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THE IMPACT OF DISRUPTIVE INNOVATIONS ON COMPETITION LAW ENFORCEMENT

Contribution from European Commission

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-- European Commission --

1. Introduction

1. This paper submits that the merger control system of the European Union (EU) is well equipped to deal with negative and positive innovation effects of mergers falling within its jurisdiction. This includes effects of product and process innovation both of a potentially disruptive and a more incremental nature.[1] The first part sets out how the EU legal framework addresses the loss of, or harm to, innovation potentially caused by a merger, and conversely, how merger analysis takes into account positive effects on innovation. The second part discusses how the possible harm to innovation has been analysed in a number of recent horizontal and non-horizontal cases.

2. EU legal framework for analysis of innovation effects

2. The current legal framework for EU merger control acknowledges the importance of innovation in merger analysis. The substantive test for assessing mergers as embedded in the EU's Merger Regulation[2] is based on significant impediment of effective competition (SIEC). The SIEC test is covering all aspects of a loss of competition, including harm to competition resulting from hampering innovation. The Merger Regulation also takes into account efficiencies which bring positive effects on innovation provided they are verifiable, merger-specific and likely to be passed on to consumers.

a. Horizontal mergers

3. The European Commission's Horizontal Merger Guidelines[3] ("HMG") state that one of the effects to be analysed in merger control is "the effect on innovation", putting the competitive harm caused by a reduction of innovation on an equal footing with an increase of prices, or a reduction of output, choice or quality of goods and services.[4] According to the Guidelines, the aim of the Commission's merger control is to prevent mergers that would be likely to deprive customers of these benefits, including innovation.

[1] The review of some of the Commission's recent merger cases involving innovation also suggests that innovators, including disruptive innovators, are often firms who have successfully innovated in the past, or who own assets to commercialise innovations, and as a result are established businesses. In other words, disruptive innovation is certainly not restricted to innovation by start-ups or small firms.

[2] Council Regulation (EC) No 139/2004 of 20 January 2004 on the control of concentrations between undertakings (the EC Merger Regulation), Official Journal L 24, 29.01.2004, p. 1-22.

[3] Guidelines on the assessment of horizontal mergers under the Council Regulation on the control of concentrations between undertakings, Official Journal C 31, 5.2.2004. p. 5-18.

[4] Paragraph 8 HMG.

4. The loss of innovation post-merger can be at the heart of the anti-competitive effects of a merger as the HMG ensure that mergers harmful for innovation are caught by the analysis. The HMG specify that if a merger combines two important innovators, or if it eliminates a firm with promising pipeline products, the transaction can eliminate an *important competitive force* and thus lead to a significant impediment of effective competition against which the Commission should intervene.[5] This innovation potential of the merging firms is taken into account *regardless of the current market position of the companie*s,[6] which allows capturing a firm that is not present in a market but is a potential competitor.

5. For a merger with a potential competitor to raise serious competition concerns, it is in principle necessary to show, firstly, that the potential competitor currently acts as a significant competitive constraint or there is a significant likelihood that, absent the merger, it would grow into an effective competitive force in the market in the foreseeable future. This criterion implies that the market must be already concentrated, as in a market with many actual competitors it is unlikely that a potential entrant is a significant competitive constraint. Second, it needs to be established that there is an absence of a sufficient number of other potential competitors to maintain the necessary competitive pressure after the merger. In other words, barriers to entry must be high enough to exclude the existence of several other potential competitors, but the merging firm potentially entering the market must be well positioned to overcome these barriers, for instance as it is present in an adjacent or vertically related market or already has entry plans.

b. Non-horizontal mergers

6. In the context of vertical or conglomerate mergers, the Non-Horizontal Merger Guidelines[7] (NHMG) provide a similar framework for the assessment of innovation effects than the HMG, acknowledging that one of the effects to be analysed in merger control is the effect on innovation,[8] and relativizing the importance of the current market position in case of innovative companies.[9] Non-horizontal mergers may involve foreclosure scenarios that hinder innovation by other market players, for instance when a competitor would likely lose access to the merged entity's product that is needed for it to innovate and remain in the market.

c. Efficiencies

7. The HMG specifically acknowledge that a merger may bring positive innovation effects. These can generally be assessed in the context of efficiencies put forward by the merging parties.[10] The HMG specify that consumers may benefit from new or improved products or services, for instance resulting from efficiency gains in the sphere of R&D and innovation.[11] The parties have to demonstrate that the innovation-related efficiencies (i) indeed bring positive effects which will be passed-on to consumers, (ii) that these efficiencies are verifiable and (iii) that they are merger-specific, that is, that they can only be

[5] Paragraph 38 HMG.

