R&D cooperation agreements concluded by SMEs – Exempted under the EU R&D Block Exemption Regulation?

Final Report

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Contents

Abstract

The issue addressed in this report is whether SMEs should be granted special status under the R&D BER to promote SMEs' involvement in horizontal R&D cooperation agreements. Limiting the regulatory burden for SMEs may promote SMEs to join R&D cooperation agreements. The report therefore discusses three possible tests to identify R&D cooperation agreements between competing SMEs that should be exempted under the R&D BER.

The report also considers whether, with regard to SMEs, the exception foreseen in Article 3(2) R&D BER for research institutes and academic bodies (i.e. limitation of the requirement of full access to R&D results) could also be made available to SMEs that are part of R&D cooperation agreements.

Executive summary

1. There is great diversity in the role of micro, small and medium-sized enterprises ('SMEs') in the field of R&D, and on the types of collaborative relationships SMEs and large firms enter into regarding R&D. Such relationships may differ depending on the type of industry in which the parties to the R&D agreement are active. However, some common themes can be spotted. For example, when there is a need to obtain funding and other resources to conduct R&D or to overcome regulatory procedures to enable research result to develop into marketed products, funding is often obtained by the SMEs through cooperation with large firms. Cooperation with large firms can be vital to successfully develop and commercialise products.

2. Given the research conducted for the benefit of the review of the Horizontal Block Exemption Regulations ('HBERs')[1] and the Horizontal Guidelines,[2] it seems however evident that there is general uncertainty among SMEs regarding (i) the application of the R&D Block Exemption Regulation ('R&D BER'), in particular regarding the market share threshold, (ii) what clauses and covenants are covered by the R&D BER, (iii) the safe harbours in the Horizontal Guidelines, and (iv) under which circumstances R&D cooperation agreements violate Article 101 TFEU. Moreover, there is evidence that the uncertainty causes SMEs not to enter procompetitive R&D cooperation agreements. The system could, therefore, be clarified and made more transparent.

3. The HBERs, to a certain extent, generally cater to SMEs due to the level of the market share threshold. It may however be difficult for SMEs to identify their relevant markets, competitors and to calculate their market shares, in particular

[1] The Horizontal Block Exemption Regulations refer to Commission Regulation (EU) No 1217/2010 of 14 December 2010 on the application of Article 101(3) of the Treaty on the Functioning of the European Union to certain categories of research and development agreements, OJ L 335, 18.12.2010, p. 36–42 (the 'R&D BER') and Commission Regulation (EU) No 1218/2010 of 14 December 2010 on the application of Article 101(3) of the Treaty on the Functioning of the European Union to certain categories of specialisation agreements, OJ L 335, 18.12.2010, p. 43–47 (the 'SBER').

[2] Commission's Guidelines on the applicability of Article 101 of the Treaty on the Functioning of the European Union to horizontal co-operation agreements, OJ C 11, 14.1.2011, p. 1–72 (the 'Horizontal Guidelines').

when R&D activities are assessed. Therefore, there might be other parameters to identify pro-competitive R&D cooperation agreements concluded by SMEs that should benefit from the exemption of the R&D BER.

4. The report therefore proposes three new *additional* tests to identify pro-competitive horizontal R&D agreements concluded by SMEs that should trigger the applicability of the exemption under the R&D BER.

5. Firstly, a test for competition in innovation. A new threshold could be introduced in the R&D BER based on the existence of other rival R&D efforts or competing technologies. The requirement would therefore be that, if the competing undertakings cooperating in R&D can show that there are other rival R&D efforts or competing technologies already in the market, their R&D cooperation agreement could benefit from the exemption under the R&D BER because there would still be a sufficient level of competition in innovation. A similar safe harbour exist in the U.S.

