Brandeis" movement or "*hipster antitrust*" by its detractors) have been in vain advocating a more interventionist enforcement policy from antitrust agencies,[13] the EU is actually the one who *walks the talk*.

7. Clayton M. Christensen, Michael E. Raynor, & Rory McDonald, *Disruptive Technologies: Catching the Wave, What Is Disruptive Innovation?* Harv. Bus. L. Rev., 44–53 (Dec. 2015); Daniel Sokol, *Understanding Online Markets and Antitrust Analysis*, 15 Nw. J. Tech. & Intell. Prop. 43 (2017), https://ssrn.com/abstract=2813855.
8. Diane Coyle, *Platform Dominance: The Shortcomings of Antitrust Policy*, *in* Digital Dominance: Implications and Risks (Martin Moore & Damian Tambini eds., 2018).
9. *Id.*
10. In the last twenty-five years, net profit margins of U.S. firms have roughly doubled, from around 4.5% to around 9.0% of revenues: Tommaso M. Valletti & Hans Zenger, *Should Profit Margins Play a More Decisive Role in Merger Control? – A Rejoinder to Jorge Padilla*, 9 J. Eur. Competition L. & Prac. 5, 1 (2018).
11. Simcha Barkai, *Declining Labor and Capital Shares* (Job Market Paper, Un. of Chi. 2017), http://home.uchicago.edu/~barkai/doc/BarkaiDecliningLaborCapital.pdf. *For example, see* Gustavo Grullon, Yelena Larkin, & Roni Michaely, *Are US Industries Becoming More Concentrated?* 9, 38–41 (2016), https://finance.eller.arizona.edu/sites/finance/files/grullon_11.4.16.pdf. They examined publicly traded companies in the U.S. and found that concentration increased in 75% of all industries since 2000 and that the number of publicly traded firms in the U.S. shrank by almost 50% during the last two decades. In this context, the Obama administration suggested to rethink the U.S. competition policy to address recent anticompetitive developments and published a presidential order to oblige antitrust agencies to propose steps for increasing competition in the US market. *See* Executive Order No. 13725, *Steps to Increase Competition and Better Inform Consumers and Workers to Support Continued Growth of the American Economy*, 81 Fed. Reg. 76, 23417, (2016), https://www.gpo.gov/fdsys/pkg/FR-2016-04-20/pdf/2016-09346.pdf.
12. John P. Weche & Achim Wambach, *The Fall and Rise of Market Power in Europe*, Zew (2018), http://ftp.zew.de/pub/zew-docs/dp/dp18003.pdf.
13. The movement's criticism of the current antitrust policy is that it focuses excessively on price and overlooks problems arising from corporate concentration, whereby the shape of dominance in the contemporary digital economy remains

Enforcement action against tech giants best epitomizes the fundamental differences between the two sides of the Atlantic.[14] While the U.S. agencies have been substantially inactive, European competition authorities have taken significant enforcement action in a string of landmark cases.[15]

The European Commission's appetite for intervention is also evident in merger control, where an increasingly tougher stance is becoming discernible in the treatment of (1) the so-called "*gap*" cases[16] and (2) horizontal mergers involving differentiated products, to the extent that the removal of a close competitor—instead of the closest competitor—appears to suffice to establish harm to competition; [17] mergers giving rise to coordinated effects;[18] and mergers raising vertical and conglomerate issues, where the level of scrutiny and attention has significantly increased, although not yet translated into a higher rate of intervention.[19]

It is against this background that innovation is being regarded as one of the main antidotes against market power accumulation, thus becoming the priority of the European Commission's merger control enforcement activity.

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uncaptured. *See e.g.* Lina M. Khan, *Amazon's Antitrust Paradox*, 126 Yale L. J., 710–805 (2017). Christopher S. Yoo, *Hipster Antitrust: New Bottles, Same Old W(h)ine*, 1 CPI Antitrust Chron. (Spring 2018), https://www.competitionpolicyinternational.com/wp-content/uploads/2018/05/AC_APRIL.pdf. Elyse Dorsey, Jan M. Rybnicek, & Joshua D. Wright, *Hipster Antitrust Meets Public Choice Economics: The Consumer Welfare Standard, Rule of Law, and Rent-Seeking*, SSRN (2018), https://ssrn.com/abstract=3165192.

14. For instance, the U.S. Federal Trade Commission's top economist recently dismissed the need for a "*hipster antitrust*" policy, while to the contrary, the deputy chief economist at the European Commission's Directorate-General for Competition suggested that EU enforcers can "*stretch*" antitrust to handle dominant technology companies; *EU and US Economists Differ on Innovation and "Hipster Antitrust"* (GCR 7th Annual Antitrust Law Leaders Forum, 2018), https://globalcompetitionreview.com/article/1153481/eu-and-us-economists-differ-on-innovation-and-%E2%80%9Chipster-antitrust%E2%80%9D.
15. Europe, in particular, has focused significant attention on competition, big data, and regulation of digital platforms. Recent landmark cases in the EU include the Commission's €2.4 billion fine against Google for abusing a dominant position as a search engine by giving its comparison shopping service an illegal advantage, a second decision against Google in connection with the abusive use of the android operating system, a €110 million fine against Facebook for having provided misleading information about the way the users' private data would be handled postmerger with WhatsApp, a €997 million fine against Qualcomm for abuse of dominance because it prevented rivals from competing by paying off Apple to exclusively use its chipsets, and Germany's investigation into Facebook's practice of forcing customers to agree to unfair terms about the way the company uses their data.
16. Transactions giving rise to anticompetitive unilateral effects, despite the absence of the creation or strengthening of a dominant position as a result of the merger, in particular in the telecom sector; for recent examples, *see* Eur. Comm'n, Case M.6992, *Hutchison 3G UK/Telefonica Ireland, Decision C(2014)3561*, http://ec.europa.eu/competition/mergers/cases/decisions/m6992_20140528_20600_4004267_EN.pdf. Eur. Comm'n, Case M.7018, *Telefónica Deutschland/E-Plus, Decision C(2014)4443*, http://ec.europa.eu/competition/mergers/cases/decisions/m7018_6053_3.pdf. Eur. Comm'n, Case M.7419, *Teliasonera/Telenor* (withdrawn); Eur. Comm'n, Case M.7758, *Hutchison 3G Italy/Wind/JV, Decision C(2016)5487*, http://ec.europa.eu/competition/mergers/cases/decisions/m7758_2937_3.pdf; Eur. Comm'n, Case M.7612, *Hutchison 3G UK/Telefonica UK*, Decision C(2016)2796, http://ec.europa.eu/competition/mergers/cases/decisions/m7612_6555_3.pdf.
17. The Commission now routinely assesses whether the parties are "close" competitors, whereas it previously focused on "closest" competitors. *See* Nikolaos Peristerakis, Lodewick Prompers, & Mar García, *The Commission's Merger Enforcement in Mobile Mergers: Brave New World for Non-coordinated Effects?* 1 CPI Antitrust Chron. (November 2015).
18. For example, coordinated effects were raised in certain mobile mergers, *Hutchison 3G Italy/Wind/JV* and *Teliasonera/Telenor/JV*, but also in more traditional markets, namely, in Eur. Comm'n, Case M.7881, *AB Inbev/SAB Miller*, Decision C(2016)3212, http://ec.europa.eu/competition/mergers/cases/decisions/m7881_3286_3.pdf.
19. Conglomerate effects were very recently raised in Eur. Comm'n, Case M.8394, *Essilor/Luxottica, Decision C(2018)1198*, http://ec.europa.eu/competition/mergers/cases/decisions/m8394_4217_3.pdf, and in Eur. Comm'n, Case M.8306, *Qualcomm/NXP*, Decision C(2018)167, http://ec.europa.eu/competition/mergers/cases/decisions/m8306_3479_3.pdf.