[6] See paragraphs 38 and 20b HMG.

[7] Guidelines on the assessment of non-horizontal mergers under the Council Regulation on the control of concentrations between undertakings, Official Journal C 265, 18.10.2008, p. 6-25.

[8] See paragraph 10 NHMG.

[9] See paragraph 26 NHMG.

[10] On efficiencies, see recital 29 of the EU Merger Regulation, as well as section VII of the HMG.

[11] See paragraph 81 HMG.

attained through the merger (and for example not via a cooperation agreement). Such efficiencies may outweigh the possible anti-competitive effects of a merger.

8. The NHMG also tackle positive innovation effects and provide that non-horizontal mergers are normally more likely to create efficiencies than horizontal mergers between rivals. The guidelines acknowledge explicitly that vertical and conglomerate mergers provide substantial scope for efficiencies.[12] They further state that the integration of complementary activities or products within a single firm may produce significant efficiencies and be pro-competitive, mentioning innovation as one of the possible efficiencies to be achieved.

3. Recent cases assessing potential negative effects on innovation

9. The European Commission analysed a number of recent mergers involving innovations that could have a negative impact although the Commission did not ultimately find anticompetitive effects in all of these cases. The following discusses, first, a number of recent horizontal mergers that would have resulted in a loss of innovation as the innovation owned by one of the merging firms would have likely been lost. A second type of cases concerns vertical or conglomerate mergers where the Commission assessed whether the merged entity could potentially harm innovation by hampering the ability of other market players to innovate. The final part will discuss a merger that potentially resulted in positive innovation efficiencies.

a. Horizontal mergers resulting in loss of innovation

10. Finding and testing new drugs or medical devices to treat diseases that currently have no cure and to offer a better quality of life to patients crucially depends on innovation by pharmaceutical and medical devices companies. A merger can lead to a loss of innovation by eliminating pipeline products that otherwise would likely have come to the market and spurred competition. In three recent cases, the Commission assessed – and remedied – the mergers' negative effects on pipeline products. This regarded not only cases where late-stage clinical trials were ongoing – in which case the product is most likely to come to the market – but also early stage testing of drugs where a possible commercialisation is more uncertain and, in any case, years away.

11. The ***Medtronic/Covidien*** merger[13] – conditionally approved in November 2014 – brought together two medical devices companies. Medtronic is the market leader on the market for drug coated balloons. There are only few competitors currently active in this market and they exert limited competitive pressure on Medtronic. The target company Covidien had a promising late stage pipeline product, a drug-coated balloon called *'Stellarex'*. The Commission found that Covidien would have constrained Medtronic in the near future, in view of the promising clinical trials' results of *Stellarex*. The transaction would therefore have eliminated a credible competitor and would likely have reduced innovation in this area. In order to address these concerns, Medtronic committed to sell Covidien's worldwide *Stellarex* business, including in particular: manufacturing equipment, related intellectual property and scientific and regulatory material necessary for ensuring the completion of the *Stellarex* trials and key personnel. The remedies provide the purchaser with all assets necessary to bring *Stellarex* to the market. In January 2015, Spectranetics Corporation publicly announced that it had completed the acquisition of Covidien's *Stellarex*.

12. The acquisition by pharmaceutical company ***Novartis*** of ***GlaxoSmithKline*** (***GSK)'s oncology business***[14] was different in that the Commission's concerns regarded both the late-stage and the earlier

[12] See paragraph 13 NHMG.

[13] Case No COMP/M.7326, Medtronic/ Covidien, Commission decision of 28 November 2014.

[14] Case No COMP/M.7275, Novartis/ GlaxoSmithKline's oncology business, Commission decision of 28 January 2015.

stage pipelines. The Commission identified the risk that Novartis would likely stop developing two innovative drugs that show great promise for the treatment of skin cancer (late stage clinical trials were being conducted) and that are also trialled for treating several other cancer types (for which early stage clinical trials were ongoing). This is because Novartis would acquire similar drugs from GSK and clinical trials of cancer drugs are lengthy and costly.