6. Secondly, an additional test based on the definition of an SME based on absolute parameters (e.g. employees, turnover, etc.) is discussed in the report. A similar type of test is used in other areas of EU law such as when the administration may provide funding for SMEs. SMEs are defined in the Annex to Commission Recommendation 96/280/EC as enterprises which employ fewer than 250 people and which have an annual turnover not exceeding EUR 50 million, and/or an annual balance sheet total not exceeding EUR 43 million. The exemption would be applicable to undertakings that fall within such definition. However, creating an exemption for SMEs catering to all industries based on absolute parameters (e.g. annual turnover, balance sheet, number of employees) is a challenge since industries and markets are different in reference to size, turnover and structure. Therefore, the definition of SMEs based on absolute parameters can be a first prong in the test, and thus a useful starting point. It should however be mentioned that the numeric parameters is already connected to EU Competition law, since the Notice on Effects on Trade indicate that undertakings fulfilling the parameters for 'SME' are normally not capable of affecting trade between Member States; however, they may be able to do so when SMEs engage in cross-border economic activity.

7. Thirdly, another test could be to require SMEs entering into a R&D cooperation agreement to show that they are not part of the largest firms on the relevant

market (e.g. top 2 or top 3). This third test can be either stand-alone test or work as the second prong (for example in combination with the second test) to identify horizontal R&D cooperation agreement concluded by SMEs that should be exempted under the R&D BER. To show that the undertaking is not part of the [two or three] largest firms on the relevant market, a number of factors, apart from market share, could be weighed in, such as access to financial support, access to intellectual property, skilled personnel, or other specialized assets.

8. In reference to Article 3(2) of the R&D BER, the rules stipulate a right to access the research results for all parties of the R&D cooperation agreement. With regard to SMEs, it could be considered whether the exception foreseen in Article 3(2) R&D BER for research institutes and academic bodies could also be made available to SMEs that are part of a horizontal R&D cooperation agreements. This exception allows to limit the requirement of full access to the R&D results so that such results can only be used for the purposes of further research. It should however be acknowledged that such modification may potentially restrict growth for SMEs. Therefore, the proposed modification could thus be allowed only under certain circumstances (e.g. presence of other R&D efforts, low level of concentration in the relevant R&D field).

9. In reference to Article 3(3) of the R&D BER, the requirement of access to pre-existing know-how could benefit from further clarity but no significant changes seem necessary.

Introduction

Micro-, small and medium business enterprises (SMEs) represent a large part of the global economy and play a major role in spurring economic development.[3] However, SMEs are subject to constraints in internal resources such as capital, human resources, and knowledge due to their limited size. Also, access to external resources is limited due to lack of networks and market failures. Thus, SMEs often have disadvantages in R&D and innovation when compared to large firms. To overcome these gaps, various public policies have been implemented to include financial, networking, and intellectual property right support programs.

The issue addressed in this report is whether SMEs should be granted special status to promote SMEs involvement in horizontal R&D cooperation. R&D cooperation with other SMEs or with large firms may provide the SMEs with access to funding, knowledge and other necessary resources. Compliance uncertainty in relation to a potential R&D cooperation may lead to the cooperation being abandoned with the consequence of missed opportunities and innovation delays.[4] Limiting the regulatory burden for SMEs may promote SMEs to join R&D cooperation.

R&D cooperation agreements may be exempted from the applicability of Article 101(1) TFEU pursuant to Article 101(3) TFEU under the R&D BER. While acknowledging that the R&D BER and the corresponding chapter in the Horizontal Guidelines provide an adequate level of legal certainty, some stakeholders highlighted in the course of the ongoing review process of the HBERs being conducted by the Commission's

[3] The size of the industry consisting of SMEs may vary, but often makes up the great majority of firms in certain Member States, such as Italy. See Financing SMEs and Entrepreneurs 2020: An OECD Scoreboard https://www.oecd-ilibrary.org/sites/061fe03d-en/1/3/3/index.html?itemId=/content/publication/061fe03d-en&_csp_=5d0be09b32d3f3a6aa507a1c266f5551&itemIGO=oecd&itemContentType=book#section-d1e38836