II. The European Commission's Analytical Framework for Assessing Innovation in Merger Control

Innovation has its own specific place in the EU legal framework on merger control as a key parameter of competition alongside price and output. According to the European Commission's Horizontal Merger Guidelines[20] (HMG), one of the effects to be analyzed in merger control is the effect on innovation, whereby the competitive harm caused by a reduction of innovation is put on an equal footing with price increases, or a reduction of output. Indeed, the introduction to the HMG clarifies that "price increase" is used as a shorthand for the various ways in which a merger may result in competitive harm, including diminishing innovation.[21]

The HMG specify that in markets where innovation is an important competitive force, a merger may increase the firms' ability and incentive to bring innovation to the market and, thereby, the competitive pressure on rivals to innovate in that market. On the other hand, the HMG state that "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" in which case the transaction can eliminate an important competitive force and thus lead to a significant impediment of effective competition.[22] Admittedly, the use of the wording "*for instance*" in the HMG hints to the possibility for the Commission to intervene in mergers involving two important innovators,[23] even where no pipeline products are identified.[24] However, the HMG do not set out a framework of analysis for harm to innovation in the absence of identified pipeline products, and until recently, the Commission had not investigated mergers impacting innovation based on theories of harm other than the traditional one relating to potential competition generated by pipeline products.[25]

A. The Commission's Traditional Approach to Mergers Impacting Innovation

Under the Commission's traditional approach as set forth in the HMG, the assessment of mergers impacting innovation is typically conducted from the angle of identified pipeline products resulting in

20. Eur. Comm'n, Guidelines on the Assessment of Horizontal Mergers under the Council Regulation on the Control of Concentrations between Undertakings, OJ C 31 (February 5, 2004) (hereinafter, "Horizontal Merger Guidelines" or "HMG"), 5–18.
21. *Id.* at ¶ 8.
22. *Id.* at ¶ 38.
23. *Supra* note 15, at ¶ 20 b. Further, the innovation potential of the merging firms is one of the factors that the Commission can take into account to identify horizontal competition concerns, even in cases where postmerger concentration indexes are at a level that do not normally raise concerns. Where "one or more merging parties are important innovators in ways not reflected in market shares," this may lead the Commission to identify horizontal competition concerns in a merger with a postmerger Herfindahl-Hirschman index (HHI) between 1,000 and 2,000 and a delta below 250, or a merger with a postmerger HHI above 2,000 and a delta below 150. Conversely, this does not apply where the postmerger HHI is below 1,000, as such markets do not normally require extensive analysis.
24. It has been argued that the elimination of an important innovator with pipeline products is not the only example that the HMG refer to, and that the HMG also cover another type of mergers' effects on innovation, namely, harm to generic innovation. The issue of harm to generic innovation had allegedly been present in the Commission's enforcement practice before *Dow/DuPont* in cases such as *GE/Alstom* and *Deutsche Borse AG v. Commission*. *See* Carles E. Mosso, *Innovation in EU Merger Control* (Remarks prepared for the 66th ABA Section of Antitrust Law Spring Meeting, Washington, DC, 2018), p. 8, http://ec.europa.eu/competition/speeches/text/sp2018_05_en.pdf.
25. The concept of "innovation markets" has its origins in U.S. antitrust law, where it first appeared in the Antitrust Guidelines for the Licensing of Intellectual Property of 1995, and is now reflected in U.S. Dept. of Justice and Fed. Trade Comm'n, Antitrust Guidelines for the Licensing of Intellectual Property (Jan. 12, 2017), where it is specified at p. 11 that "the Agencies will delineate an innovation market only when the capabilities to engage in the relevant research and development can be associated with specialized assets or characteristics of specific firms," sec. 3.2.3.3, https://www.ftc.gov/system/files/documents/public_statements/1049793/ip_guidelines_2017.pdf.

potential competition, that is, by evaluating whether the merger would remove pipeline products of the merging parties, capable of exerting a significant competitive constraint in the market. In this respect, only specific products in a late stage of development come into the picture, for only those products whose market entry is imminent can be found to exert—as potential competitors—significant competitive constraint over existing products of the acquiring party. In particular, a merger with a potential competitor can have horizontal anticompetitive effects if two cumulative conditions apply: first, the potential competitor significantly constrains the behavior of the firms active in the market; and second, there is not a sufficient number of other potential competitors, capable of maintaining postmerger sufficient competitive pressure.[26] The first condition can be met in two different situations: either the potential competitor (1) already significantly constrains the behavior of the firms active in the market; or (2) it is likely to enter the market in a relatively short period of time, after which it would constrain the behavior of firms currently active in the market.[27]

This well-established practice of analyzing potential competition through pipeline products is illustrated in numerous past cases.[28] *J&J/Guidant*[29] is one of the cases that best illustrates the way the Commission used to apply the "traditional" theory of harm to innovation.

J&J was active in the very concentrated market for drug eluting stents (DES), with only one other major supplier active worldwide—Boston Scientific—plus a number of imminent entrants such as Guidant, Medtronic, and Abbott, which were all developing stage III pipeline products. The Commission had to assess whether by eliminating Guidant as a potential competitor in the DES market, the merger would remove the major competitive constraint in the DES market, with the other new entrants being unable to compensate for the loss of competition resulting from Guidant's elimination from the market.

The Commission's market investigation revealed that the proposed merger would eliminate one of the potential entrants with the best prospect of success in the market for DES, which was at the "*forefront of innovation*,"[30] could rely on numerous assets, and "*would have acted as a major competitive constraint in such a market*."[31] However, the Commission also acknowledged the existence of equally credible "potential" competitors, Medtronic and Abbott, who were also about to enter the market and therefore could compensate for the loss of competition resulting from J&J's acquisition of Guidant.[32]

To reach this conclusion, the Commission relied upon a substantive amount of documentary evidence, such as review of clinical evidence, assistance from a pool of eminent physicians who had been involved in clinical trials, and studies prepared by specialized consultants. Moreover, and perhaps more importantly, the Commission took a symmetric approach to assess potential competition from third parties and potential competition stemming from the merging parties. Potential competition stemming from third parties therefore played an important role in the competitive

26. *Supra* note 15, at ¶¶ 59–60.
27. *Id.* at ¶ 60. See also Eur. Comm'n, Case M.7801, *Wabtec/Faiveley Transport*, Decision C(2016)6325, http://ec.europa.eu/competition/mergers/cases/decisions/m7801_2121_3.pdf, ¶ 108.
28. See Eur. Comm'n, Case M.2922, *Pfizer/Pharmacia*, Decision SG(2003)D/228752, http://ec.europa.eu/competition/mergers/cases/decisions/m2922_en.pdf. Eur. Comm'n, Case M. 3687, *Johnson & Johnson/Guidant*, Decision C(2005)3230, http://ec.europa.eu/competition/mergers/cases/decisions/m3687_20050825_20600_en.pdf. Eur. Comm'n, Case M.1846, *Glaxo/Smith Kline*, Decision C(2000), http://ec.europa.eu/competition/mergers/cases/decisions/m1846_en.pdf (hereinafter, *Johnson & Johnson/Guidant*).
29. The merger was cleared following an in-depth investigation, *Johnson & Johnson/Guidant*, *supra* note 28.
30. *Id.* at ¶ 113.
31. *Id.* at ¶ 165.
32. *Id.* at ¶ 129.

assessment and was likely one of the reasons why the merger was cleared without commitments in the DES market.[33]

B. The "New" Approach

To recap, under the *traditional* analytical framework applied by the Commission in a great number of past cases and well exemplified in *J&J/Guidant:*[34] harm to innovation should inevitably be linked to late-stage pipeline products (e.g., Phase III drugs or medical devices). Hence, time to market was supposed to occur in a short time horizon, at the most within two to three years; prospect for a successful market entry should be proved based on particularly cogent evidence collected throughout the market investigation; and closeness of competition should be very carefully investigated, especially in a context where the pipeline product has not yet entered the market. Importantly, a symmetric approach was applied when assessing potential competition from third parties and potential competition stemming from the merging parties. All in all, a very high standard of proof was required for the Commission to prove that a merger raised concerns by removing a potential competitor capable of exerting a significant competitive constraint.