13. In its decision of January 2015, the Commission found that the transaction would have led to a duopoly between the merged entity and Roche for skin cancer treatment. Furthermore, the Commission took into account the expected role of these drugs in the treatment of a number of other cancers such as ovarian, colorectal or lung cancer. The Commission found that the merger would have reduced innovation by Novartis, as it would likely abandon its early stage clinical trial programme of the two drugs for treating a number of other cancers.

14. The Commission approved the transaction subject to the condition that Novartis return its rights over one of the drugs to its owner and licensor Array BioPharma Inc. ("Array") and divest the other drug to Array. Moreover, Novartis committed to conduct and fund the late-stage trial for the skin cancer treatment drugs as well as to undertake and co-fund the early-stage trials regarding the drugs' use for treating other cancers. To address the early-stage pipeline concerns, the remedy ensures, amongst others, the worldwide development of existing and new clinical studies that, if successful, may lead to the commercialisation of new treatments in the mid and long term.

15. In the ***Pfizer / Hospira*** case[15] conditionally approved in August 2015, one of the Commission's concerns related to a specific biosimilar drug for treating autoimmune diseases (such as rheumatoid arthritis). **Biosimilar drugs** aim to have the same therapeutic mechanism as original patented biological pharmaceuticals (in this case a drug called *infliximab*), but are not exact copies. Biological drugs are among the most expensive therapies, and biosimilars are expected to lower prices for patients.

16. Hospira currently co-markets an *infliximab* biosimilar originally developed by Celltrion. Pfizer is at an advanced stage of developing one, as is Samsung Bioepis. The Commission found that following the merger, Pfizer would be likely to either delay or discontinue the development of the biosimilar drug in order to focus on Hospira's product, leading to the net loss of future competition by one of only three differentiated biosimilars in advanced stages of development. Alternatively, Pfizer could hand back Hospira's product to Celltrion, leading to the loss of current price competition between Hospira and Celltrion. The remedies preserve the future innovation in biosimilars by providing for the full divestment of the development, manufacturing and EEA-wide marketing rights of Pfizer's *infliximab* biosimilar drug currently under development (including appropriate intellectual property, technology and know-how).

17. While innovation rivalry is a particularly important competitive dimension in the pharmaceutical and medical devices sectors, the Commission's recent merger case practice also includes innovation cases in other industries such as the engineering sector. The ***General Electric/ Alstom*** merger[16] conditionally cleared in September 2015 concerns gas turbines used to generate electricity, where incremental innovation is undertaken by the established suppliers. In fact, the Commission found that disruptive innovation from new entrants or start-ups would likely not happen in this sector due to very high barriers to entry as well as the importance customers attach to a supplier's long term track record and to product reliability. The operation, as notified to the Commission, would have eliminated one of the four full-technology companies that are able to produce world-wide the large and very large gas turbines. The Commission's investigation

[15] Case No COMP/M.7559, Pfizer/ Hospira, Commission decision of 2 October 2015.

[16] Case No COMP/M.7278, General Electric/ Alstom (Thermal Power- Renewable Power & Grid Business), Commission decision of 8 September 2015.

has shown amongst other that Alstom is an important competitive force from an innovation and technology point of view, often best in class in terms of technology allowing for operational flexibility, an aspect that is particularly important for European customers.[17] Alstom's removal would reduce the competitive pressure on the other competitors to invest significantly in innovation. Moreover, the Commission established that General Electric would likely discontinue some of Alstom's products including an existing turbine called GT26 and a pipeline product (called GT36), and to close the innovation pools developed by Alstom. This would have resulted in innovation harm both by depriving customers of new machines and by affecting future technology upgrades of those existing GT26 turbines that have already been installed and have a very long life cycle (if continuously upgraded). In addition to the standard unilateral effects, the discontinuation resulting in a loss of product variety would reduce further the competitive pressure on the market's number two, Siemens. The bidding analysis showed that the product discontinuation would further negatively affect prices in a large number of tenders in the large and very large gas turbine segments.