[4] Regulatory burdens remain an obstacle for SMEs as these firms tend to be poorly equipped to deal with the problems arising from regulations. Policy makers must ensure that the compliance procedures associated with, e.g. R&D and new technologies, are not unnecessarily costly, complex or lengthy. See the Commission's Staff Working Document regarding the review of the Horizontal Block Exemption Regulations {SWD(2021) 104 final}, 48. 61 (the 'Staff Working Document').

evaluation[5] that their technicality and complexity may lead to misunderstandings and misinterpretation. Concerns and issues related to the self-assessment of the conditions for the exemption for R&D agreements are mostly due to administrative burden and to the lack of technical skills (especially for SMEs) to define markets and to calculate the relevant market shares.

Moreover, the R&D BER is also perceived by some large companies as too strict on requirements for access to research result and intellectual property under Article 3, and lacking clarity on the conditions for exploitation to meet the requirements. This may deter the entering into generally beneficial R&D cooperation with SMEs.[6]

The purpose of this report is to analyse whether the R&D BER should:

(a) Include a specific category of R&D agreements covered by the R&D BER, subject to conditions to be defined, in case such agreements are concluded by SMEs; and/or
(b) Modify and potentially remove the requirement(s) in the R&D BER of full access to the final results and/or access to pre-existing know–how when the horizontal R&D cooperation agreements are concluded by SMEs.

The report intends to answer the above questions and is structured as follows:

(a) Firstly, the report presents an overview of R&D cooperation agreements involving SMEs. The overview includes the difficulties SMEs face in making use of the R&D BER and describes R&D agreements focusing on two industries, the human medicine and ICT/Telecom industries. In these industries, R&D cooperation is widespread and they also display a common industry structure, *inter alia* that smaller firms are obliged to enter into R&D cooperation with other often large firms to be able to access necessary markets and technologies.

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5 Review of the Horizontal Block Exemption Regulations. The purpose of the review is to allow the Commission to determine whether it should let the two Regulations lapse, prolong their duration or revise them; available at: https://ec.europa.eu/competition-policy/public-consultations/2019-hbers_en.

6 VVA and London Economics, 'Evaluation support study on the EU competition rules applicable to horizontal cooperation agreements in the HBERs and the Guidelines', Final Report, May 2021, p. 99, available at DG Competition's website at: https://ec.europa.eu/competition-policy/evaluation-support-study-eu-competition-rules-applicable-horizontal-cooperation-agreements-hbers_en ('Evaluation Support Study' or 'evaluation study').

(b) Secondly, the report explores ways going beyond the definition of SMEs for the purpose of identifying SMEs that may be exempted.

(c) Thirdly, the report explores ways to identify the procompetitive cooperations that possibly include SMEs that should gain access to the R&D BER. In other words, should SMEs or R&D cooperation engaged by SMEs more generally be included in the R&D BER.

(d) In the end, the Report presents tests and some examples where the aim is to identify the R&D cooperation entered by SMEs that do not cause anticompetitive effects and that should be encompassed by the R&D BER, while still uphold the general rule that the R&D cooperation that are likely to cause anticompetitive effects should fall outside the R&D BER.

R&D cooperation agreements involving SMEs

Difficulties making use of the R&D BER

The report addresses the issue of SMEs conducting R&D cooperation. The structure for such collaborations is different due to the differences in industry settings, and practice and also experience. However, some common themes can be identified.

According to the findings of the Evaluation Support Study and the Commission's Staff Working Document, SMEs enter R&D cooperation agreements, while they seldomly consult the R&D BER or the Horizontal Guidelines.[7] The firms that do consult the guiding documents purport that they have difficulties understanding the definition of the exemption and calculating the relevant market share. A few respondents indicated that costs associated with the application of the R&D BER are high because the exemption is too narrow and requires several individual assessments.[8] The legal-technical difficulties understanding the R&D BER causes them to seek external legal advice which is costly and still does not always provide adequate answers.[9] Moreover, it seems that smaller firms, often centred around universities, according to the interviews and discussions conducted by the author, utilize certain model R&D cooperation agreements that are common when public funding is obtained, which they are not inclined to deviate from.[10]

Some legal practitioners also mention that in-house legal departments or even the external law firms used by SMEs often do not include experts in competition law. They may use licensing (technology transfer) agreements with which they are familiar even though the cooperation may include substantial joint research and development of patent protected research result.[11] For many in-house legal teams, especially within the human medicine industry, the analysis of a specific R&D cooperation may often be

7 See the Staff Working Document, p. 17 et seq., 48. 61, 95.

8 ibid.