The first signs of the Commission gradually revisiting its traditional approach by lowering the intervention thresholds are visible in a string of cases dating back to 2014 to 2016, namely, *Medtronic/Covidien*,[35] *Novartis/GSK*,[36] and *Pfizer Hospira.*[37]

C. Medtronic/Covidien (2014)

Medtronic/Covidien[38] impacted the market for drug-coated balloons (DCB) to treat vascular diseases, where Medtronic was market leader and Covidien had a promising pipeline product.[39] Competitors were scarce, with only Bard being perceived as a close competitor to Medtronic, while other DCB suppliers could not rely on robust clinical data to compete with Medtronic and Bard, the competitive pressure on Medtronic being thus limited. The pipeline product of the target company, Stellarex, was in Phase III of development, but the prospect of a successful entry was uncertain because of the lack of sufficient clinical data on efficacy.[40] Nonetheless, the Commission held that the transaction would have eliminated a credible competitor and might have undermined innovation in the market for DCB.

What is striking in this case is that the Commission reached the conclusion that Covidien pipeline product constituted a credible potential competitor capable of exerting an important constraint, despite very mitigated feedback from physicians, while the competitive pressure coming from already existing products from established competitors was altogether discarded. The Commission concluded that the existing competitors (Bard, Biotronik and Eurocor) would not be in a position to exert sufficient

33. For a comment of this case, *see* Mario Todino, Alberto Bacchiega, & Stéphane Dionnet, *Johnson & Johnson/Guidant: Potential Competition and Unilateral Effects in Innovative Markets*, 3 Competition Pol'y Newsletter 87–94 (2005).
34. *Johnson & Johnson/Guidant*, supra note 28.
35. *Medtronic/Covidien*, *supra* note 4.
36. *Novartis/GSK*, *supra* note 5.
37. Eur. Comm'n, Case M. 7559, *Pfizer/Hospira*, Decision C(2015) 5639, http://ec.europa.eu/competition/mergers/cases/decisions/m7559_20150804_20212_4504355_EN.pdf (hereinafter, *Pfizer/Hospira*).
38. *Medtronic/Covidien*, *supra* note 4.
39. *Id.* at ¶ 214. The Commission considered that only the devices of Bard, Biotronik, and Eurocor had a sizeable presence in the market.
40. During the market investigation, several key opinion leaders indicated that Covidien's product cannot really be compared with competitors' products and in particular Medtronic's at this stage, as there were no sufficient clinical data and no similar data. Covidien did not yet have the results of any rigorous investigational device exemption (IDE) testing but instead has simply had a "first in human" study of 50–80 patients, *Medtronic/Covidien*, *supra* note 4, at ¶ 236.

competitive pressure on the merged entity on the DCB market post-Transaction, even though Bard, for example, was Medtronic's closest competitor and the only one with comparable clinical data to Medtronic.[41]

The Commission's reasoning and conclusions are in stark contrast with the findings in *J&J/Guidant*,[42] which displays resemblances with the *Medtronic/Covidien*[43] case, in terms of market features and competitive landscape (cardiovascular devices). For instance, in the latter case, the Commission discounted the fact that no sufficiently solid clinical data was available to prove the efficacy of the pipeline product. It also downplayed opinions of physicians indicating that the target's product could not really be compared with Medtronic's product at this stage due to the lack of clinical data.[44] In contrast to the *J&J/ Guidant* case,[45] where abundant evidence about clinical trials and availability of angiographic parameters proved the prospect of success of the target and the other pipeline products, in *Medtronic/Covidien*,[46] the Commission only relied on statements from two surgeons and on the parties' internal documents to conclude that the pipeline product could exert a sufficient competitive constraint on Medtronic.[47] Conversely, the relevance of actual and potential competition coming from third-party suppliers was restrained by applying a higher standard of care in assessing the reliability of the evidence.

In sum, the amount of documentary and statistical evidence used by the Commission to support the claim that the target's product could constitute a potential competitor appears to be unconvincing in absolute terms, and much poorer in relative terms as opposed to *J&J/Guidant* case,[48] with the prognostic analysis typical of a merger assessment slipping towards a speculative guess unsubstantiated by objective factors.[49]

Admittedly, there are two apparent mitigating factors possibly explaining the Commission's decision.

First, *J&J/Guidant*[50] is a Phase II decision, as opposed to *Medtronic/Covidien*,[51] which is a Phase I decision where the legal test to raise concerns relates to "*serious doubts about the compatibility of the transaction with the common market*." However, as clarified by the case law, the standard of proof for decisions under Article 6 of the European Union Merger Regulation (EUMR) is just the same as for those adopted under Article 8.[52] Accordingly, the "serious doubts" test should nonetheless be interpreted as meaning that, based on a balance of probabilities judgement, sufficiently cogent evidence should be collected to demonstrate that the transaction is likely to significantly lessen competition; the difference with a finding of a significant impediment of effective competition (SIEC) in a Phase II case

41. Bard was Medtronic's closest competitor and the only one with comparable clinical data to Medtronic, having realized the IDE testing on 476 patients in randomized control trials for safety and efficacy, *Medtronic/Covidien*, *supra* note 4, ¶ 216.
42. *Johnson & Johnson/Guidant*, *supra* note 28.
43. *Medtronic/Covidien*, *supra* note 4.
44. The Commission relied only on statements from two surgeons and on internal documents to conclude that the pipeline product could exert a sufficient competitive constraint on Medtronic.
45. *Johnson & Johnson/Guidant*, *supra* note 28.
46. *Medtronic/Covidien*, *supra* note 4.
47. *Id.* at ¶ 236.
48. *Johnson & Johnson/Guidant*, *supra* note 28.
49. The interventionist approach of the Commission in this particular case might possibly also be explained by the evidence of the planned discontinuation of Covidien pipeline product the Commission found in Medtronic's internal planning. The fear that customers would have been deprived of an innovative and potentially effective device might thus have prompted the Commission to even discard competition from already established players and to center its competitive assessment on the loss of potential innovation. *Medtronic/Covidien*, *supra* note 4, ¶ 247.
50. *Johnson & Johnson/Guidant*, *supra* note 28.
51. *Medtronic/Covidien*, *supra* note 4.
52. EGC, Case T-79/12, *Cisco v Commission*, EU: T:2013:635, ¶ 46.

possibly being only a matter of quantity of evidence collected in the investigation (in principle less significant in the first phase) rather than quality of evidence.

Secondly, the Commission seems to have found internal evidence hinting to the parties planning to discontinue the pipeline product. It is apparent that whenever the Commission finds internal evidence proving discontinuation of pipeline products, it does not seem keen to engage in a solid demonstration of what real prospect of success the pipeline product would have when hitting the market in the first place.[53] In other words, to the extent there is evidence that some harm to innovation is likely to materialize, this finding appears to be sufficient for the Commission to truncate its analysis. However, the enforcer cannot be exempted from running a proper qualitative assessment as to whether the pipeline product under threat of discontinuation could ever become a serious contender of the incumbent players.