18. The Commission cleared the transaction subject to a comprehensive remedies package that ensures that competition, and in particular, innovation, will continue in this sector. The package comprises the divestment of the technology for the GT 26 and GT 36 turbines, of existing upgrades and of pipeline technology for future upgrades of turbines. Furthermore, it includes the two test facilities for the aforementioned turbines as well as a large number of Alstom R&D engineers.

b. Non-horizontal mergers potentially hampering third parties' ability to innovate

19. The European Commission has analysed a number of vertical or conglomerate transactions in the ICT sector that may have harmed the ability of the merged entity's rivals to innovate. The ***Intel/ McAfee*** case[18] was approved in 2011 in first phase, involving a combination of anti-virus software with Intel chips. A key competition concern was the possible foreclosure of rival companies in anti-virus software (by Intel embedding its own security solutions into its chips). Such foreclosure would have had a negative effect on McAffee's rivals to innovate in this market. The remedy was designed so as to preserve the beneficial effects of the merger (allowing for a combination of chips with security software), while ensuring that Intel cannot block other security software providers from being fully operational on its chips and from bringing up innovative competing solutions on the market. This involved a remedy giving access to McAffee's competitors to all necessary Intel technical information and a commitment not to actively impede competitors' security solutions from running on Intel chips. This was combined with an effective monitoring system and a fast-track arbitration mechanism resolving any disputes between Intel and other security software providers.

20. In the 2012 Mobile wallet case ***Telefonica UK/ Vodafone UK/ Everything Everywhere/ JV***,[19] the Commission investigated whether a joint venture ("JV") for mobile commerce services in the UK created by three out of four UK mobile network operators to develop a mobile wallet platform could harm innovation in mobile payment systems by other players including Apple and Google. The Commission investigated in-depth whether the JV's three parent companies – via their strong collective position in the market for retail mobile telephony services - would have the technical and/or commercial ability and

[17] For instance, the sizeable share of renewables in the EU's energy markets leads to temporary peaks in energy creation, during which gas turbines need to operate at part-load efficiency or be turned down. Alstom's technology is distinctive, based on unique sequential combustion. The GT24/GT26/GT36 sequential combustion gas turbine family allows the highest operational flexibility, providing superior part-load efficiency and turndown capability.

[18] Case No COMP/ M.5984 – Intel/ McAfee, Commission decision of 26 January 2011.

[19] Case No COMP/M.6314 – Telefónica UK/ Vodafone UK/ Everything Everywhere/ JV, Commission decision of 4 September 2012.

incentive to block other potential entrants in the wholesale mobile wallet platform market from offering their own mobile wallet services to UK customers, notably by foreclosing access to the handset SIM-cards that the mobile network operators control. SIM-cards are an input for mobile wallets as they can play the role of the so called 'secure element' to safely store sensitive information needed for mobile payments.

21. The case was cleared unconditionally and without issuing a Statement of Objections. The Commission concluded that the mobile network operators are unlikely to have the ability and/or the incentive to foreclose potential rivals. First, a number of alternative offerings already existed (in other markets than the UK) which do not store sensitive data on SIM-cards but on a secure element embedded in the handset itself. Second, the Commission found it was unlikely that the JV's parents could block access to embedded secure elements by using technical or commercial means..

c. Merger potentially resulting in innovation efficiencies

22. The case ***TomTom/ TeleAtlas***[20] unconditionally cleared in 2008 concerned a vertical merger combining a main producer of navigation systems with a digital maps developer. The Commission recognised that the removal of certain double mark-ups was plausible and merger-specific. The Parties had claimed that innovation efficiencies were the main deal rationale: information obtained from TomTom's users can be used to improve quality and timing of Tele Atlas maps-creation. While the Commission did not reach a definitive conclusion as the parties' quantifications were not convincing, it did acknowledge that the innovation efficiencies were at least partly merger–specific and bring consumer benefits.

4. Conclusion

23. The EU's legal framework for merger control explicitly addresses a merger's positive and/or negative effects on innovation. The discussion of a number of recent horizontal and non-horizontal merger cases illustrates how that legal framework has been applied in practice. It shows that innovation can be an important competitive dimension, which merger control is well equipped to safeguard. First, theories of harm involving loss of, or harm to, innovation have been at the core of a number of merger cases where the European Commission intervened. Second, remedies can be designed with the specific goal of preserving innovation. While remedies are tailored to each case, divestments of pipeline products are frequently part of remedies in horizontal cases. Non-horizontal mergers likely hampering innovation by other market players may in certain instances, depending on the specifics of the case, also be solved by means of access remedies and/or other non-divestiture remedies. Finally, the EU legal framework also acknowledges that a merger can bring positive innovation effects, which are assessed in the context of efficiencies. Such innovation efficiencies need to be verifiable, merger-specific and likely to be passed on to consumers.

[20] Case No COMP/M.4854, TomTom/ TeleAtlas, Commission decision of 14 May 2008.