9 ibid.

10 See for example FP7 Grant Agreement Annex II General Conditions II.1. Definitions and Part C Section 2 – Access Rights. https://ec.europa.eu/research/participants/data/ref/fp7/93289/fp7-ga-annex2_en.pdf. The FP7 and previously FP6 have inspired national model agreements, see Vinnova modelavtal, https://docplayer.se/4445713-Vinnovas-modellavtal-for-vinn-excellence-center-och-kunskapscenter-vid-forskningsinstitut-med-kommentarer-av-adv-adj-prof-eric-m.html

11 See Evaluation Support Study, p. 98.

individually analysed as to whether Article 101(3) TFEU is applicable, or not. This is due to the commercial reality that one of the parties seeks exclusive access and exploitation rights to the research result even in reference to further research. In these cases, an exclusive license agreement may be preferable.

In the academic sector, universities as well as research institutes, or commercial spin offs from universities, such as university owned undertakings which supply research and development as a commercial service, can fulfil the requirements to be qualified as SMEs (i.e. enterprises which employ fewer than 250 people and which have an annual turnover not exceeding EUR 50 million, and/or an annual balance sheet total not exceeding EUR 43 million).[12] Moreover, individual researchers can form their own limited companies that may fulfil the requirements of SMEs. These forms of SMEs may provide research as a service either directly with collaborating partners or through the university or research institution, or as subcontractors. Individual researchers can directly or through vehicles (limited companies) also act as subcontractors.[13]

It should be clear that the general model contracts for R&D provided in public funding schemes and which are drafted for the benefit of research institutes or academic bodies often stipulate broader access rights than what is currently required under the R&D BER, including access also to background proprietary information.[14] Such access rights may reflect the right to conduct research on behalf of the researcher(s) in question. However, they also reflect that these organisations mainly get their income from licensing of the research result (foreground intellectual property rights). Indeed, model agreements with commentaries may state that a compelling reason for contractual compulsory access to foreground intellectual property rights is that research institutes gain revenues from the exploitation of the research results through licensing. Licensing fees (royalties) are an important source of revenues and they

12 Commission Recommendation 96/280/EC of 3 April 1996 concerning the definition of small and medium-sized enterprises, OJ L 107, 30.4.1996, p. 4–9.

13 See FP7 Grant Agreement Annex II General Conditions II.1. Definitions and Part C Section 2 – Access Rights. https://ec.europa.eu/research/participants/data/ref/fp7/93289/fp7-ga-annex2_en.pdf. The FP7 has inspired national model agreements, see Vinnova modelavtal, https://docplayer.se/4445713-Vinnovas-modellavtal-for-vinn-excellence-center-och-kunskapscenter-vid-forskningsinstitut-med-kommentarer-av-adv-adj-prof-eric-m.html

14 ibid.

should therefore have a 'right' to exploit the research result through licensing.[15] Moreover, national and European patent legislation may influence the contractual rights to conduct research based on research result. For example, Article 27(b) of the European Unified Patent Court Agreement (UPCA) stipulates that "*the rights of a patentee shall not extend to (…) acts done for experimental purposes relating to the subject matter of the patented invention*".[16] Under national patent law, the research exemption can be broader. In other words, there is certain R&D that can be conducted regarding a technology even though the R&D cooperation agreement assign ownership and an exclusive exploitation right regarding the intellectual property rights covering the technology to one party.