D. Novartis/GSK (2015)

In the *Novartis/GSK* case,[54] Novartis intended to acquire from GSK's portfolio three potential blockbuster anticancer drugs. Both Novartis and GSK had advanced pipeline products (Phase III) for the treatment of skin and ovarian cancer.[55] In terms of the competitive landscape, only one additional competitor was present with a marketed or advanced pipeline drug. Moreover, the same inhibitors were being tested by both Novartis and GSK for the treatment of other cancers based on the same mechanism of action (in early development stages; Phase I and II, respectively), for which only one additional competitor had a late-stage competing pipeline product (Roche).

The Commission feared that Novartis would stop developing its pipeline products given that, postmerger, Novartis would acquire drugs with the same mechanism of action from GSK and given that the duplication of clinical programs is lengthy and costly.[56] Complex structural and behavioral remedies were implemented to address these concerns.

Importantly, rather than limiting itself to pipeline products in advanced stages of clinical development like it did in earlier cases, the Commission looked at all phases of clinical research and concluded that the transaction would have caused a reduction of innovation; that is, Novartis would have abandoned both the late-stage clinical trial programs (Phase III) for the two drugs for skin and ovarian cancer, as well as the early-stage clinical trial programs (Phases I and II) for the other types of cancer.

The novelty of this case lies in the fact that for the first time the Commission stretched the timeframe relevant to assess successful market entry by pipeline products and ventures in a territory where the prognostic analysis becomes very speculative; for the higher we climb the "pipeline," the more difficult and uncertain a prediction about market entry becomes.[57]

Moreover, it is also visible that for the first time the Commission begins to distance itself from a traditional analysis anchored to specific products and brings the discussion about harm to innovation at a higher level, by discussing the merger's chilling effect on the parties' "*incentive to innovate*," [58] and

53. Similarly, in *Dow/DuPont*, the Commission found internal evidence hinting to the discontinuation and reorientation of ongoing and overlapping lines of R&D of the merging parties, showing that "the synergies of the transaction are therefore set from the beginning to focus on cost cutting, rather than on creating value," *Dow/DuPont*, *supra* note 1, ¶¶ 3071 *ff*.
54. *Novartis/GSK*, *supra* note 5.
55. The products concerned B-Raf and MEK inhibitors.
56. According to the Commission, the cost for Novartis to pursue research would likely be disproportionate compared to the expected return on investment, which is why Novartis would most likely prioritize the developments of GSK's inhibitors.
57. Whereas products in phase III of clinical trials have a 50% prospect of reaching the market, products in phase I of clinical trials, like the ones in the case before hand, only have a 10% probability of being launched.
58. *Novartis/GSK*, *supra* note 5, at ¶ 104.

about "competition in innovation" as such. In this respect, *Novartis/GSK*[59] is the prelude to *Dow/DuPont*[60] and the new theory of harm that will be fully developed later.

E. Pfizer/Hospira (2015)

In this case, the transaction gave rise to an overlap in relation to biosimilars used to treat some autoimmune diseases (rheumatoid arthritis).[61] Only one reference biological drug based on the molecule infliximab was available on the market and marketed by MSD (Remicade), and only one biosimilar was available on the market, developed by Celltrion and comarketed independently and under competing brands by Hospira and Celltrion. Samsung Bioepis was at an advanced stage of development of a competing biosimilar based on the same molecule (infliximab) and planned an imminent entry, while Pfizer was also developing a competing biosimilar although it was still a number of years away from entry.[62]

Despite limited information about clinical evidence proving the efficacy of Pfizer pipeline biosimilar, the Commission raised nonetheless concerns that, postmerger, Pfizer would have delayed or discontinued development of its pipeline biosimilar drug to focus on Hospira's product, which would mean a loss of significant competition in view of Pfizer biosimilar's good prospect of a successful market entry. A full divestment of Pfizer's infliximab biosimilar drug[63] was required in order to preserve future innovation in biosimilars.

This case not only confirms the new tendency of the Commission to truncate the qualitative assessment about the prospect of success of the pipeline product to the extent there is a threat of discontinuation of such a product, but also shows the insurgence of a double standard when assessing the relevance of potential competition: when it comes to a third-party potential competitor, the Commission sticks to the traditional short timeframe (generally two years) in order to assess whether such company can become a competitive force in the foreseeable future.[64] When potential competition concerns one of the merging parties, the Commission takes into account a much longer timeframe—six to eight years for Pfizer to develop infliximab in the present case—and does not consider itself to be bound by the two-year period.[65]

F. Dow/DuPont (2017)

The tendency to assess harm to innovation in an increasingly "intangible" manner culminates in the "wholesale" approach taken in *Dow/DuPont*,[66] where harm to innovation is looked at from an "overall industry" level.

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59. *Id.*
60. *Dow/DuPont*, *supra* note 1.
61. *Pfizer/Hospira*, *supra* note 37.
62. As regards the product market, the Commission found the originator drug, Remicade, to belong to the same market as biosimilars due to close competition for newly diagnosed patients yet was considered only a distant competitor relative to infliximab biosimilars due to market power over patients in treatment. However, it considered that there was direct price competition between the two Infliximab biosimilars present on the market, and that Pfizer's pipeline biosimilar—based on the same molecule—would have constituted a significant competitive constraint on such biosimilars. The market segmentation was devised very narrowly in order to discard potential competition over biosimilar drugs coming from generic drugs with the same therapeutic action.
63. Including global development and manufacturing rights, IP rights, know-how, and technology.
64. See also *supra* note 15, ¶ 74.
65. *Pfizer/Hospira*, *supra* note 37, at ¶¶ 40, 47–54.
66. *Dow/DuPont*, *supra* note 1.

The Commission's Phase II investigation in *Dow/DuPont*[67] concerned the parties' activities in pesticides, where the merger would create the number one seed and pesticide company in the world.

In addition to standard horizontal unilateral effects, the Commission also raised concerns with respect to overlapping lines of research in innovation of pesticides, that is, the likelihood of negative effects of the transaction on the parties' research and development (R&D) lines, as well a reduction in the overall incentives to innovate postmerger. The Commission's assessment of how the merger would chill innovation was based on several elements, such as (1) the market features, that is, high barrier to entry; (2) the importance of the merging parties as innovators, in particular DuPont; (3) how close the parties competed in innovation; (4) the likely negative effects on innovation stemming from the transaction; and (5) whether the remaining competitors could compensate for the loss of innovation competition.

From a qualitative point of view, the Commission analyzed the parties' internal documents to identify the characteristics of research targets, R&D capabilities, and pipelines at the research stage, *without assigning these R&D activities to a particular product market*. Indeed, the Commission acknowledged that "*it may not be able to identify precisely which early pipeline products or lines of research the Parties would likely discontinue, defer or re-direct*."[68]

The investigation showed that the merging parties had (1) some overlapping R&D capabilities; (2) some overlapping lines of research in the discovery stage, where the parties had a number of promising competitive pipeline products; and (3) other overlaps across the different stages of a product lifetime (e.g., discovery-to-development pipelines overlaps and discovery-to-existing product overlaps).

Based on the analysis of patent data related to crop protection, the Commission then inferred the high importance of both merging parties as innovators, the high degree of concentration in research for new active ingredients (AIs) (discovery stage), and the significant combined share of research for *new* AIs accounted by the merging parties, notably in selective herbicides and insecticides.[69] On this basis, the Commission found that there was a concentrated "innovation market," with five players on a global level—a higher level of concentration than in the product market.