Indeed, the access rights to background and foreground intellectual property rights stem from other sources than competition law or more specifically are not encompassed by the R&D BER. Thus, the covenants regarding for example the parties access rights to research result, background intellectual property rights and know-how after the termination of the cooperation also go beyond what might be justified from a strict competition law concern.

As to R&D cooperation agreements between large firms and SMEs, a quite substantial part of the agreement may deal with the issue of ownership of the research result and access to pre-existing know-how and intellectual property rights. Often these issues are dealt with upfront when the cooperation is entered into, and the parties agree commercially on how the ownership should be divided, cross-licensed, royalty streams calculated and how access to know-how should be dealt with. The issue of business secrets, non-disclosure agreements and publication rights for employees/university researchers are also addressed. According to the author's knowledge, the negotiations are often concluded on commercial terms without difficulties. An issue of concern in cooperation including researchers active in universities, may be that the R&D cooperation may provide for a stand still period of a number of months, where the researcher is not allowed to publish the research results, giving the large firm time to file applications for patents in the relevant jurisdictions.

15 See comments for the Vinnova modelavtal, https://docplayer.se/4445713-Vinnovas-modellavtal-for-vinn-excellence-center-och-kunskapscenter-vid-forskningsinstitut-med-kommentarer-av-adv-adj-prof-eric-m.html

16 See Agreement on a Unified Patent Court ('UPCA') (published in OJ EPO 2013, 287).

Normally, SMEs cooperating with other SMEs address the issue of ownership and they follow the general pragmatic business oriented method of dividing the research result, while still granting each other access under a cross-license. However, on occasions, SMEs do not to address the issue of ownership of the research result upfront causing the fall back solution of joint ownership to become applicable, which is not an efficient outcome. Interestingly, it should be pointed out that there is research indicating that in an R&D cooperation where the SMEs have not upfront agreed on the division of ownership of research result and access to background IP can cause lock-in effects. The legal default option implies joint control/ownership of research result and uncertainty in reference to whether the research result can efficiently be utilized. The uncertainty regarding access rights and ownership might cause the parties not to enter the cooperation.

It seems clear that the R&D BER could become more 'user-friendly' for SMEs. Especially smaller undertakings could be helped by having rules and principles explained more clearly and even having rules that cater to them specifically.

Initially, in an effort to clarify, it should clearly be stated in the Horizontal Guidelines that if the cooperating undertakings are not competitors or are competitors on the current market but are planning to conduct joint R&D aiming to catch an entirely new demand or market, their R&D cooperation is exempted for seven years minimum, irrespective of market shares under the R&D BER.

In an effort to simplify, the R&D BER could become more straight forward. If they are competitors in reference to the joint project, the R&D BER could be made available based on criteria other than relevant market, market share or whether the collaborators are competitors or not. The report therefore presents simplified general tests or thresholds[17] (see further below) for the applicability of the R&D BER for competing (and non-competing) SMEs.

New thresholds could be introduced for when the R&D BER becomes applicable. First, if the competing undertakings cooperating in R&D can show that there are other rival R&D efforts, their R&D effort would fall inside the R&D BER irrespective of market share and irrespective whether they are SMEs or not. This threshold would imply that competing firms with significant market share, turn-over or number of employees on a market still would benefit from the R&D BER for developing new products. As

17 See Article 4 R&D BER for the current applicable test.

discussed below, a different threshold test could be based on parameters for identifying SMEs, while a third test, also discussed below, could be based on identifying an SME by showing that it does not belong to one of the larger firms in the industry. R&D cooperation should be exempted under the R&D BER if the SME defined under either test above cooperate with another SME or only one of the largest firms on the market.

Moreover, Article 3(2) and 3(3) of the R&D BER, which seems to cause some special ambiguity among SMEs, could be clarified that when SMEs are part of cooperative research they could be restricted from actively exploiting the research results and the background know-how and confine their use of the results for the purposes of further research only.[18]

Specific industries – Pharmaceutical and biotechnology sectors

There is a great diversity in how SMEs conduct R&D and in the types of collaborative R&D relationships between SMEs and the large firms in specific sectors or industries. In the biotech and pharmaceutical industries, the general picture seems to show that smaller specialised research entities initiate collaboration with large pharmaceutical firms when the smaller firms have achieved promising research results.[19] The

[18] Previously, the rules was that research institutes, academic bodies, or undertakings which supply research and development as a commercial service without normally being active in the exploitation of results may agree to confine their use of the results for the purposes of further research. SMEs were not included.