The Commission's investigation concluded that innovation was an important parameter of competition in the crop protection sector, that the parties were head-to-head competitors in terms of innovation in specific crop protection areas, and that they were planning to cut back their R&D efforts postmerger.

Based on this, the Commission found that it was likely the merger would have restricted competition, not only because of reduced competition on *existing* products, but also because of its adverse effects on *future efforts* to innovate. The theory of harm to innovation was phrased as "removing the parties' incentives to both pursue parallel R&D and bring new products to the market."[70]

Unlike the cases exposed above, where innovation concerns related to transactions in which pipeline products were overlapping, *Dow/DuPont*[71] involves therefore the effects on innovation at earlier stages, that is, on early R&D efforts of the parties that have not yet taken the shape of concrete products.[72]

67. *Id.*
68. *Id.* at ¶ 3025.
69. For a detailed analysis of quantitative evidence from the analysis of patent data, *see* Benno Buehler, Daniel Coublucq, Cyril Hariton, Gregor Langus, & Tommaso Valletti, *Recent Developments at DG Competition: 2016/2017*, 51 Rev. Indust. Org. 397 (2017), https://doi.org/10.1007/s11151-017-9592-x.
70. *Dow/DuPont*, *supra* note 1, at ¶ 3015.
71. *Id.*
72. A concrete concern in such cases is the discontinuation, delay, or reorientation of ongoing and overlapping lines of research of the merging parties. The existing overlapping lines of research or pipeline projects of one merged party may be abandoned, delayed or reoriented postmerger, because those R&D efforts could cannibalize the profits from existing and future products of the other merged party.

Such R&D efforts may target an existing product market or take place upstream of actual product markets in wider innovation areas.[73]

G. Dow/Dupont and Its Critics

The *Dow/DuPont*[74] case has sparked an incessant "search for meaning" with respect to the theory of harm employed by the Commission from both economists and legal scholars.

From an economic point of view, critics have argued that predicting the success of innovation efforts is by definition uncertain and that it is thus not well-suited for a solid merger control decision.[75] In addition, it has been argued that the decision does not calculate the innovation diversion ratio; nor does it discuss efficiency gains.[76] Such efficiency gains can materialize through incentives to streamline R&D by shutting down certain less-efficient research units in the postmerger entity and focusing their efforts on others.[77] The merging parties can therefore benefit of the avoidance of replication of discovery, increasing the ultimate returns on R&D.[78]

From a legal point of view, it has been argued that *Dow/DuPont*[79] marks a new development in the Commission's legal analysis, for it takes into account R&D activities unrelated to specific products in the antitrust analysis and speaks of "*innovation competition*" and "*innovation spaces*," instead of, respectively, product and price competition and clearly defined product markets.[80] This would mark a shift in the Commission's analytical framework, whereby a new "s*ignificant impediment to effective*

73. See *supra* note 19, p. 7.
74. *Dow/DuPont*, *supra* note 1.
75. Laurence Bary & Frédéric de Bure, *Disruptive Innovation and Merger Remedies: How to Predict the Unpredictable?* 3 Concurrences (2017). Critics also highlighted that a reduction of R&D spend, on which the Commission focused in *Dow/DuPont*, does not equate a reduction in innovation. In that respect, authors highlighted that innovation effects are fundamentally different from price effects. Companies can decide whether to raise or to lower prices, whereas they cannot *decide* to innovate; they can only *try* to innovate, and the result of this is pretty much intangible until the outcome is finally becoming visible. The practical challenge is how to determine that R&D expenditure has a clear impact on the competitive position of companies in innovation—expenditure may be one aspect that, however, does not equal success.
76. Joseph Farrell & Carl Shapiro, *Antitrust Evaluation of Horizontal Mergers: An Economic Alternative to Market Definition*, SSRN (2010), https://ssrn.com/abstract=1313782. *See also* Bundeskartellamt, Innovationen – Herausforderungen für die Kartellrechtspraxis (Tagung des Arbeitskreises Kartellrecht, 2017), https://www.bundeskartellamt.de/SharedDocs/Publikation/DE/Diskussions_Hintergrundpapier/AK_Kartellrecht_2017_Hintergrundpapier.pdf?_blob=publicationFile&v=2, *BKA Innovation Paper*. As underlined by the German Bundeskartellamt, the decision fails to balance the allegedly negative effects on innovation against economic theory that shows that under certain circumstances increased concentration may also be beneficial for innovation incentives.
77. Vincenzo Denicolò & Michele Polo, *The Innovation Theory of Harm: An Appraisal*, SSRN (2018), https://ssrn.com/abstract=3146731.
78. Denicolo & Polo, *id.*, also focus on the postmerger entity's ability to apply R&D findings across a broader output, thereby further increasing R&D returns. The conclusion that Denicolo and Polo draw is that while mechanisms whereby mergers reduce innovation certainly exist, there are also others by which mergers spur innovation; therefore, the case for an *a priori* presumption of harm against mergers in innovative industries is shaky at best. The Commission's chief economist, Prof. Valletti, did respond to the criticism that recent academic literature had voiced against the Commission's approach in *Dow/DuPont*. At a recent conference, GCR Live IP, he clarified his position, in a personal capacity, as the fact that he does not consider "every merger harmful to innovation," accusing practitioners to have been misrepresenting their approach through "selective reading," https://globalcompetitionreview.com/article/1166591/valletti-attacks-innovation-myths. *See also* Andrea Lofaro, Stephen Lewis, & Paulo Abecasis, *An Innovation in Merger Assessment? The European Commission's Novel Theory of Harm in the Dow/DuPont Merger*, 32 Antitrust, 1 (2017); Massimo Motta & Emanuele Tarantino, *The Effect of Horizontal Mergers, When Firms Compete in Investments and Prices* (Universitat Pompeu Fabra, 2017), https://econ-papers.upf.edu/papers/1579.pdf.
79. *Dow/DuPont*, *supra* note 1.
80. *Supra* note 72, ¶ 54.

innovation competition" test is established and the scope of the merger review is expanded to early stage R&D efforts, where products are several years away from reaching the market.[81]

The case raises indeed legitimate legal questions, such as whether the theory of harm to innovation in a *generic* sense (on the industry level) is supported by the Commission's guidance, in the HMG or in other legal sources.

As said, the HMG mention innovation as a dimension of competition on the same footing with prices, but fail to set out a framework for analyzing *generic* harm to innovation unconnected to a specific product or technology market, contrary to the well-established practice of analyzing potential competition through pipeline products.[82] Even though the Commission has tangentially mentioned the importance of preserving innovation pressure already since early cases,[83] it traditionally refrained from assessing longer-term effects of innovation as a specific concern and, instead, focused on the shorter-term impact of mergers as regards innovation concerns.[84]

Outside of merger control, the guidelines[85] on horizontal cooperation agreements deal with R&D and to this end clarify that the impact on competition coming from such agreements should be assessed primarily with reference to existing products and technologies, that is, analyzing whether these products or technologies are close substitutes and whether the parties have market power. In connection instead with innovation involving entirely new products or technologies for which, by definition, no market currently exists, the guidelines clarify that "the effects on competition in innovation are important in these situations, but can in some cases not be sufficiently assessed by analysing actual or potential competition in existing product/technology markets." If so, two scenarios can be distinguished: either the innovation process is structured, and innovation "poles" can be identified, as is typically the case in the pharmaceutical industry, or the process is not structured and no specific R&D poles can be identified.

In the first case, the Commission proposes to analyze competition between the R&D poles and assess the closeness of competition between the parties and the existence of other competing poles. In doing so, the Commission would take 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.[86]

81. Nicolas Petit, *Innovation Competition, Unilateral Effects and Merger Control Policy* (ICLE, 2018), https://laweconcenter.org/wp-content/uploads/2018/06/ICLE-Petit-Innovation-Competition-Merger-Control-Policy-ICLE-2018.pdf. The Commission itself, shortly after the decision, made clear that, in the Commission's view, innovation concerns do not need to be tied to harm in any specific market: "In some cases, you can know in which product the companies are innovating and you can identify an overlap in the future. But there could be situations where we don't know the outcome of the innovation process, but we nevertheless know the innovation process would be harmed as a result of the merger." Matthew Newman, *Dow-DuPont Merger Remedy Reflects EU's Growing Focus on Innovation, Mosso Says*, mLex (2017), http://www.mlex.com/GlobalAntitrust/DetailView.aspx?cid=877094&siteid=190&rdir=1.
82. *See also supra* note 19.
83. *See*, *e.g.*, Eur. Comm'n, Case M.214, *Du Pont/ICI*, http://ec.europa.eu/competition/mergers/cases/decisions/m214_en.pdf, ¶ 47: "the strengthening of Du Pont leads to a considerable reduction of competition, in particular with regard to the competition in product development. Product differentiation resulting from continuing innovation is one of the driving forces of this market. Competition in product development between Du Pont and [the target] in the past has been an important source of innovation." As quoted in a recent speech by Mosso, *supra* note 24.
84. Eur. Comm'n, *supra* note 20, at 6.
85. Guidelines, as a soft law instrument, express the Commission's interpretation of the law, and can be a "useful point of reference"; they are not binding on courts and do not express the law. *See* CJEU, Case C-310/99, *Italy v Commission*, EU:C:2002:143, ¶ 52.
86. Eur. Comm'n, Guidelines on the Applicability of Article 101 of the Treaty on the Functioning of the European Union to Horizontal Co-operation Agreements, O J C 11 (Jan. 14, 2011) (hereinafter, *Horizontal Cooperation Guidelines*), 1–72, ¶ 120.

The guidelines do not specify the "timing" to be taken into account in such an analysis of R&D poles. However, the implicit logic of analyzing R&D poles as opposed to pipeline products is that a longer time horizon can be taken into account.[87]

By contrast, when R&D poles cannot be clearly identified, the Commission "would not try to assess the impact of a given R&D co-operation on innovation, but would limit its assessment to existing product and/or technology markets which are related to the R&D co-operation in question."[88]

Similarly, in its guidelines concerning technology transfer, the Commission explains that "the Commission will normally confine itself to examining the impact of the agreement on competition within existing product and technology markets," even though

> in a limited number of cases, however, it may be useful and necessary to also analyse the effects on competition in innovation separately. This is particularly the case where the agreement affects innovation aiming at creating new products and where it is possible at an early stage to identify research and development poles.[89]

The legal framework can thus be summarized as follows. Harm to innovation is a relevant concern under the HMG, on equal footing with effects on prices, output, or consumer choice. However, harm to innovation in a way that is unconnected to a specific product or technology market can conceivably only be a valid concern if identified structured R&D poles can be identified. In the absence of such structured R&D poles, any assessment of harm to an abstract "innovation" concern would be too speculative to be treated as a significant impediment to effective competition under the EUMR.

In that sense, the relevant question is to what extent the "innovation spaces" identified in the *Dow/DuPont*[90] case are structured enough to be qualified as R&D poles and can therefore allow a robust legal analysis. The overlapping "innovation spaces" were identified as being development-to-development overlaps and development-to-products overlaps with respect to herbicides, insecticides, and fungicides. From a quantitative point of view, the Commission assessed these "innovation spaces" by carrying out a very detailed analysis of patent data, which confirmed the high importance of both merging parties, and in particular one merging party, as innovators and the significant combined share of research for new active ingredients accounted by the merging parties, notably in selective herbicides and insecticides.[91]

In sum, the Commission did indeed employ a structured approach when defining "innovation spaces," which could therefore be qualified as R&D poles. It is hence fair to say that even though the theory of harm to innovation in a generic sense is in no way backed by the HMG, the competitive assessment employed by the Commission could potentially be anchored in the Guidelines on horizontal cooperation agreements, at least on a conceptual basis.[92]

87. Nevertheless, it should be noted that an overextensive interpretation of the relevant timeframe to be taken into account creates an issue of predictability and legitimate expectations for the parties to the concentration. Thus, it is submitted that the analysis of R&D poles should be carried out within a reasonable timeframe, in view of the characteristics of the industry.
88. Eur. Comm'n, *supra* note 86, at ¶ 122.
89. *Id.* at ¶ 26.
90. *Dow/DuPont*, *supra* note 1.
91. *Id.* at ¶¶ 2900 *ff*. For a detailed analysis of quantitative evidence from the analysis of patent data, *see supra* note 49.
92. *Supra* note 82.

III. Revisiting the "Traditional" Approach

While *Dow/DuPont*[93] keeps attracting a lot of criticism, the lines that were crossed during the journey leading to that outcome have gone largely unnoticed. *Medtronic/Covidien*[94] raises an issue of *standard of proof*: the Commission upholds the claim that the target's product could constitute a potential competitor based on poor evidence. *Novartis/GSK*[95] raises a related issue of *causation*: the Commission overstretches the timeframe relevant to assess when a pipeline product can grow into a competing product.[96] *Pfizer/Hospira*[97] raises an issue of *symmetry:* the Commission applies a double standard when analyzing potential competition coming from a third party in comparison to potential competition from one of the merging parties.

The principles the Commission has endorsed in such cases raise much more serious concerns from a legal standpoint and carry potentially more far-reaching and troubling implications than the novel theory of harm developed in *Dow/DuPont*.[98] They alter some of the key features of the traditional analytical framework the Commission applies to assess horizontal mergers involving issues of potential competition: the standard of proof necessary to demonstrate the existence of competition concerns, that is, the quantity and quality of evidence necessary to support the finding that a potential competitor would likely turn into a significant competitive constraint; the related issue of causation, which requires a rigorous analysis of the chains of cause and effect aimed at predicting whether future postmerger events are likely to materialize; and the symmetry principle guiding the Commission when assessing the issue of potential competition, be it from the merging parties or from third parties.

A. Standard of Proof

The standard of proof incumbent upon the Commission when assessing a merger is to do with the amount and the quality of evidence the Commission needs to gather in order to assess a concentration and come to a decision, be it a clearance, a conditional clearance, or a prohibition.[99] In the field of merger control, because of the prognostic nature of the assessments, coupled with the relevant role that economics play in such analysis, the Commission has traditionally advocated a wide margin of discretion, which in turn would entail a restrained judicial scrutiny. The EU judges, though, in a sting of famous precedents (see *inter alia Airtours/First* Choice,[100] *Schneider/Le Grand*,[101] *Tetra Laval/Sidel*,[102] and *GE/Honeywell*[103]*)* have set a high standard, noting that

93. *Dow/DuPont*, *supra* note 1.
94. *Medtronic/Covidien*, *supra* note 4.
95. *Novartis/GSK*, *supra* note 5.
96. The Commission considered as potential competitors pipeline products in phase I of clinical trials, which only have an approximately 10% prospect of entering the market. In this respect, *Novartis/GSK* is similar to *Dow/DuPont* with respect to the underlying intangible harm to innovation. It can be argued that the *Dow/DuPont* case is the next step in continuation of these cases, rather than an entirely new animal.
97. *Pfizer/Hospira*, *supra* note 37.
98. *Dow/DuPont*, *supra* note 1.
99. This standard is directly related to the scope of judicial review the General Court is entitled to apply towards the Commission's decisions, that is, the intensity of the scrutiny that the EGC applies when reviewing the legality of such decisions. The two concepts are intuitively interrelated to the extent the intensity of the judicial review can change depending on the underlying standard of proof incumbent upon the administrative agency having to take the decision. The more margin of discretion is allowed to an agency when taking a decision, the more restrained the judicial scrutiny.
100. EGC, Case T-342/99, *Airtours v. Commission*, EU: T:2002:146.
101. EGC, Case T-310/01, *Schneider Electric v. Commission*, EU: T:2002:254.
102. CJEU, Case C-12/03-P, *Commission v. Tetra Laval*, EU: C:2005:87, confirming the judgement of the Court of First Instance, Case T-05/02, *Tetra Laval v. Commission*, EU: C:2010:280.
103. EGC, Case T-210/01, *General Electric v. Commission*, EU: T:2005:456.