[19] The Pharmaceutical Sector Inquiry from 2009 stated that "*[i]n addition to large originator companies there are numerous SMEs, which typically lack the resources required to conduct all necessary steps from basic research to the marketing and distribution of the finished product. SMEs in the pharmaceutical sector, therefore, tend to specialise in innovation in a well-defined and narrow field (niche), for example focusing on specific indications or pharmaceutical formulations. These SMEs either decide to out-license or sell their innovations to large companies who have the resources to conduct clinical trials and the necessary marketing. Large pharmaceutical companies are increasingly in-licensing new products. Currently 25% of the molecules in clinical development have been acquired from other companies, including SMEs. This is confirmed by the findings of the sector inquiry and shows the importance of SMEs for maintaining the innovative character of the pharmaceutical sector*". See Pharmaceutical Sector Inquiry 2009 para. 55. This is also confirmed by the OECD report "Patents, Innovation and Economic Performance" (2004), p. 96.

research results are often patented and licensed.[20]

According to the Commission's Pharmaceutical Sector Inquiry published in 2009[21], large pharmaceutical companies spent on average 17% of their turnover from prescription medicines on R&D worldwide. Approximately 1.5% of turnover was spent on basic research to identify potential new medicines, while 15.5% of turnover was spent on developing the identified potential medicines through trials (phases I through III) into marketable products. A common scenario is that a large company was already marketing products in a certain therapeutic area and entered into a cooperation with a SME to expand or complete its product portfolio.[22] In the final report, the European Commission stated that in 2007 about 35% of the large companies' molecules where marketing authorisation was pending originated from third parties. Some of these third parties were SMEs.[23] The above seems to indicate that large companies rely, to a certain degree, on cooperations with SMEs and other R&D intensive organisations to conduct R&D in the pharmaceutical and biotechnology sector.

An enduring and relevant trend in the pharmaceutical sector is that R&D-intensive start-up firms, that would qualify as SMEs, often cluster around universities and medical schools, conduct research that they later patent and license, trade and co-develop with large pharmaceutical firms. Normally, the start-up SMEs seek partners or purchasers when they have conducted successful pre-clinical or even the first clinical trial of the relevant substance or molecule. Partners are needed to fund the trials, and needed to develop the research result into products sufficiently safe and efficacious to be marketed, i.e. clinical testing through phase I to III. The regulatory approvals and processes, production, distribution and marketing of medicines may also require that the partner of the SME is a large firm.

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20 Ibid. Several articles deal with licensing schemes in the pharmaceutical sector, see e.g. Daniel Simonet, Licensing Agreements in the Pharmaceutical Industry, *Journal of Medical Marketing.* 2 (2002) 329-341.

21 See Pharmaceutical Sector Inquiry from 2009, p. 48.

22 See Pharmaceutical Sector Inquiry from 2009, paragraph 1266: "*[The originator company's] approach is to identify potential targets of products which could synergize with its existing organisations (geographical approach) and/or its therapeutic domains. Potential originator companies are frequently small and midsized companies that have no or insufficient resources or expertise (in areas such as marketing and promotion, medical and regulatory, and development, when applicable) in a given country/territory"*.

23 ibid.