> the quality of the evidence produced by the Commission in order to form a sound basis for a decision declaring a concentration incompatible with the common market is particularly important, since that evidence must support the Commission's conclusion that, if such a decision were not adopted, the economic changes envisaged by it would be plausible.

Accordingly, the Commission has to prove its case based on evidence that is factually accurate, complete, abundant and consistent; moreover, based on this evidence, the adverse effects expected on competition stemming from a merger must be demonstrated with a sufficient degree of probability.

Symmetrically, the standard of review to which the European General Court (EGC) is entitled is very broad and thorough. It is for the EGC to verify primarily whether facts are accurate. Here, there is no room for discretion for the Commission. The EGC checks then very intensively whether conclusions that are drawn from such facts are correct and whether the evidence brought in support of a claim by the commission is sufficiently solid; that is, the evidence is complete, abundant, and consistent. Moreover, the intensity of the review clearly varies depending on the complexity of the theory of harm put forward by the Commission. The control is much more intense with respect to those situations whereby harm is foreseen as a result of a more complex chain of events and interplay, like in cases of coordinated effects, in conglomerate mergers, and, one could add, in cases dealing with harm to innovation.

B. Causation

Rigorous causation in merger control is a corollary of the high standard of proof that has been endorsed by the EU courts. Merger control entails a prospective analysis of future market events requiring a prognostic exercise of great accuracy, which must be based on sufficiently reliable predictions. Assessing a merger impacting innovation further complicates the exercise, for it requires a prognostic effort that stretches well into the future.[104]

As the EGC stated in *GE v. Commission*,[105] relying on *Tetra Laval v Commission*,[106]

> Conglomerate-type concentrations give rise to certain specific problems, in particular inasmuch as, first, the assessment of such a transaction may involve a prospective analysis covering a period of time stretching well into the future and, second, the specific conduct of the merged entity may determine to a great extent what effects the concentration has. Thus, the chains of cause and effect following a merger may be dimly discernible, uncertain and difficult to establish.[107]

These considerations, made in the context of a conglomerate merger, are *a fortiori* pertinent for mergers involving innovation, where the assessment of the transaction stretches well into the future and for which the chains of cause and effect may be even more dimly discernible. The analysis of competition in innovation assesses the chances of a firm to introduce a product in the market in the future and thereby to potentially grow into an effective competitive force. Given the added uncertainty inherent to a case of potential competition, it is all the more important for the Commission to demonstrate, on the basis of convincing evidence, that its envisaged scenario is the most likely to occur absent the concentration. When early pipeline products, with an inherently uncertain prospect of success, are promoted to significant competitive constraints based on thin evidence and poor cause-

104. *Id.*
105. *Id.*
106. CJEU, Case C-12/03-P, *Commission v. Tetra Laval*, EU: C:2005:87, confirming the judgement of the Court of First Instance, Case T-05/02, *Tetra Laval v. Commission*, EU: C:2010:280.
107. *General Electric v. Commission*, *supra* note 103, at 456.

effect analysis, it is legitimate to doubt that the Commission has properly addressed the issue of causation.

C. Symmetry

The EU merger control system is governed by a general principle of symmetry.[108] This entails that under the EU merger control system there is no presumption of either legality or illegality of a merger transaction. Under this system, the Commission is required to either approve or prohibit a concentration following a judgment in favor of one or the other outcome based on a balance of probabilities, the latter in turn depending on the evidence collected in the investigation.

But the same standard of balance of probabilities applies across the board, that is, to any finding of the Commission in connection with its assessment, including the likely occurrence of postmerger developments in a counterfactual scenario. And while the burden of proof may shift (who is bound to bring the evidence in support of a claim), the threshold applicable for standard of proof purposes—that is, amount of quantitative and qualitative evidence required to demonstrate that an event projected in the future is more likely than not to materialize—cannot change depending on whether potential competition is an offensive or a defensive argument in the context of a merger assessment.

Against this background, it is difficult to reconcile the stretched time frame of several years over which the potential for success of the merging parties' pipeline products is evaluated, with the short timeframe (two years) the Commission considers in order for third-party potential competitors to be treated as credible future entrants capable of exerting a significant competitive constraint.[109]

The same problem of symmetry applies to the assessment of the verifiability of efficiencies in the context of an efficiency defense, notably a very challenging test. In fact, according to the HMG, verifiability is supposed to be demonstrated based on a rigorous causation of events,[110] which however should not be different from what is required in connection with potential competition coming from the merging parties.

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108. *Id.* at ¶ 61. This policy choice could be explained with the choice of the legislator not to take side in favor of either businesses or consumers. In his Opinion of 20 May 2010 to *Tetra Laval*, Case C-12/03-P, EU:C:2004:318, Advocate General Tizzano argued that the European Commission Merger Regulation (ECMR) does not impose an identical standard for clearance and prohibition decisions. In particular, he noted that a general presumption of lawfulness of mergers seems grounded into the Regulation and the overall system. To this end, he referred in particular to the fact the ECMR is based on a system of mandatory deadlines within which the Commission is to take the decision; as a consequence, in the event of failure to act within the deadline, a merger is deemed to be authorized. Moreover, he mentioned the possibility to resort to ex post antitrust enforcement based on Articles 101 and 102, which enable the Commission to intervene in case of mistake. Among the other arguments generally invoked to support such a reading, there is also the fact that mergers are an expression of the right to property and the right to free economic enterprise, which are fundamental rights recognized in the Treaty and in the Charter of fundamental rights endorsed by the EU. Second, a pure symmetric system would also be hardly workable as there would be many cases falling in a grey zone in which it is simply impossible to prove what is more likely based on a high standard of proof. The benefit of the doubt, the argument goes, should therefore lean towards authorization of the merger.

109. In *Novartis/GSK*, the Commission assessed innovations that may or may not enter the market in five to seven years' time. In *Dow/DuPont*, the Commission assessed innovations that may or may not successfully enter the market in ten years' time. *See Dow/DuPont*, *supra* note 1, at ¶ 291: "Crop protection is a sector where large investments and significant amounts of time are needed to bring new products to the market. It thus appears to take eight to 10 years to get an AI from its discovery to the launch of formulated products, with an average cost of approximately USD 250-300 million."

110. In *Dow/DuPont*, *supra* note 1, the Commission rejected the claimed efficiencies on the basis of that "the efficiencies alleged by the Parties depend on future strategic decisions by the companies and on detailed knowledge of companies' assets and capabilities and of the function of the industry and its dynamics. They likely take place in the long-term based on a complex and long chain of events. The efficiencies are thus difficult for the Commission to verify on its own and the submissions by the Parties do not provide any concrete evidence on how these efficiencies are being planned and how much they would improve the productivity of the merged entity."

The asymmetric approach is magnified in the context of the assessment of innovation efficiencies,[111] since the merging parties are actually faced with an impossible test to meet; for the criteria that the Commission has established for an efficiency defense to succeed with respect to product and price competition simply cannot apply to innovation competition, where it is impossible to prove and quantify the pass-on.

D. Investigative Issues and Remedial Actions

There are also related practical problems resulting from this new approach that should not be underestimated.

1. Fact-finding. First, there is a serious investigative issue of how to gather credible evidence demonstrating that a pipeline product has a serious prospect of success in the market. For the more distant the events under scrutiny are, the more challenging the fact-finding exercise will become for the Commission.

In *Medtronic/Covidien*,[112] the Commission extensively relied on the parties' internal documents, and particularly on documents demonstrating Covidien's ambition about its pipeline product. Likewise, in *Pfizer/Hospira*,[113] to downgrade the competitive force of an imminent third-party entrant, the Commission based its finding on internal documents of the merging parties, claiming that the rivals' products would encounter difficulties to enter the market. However, such documents are commonly subject to "corporate chest-bumping" liable to overstate the companies' true chances of success.

In that respect, the courts have stressed that the intention of an undertaking to enter the market is not sufficient to establish its status as a potential competitor.[114] The essential factor to be assessed is whether such undertaking has the *ability* to enter the market in an economically viable way and thereby grow into an effective competitive force, constraining the incumbent firms. The EGC recently emphasized that in determining whether an undertaking is a potential competitor on the market,

> The Commission is required to determine whether, there would have been real, concrete possibilities for it to enter that market and to compete with established undertakings. Such a demonstration must not be based on a mere hypothesis, but must be supported by evidence or an analysis of the structures of the relevant market. Accordingly, an undertaking cannot be described as a potential competitor if its entry into a market is not an economically viable strategy.[115]

Submissions by third parties, whether in the context of a market investigation, or through voluntary submissions and complaints, are another type of evidence regularly used by the Commission. Here, too, caution is warranted for innovation cases. Third parties are rarely best placed to assess the chances

111. *See* Reinhilde Veugelers, *Innovation in EU Merger Control: Walking the Talk* (Bruegel Policy Contribution, Feb. 29, 2012), http://bruegel.org/wp-content/uploads/imported/publications/pc_2012_04__FINAL.pdf. According to Veugelers, from a total of forty-two EU phase II merger cases between 2004 and 2016, efficiencies were claimed in only sixteen cases, of which only eleven claimed dynamic efficiencies claims. Innovation was mentioned in the efficiency claims in only four cases.

112. *Medtronic/Covidien*, *supra* note 4.

113. *Pfizer/Hospira*, *supra* note 37.

114. EGC, Case T-370/09, *GDF Suez v Commission*, EU:T:2012:333, ¶ 84, and the case law cited therein.

115. *Id.* at ¶ 83. That case concerned proceedings under Article 101 TFEU. However, the analysis is similar as to whether two parties to an agreement or to a concentration are potential competitors. In both cases, the question is whether, absent the agreement/concentration these parties would have become competitors. In fact, in recent decisions, the Commission dismissed claims that the parties could be potential competitors, precisely on an analysis of the internal documents. Eur. Comm'n, Case M.7802*, Amadeus/Navitaire*, Decision C(2016)312, http://ec.europa.eu/competition/mergers/cases/decisions/m7802_817_8.pdf, ¶ 153; *Wabtec/Faiveley Transport*, *supra* note 27, at ¶ 199.

of success of a particular research programs, especially if the pipeline products developed in the program are still very distant from market entry.

As the discussion of the *Medtronic/Covidien*[116] case highlighted, even learned experts in the field may have vastly different views in this respect. Short of a consensus between experts, it is doubtful whether even the opinion of a majority, contradicted by sufficiently credible experts, would meet the evidentiary burden set by the courts. In addition, market participants may have their own hidden agenda driven by personal interests and thus try to influence the Commission's investigation. Potential competitors may for instance fear that a transaction could have procompetitive effects resulting in a higher innovation pace rather than less innovation, or could be interested in acquiring potential divestment packages.[117] The issue of the credibility of third-party submissions is not new in merger control, but in the context of an assessment of often secret research programs, it is all the more difficult for the Commission to assess the evidence in front of it, and all the more important to apply a high standard of care.

2. Proportional remedies. Finally, innovation, by definition, is difficult to remedy. Where a theory of harm is based on a specific, identified, research program, it may be possible to divest that program, to the extent R&D efforts are sufficiently structured[118] so that they can be divested as a going concern (including intellectual property [IP], key personnel, machinery, testing facilities, etc.).

Where the theory of harm is based on a more generic "harm to innovation" theory, it is often not possible to do so, short of divesting one of the parties' entire R&D capability. In *Dow/DuPont*,[119] virtually all of DuPont's R&D organization was divested. This raises issues of proportionality of the remedies in comparison to the alleged harm to competition, as a remedy that is too extensive would risk curtailing the efficiencies of the merger. It also raises questions on the effectiveness of these remedies, which would be particularly hard to estimate.

IV. Conclusion

In a new industrial era driven by technological progress, it is all the more legitimate that protection of innovation becomes the number one priority of the Commission's merger enforcement action. Equally sensible, perhaps, is the enforcer's choice to raise the level of care by protecting not only innovation, which translates into tangible goods or services soon to enter the market and able to exert a competitive constraint, but also innovation as a value in itself. These developments, though, should not occur to the detriment of legal certainty, which is a fundamental principle of the EU system and protects all economic actors who can take informed business decisions and are able to reasonably predict the implications of their commercial choices.

However revolutionary the new theory of harm set forth in *Dow/DuPont*[120] might appear, it is in fact less troubling than the gradual revisiting of the Commission's traditional treatment of potential competition in merger control well under way for several years. In fact, *Dow/DuPont*[121] is likely to remain an exceptional case with limited implications. In a careful reading of the decision, the standard of proof applied by the Commission to prove its case appears to be quite high (a detailed analysis of the

116. *Medtronic/Covidien*, *supra* note 4.
117. *See* Justus Haucap, *Merger Effects on Innovation: Rationale for Stricter Merger Control?* (Discussion Paper No. 268, Dusseldorf Institute for Competition Economics, 2017), 55–70, http://www.dice.hhu.de/fileadmin/redaktion/Fakultaeten/Wirtschaftswissenschaftliche_Fakultaet/DICE/Discussion_Paper/268_Haucap.pdf.
118. Absent such structured approach to R&D, it is much more difficult to identify exactly what would need to be divested.
119. *Dow/DuPont*, *supra* note 1.
120. *Id.*
121. *Id.*

overlap of innovation spaces and evidence proving the intent to discontinue some of DuPont's R&D activities).

Conversely, the increasing tendency to challenge traditional mergers involving pipeline products, by applying a lower standard of proof in the form of disregard for causation, or by applying a double standard in assessing potential competition, depending on whether this argument is used as a sword (by the Commission) or as a shield (by the parties), is likely to bear more damaging implications; for it impacts a much larger number of "ordinary" merger transactions where potential competition in the form of pipeline products and services can be of relevance. The end result is an outcome that might soon be challenged before the EU courts on grounds of the standard of proof.

Declaration of Conflicting Interests

The author(s) declared no potential conflicts of interest with respect to the research, authorship, and/or publication of this article.

Funding

The author(s) received no financial support for the research, authorship, and/or publication of this article.