The R&D cooperation between SMEs and large companies may be enacted for the duration of the life of the relevant patents.[24] Scientific boards may be set-up including researchers from the SME as well as from the large firm so to monitor the transfer of knowledge and the further development of the research result. The cooperation may include organising the clinical testing. The cooperation may also include ancillary agreements where individual researchers agree to conduct specific even basic research under the cooperation.[25]

According to some researchers, in areas of the pharmaceutical and biotech sectors where the risk and costs are lower, for instance because the requirement of clinical testing and use of a regulatory process is shorter or non-existent (this can be the case for diagnostic, biomaterial or medical services), the R&D cooperation does not need to reflect the need for obtaining funding for the regulatory process. Indeed, in these situations it is more likely that both or all parties to a R&D cooperation are SMEs.[26]

Interestingly, the size difference between the firms collaborating in the pharmaceutical and biotechnology field seems to be dependent on the length of the process to develop safe and efficacious products, i.e. time and cost of getting a research result to get approval. The increased length and cost of the regulatory process in the pharmaceutical field compared to other fields, imply that SMEs often need to collaborate with large firms, or license their research result to such firms. This will also enable the R&D result to become a marketable product. The overall high costs of developing new medicines and the high risks can explain the prevalence of cooperation in human health products where small firms otherwise do not have access to the necessary resources. According to economic research, [27] the uncertainty and

24 Pharmaceutical Sector Inquiry 2009, para. 1280.

25 See for example FP7 Grant Agreement Annex II General Conditions II.1. Definitions and Part C Section 2 – Access Rights. https://ec.europa.eu/research/participants/data/ref/fp7/93289/fp7-ga-annex2_en.pdf. The FP7 and FP6 have inspired national model agreements, see Vinnova modelavtal, https://docplayer.se/4445713-Vinnovas-modellavtal-for-vinn-excellence-center-och-kunskapscenter-vid-forskningsinstitut-med-kommentarer-av-adv-adj-prof-eric-m.html

26 Terttu Luukkonen, Variability in organisational forms of biotechnology firms, *Research Policy* 34 (2005) 555–570; Hélène Delerue, Shadow of joint patents: Intellectual property rights sharing by SMEs in contractual R&D alliances, *Journal of Business Research* 87 (2018) p 12-23.

27 Terttu Luukkonen, Variability in organisational forms of biotechnology firms, *Research Policy* 34 (2005) 555–570.

risks make large firms more inclined to contract out R&D to smaller firms. It means that the overall costs and risks in biotechnology are usually shared by a large number of organisations. Further reasons presumably affecting the need for SMEs collaborating with large firms is the (generally large) size of the potential markets and the costs related to scaling production (e.g. building large-scale manufacturing facilities).

However, certain pharmaceutical products may bring specific challenges to R&D cooperation agreements. That might be the case of orphan medicines. The definition of orphan medicine is "*a medicine for the diagnosis, prevention or treatment of a life-threatening or chronically debilitating condition that is rare (affecting not more than five in 10,000 people in the European Union) or where the medicine is unlikely to generate sufficient profit to justify research and development costs.*"[28] Orphan medicines benefit from ten years of market exclusivity once they receive a marketing authorisation in the Union.[29] This measure is intended to encourage the development of medicines for rare diseases, by protecting them from competition from similar medicines with similar indications, which cannot be marketed during the exclusivity period. Market exclusivity is an incentive awarded to a specific clinical indication with an orphan designation.

However, in case of the joint development of an orphan medicine, the right to access research result and background know-how may easily become a risk and even a "show stopper" for the parties to enter into the R&D cooperation. Given that the illnesses or conditions treated by orphan medicines are by definition very rare, the markets for the orphan medicine are often narrow. Moreover, the relevant research knowledge to be able to develop an orphan medicine for a specific rare disease can also be uniquely held by one or very few researchers in the field. Indeed, in reference to these situations, even though there are no competing or rival R&D poles or efforts, the

28 EMA, https://www.ema.europa.eu/en/glossary/orphan-medicine

29 The market exclusivity period is extended by two additional years for an orphan-designated condition when the results of specific studies are reflected in the summary of product characteristics (SmPC) addressing the paediatric population and completed in accordance with a fully compliant paediatric investigation plan (PIP). The European Commission grants the extension based on a positive compliance check from the Paediatric Committee and opinion from the Committee for Medicinal Products for Human Use (CHMP), and includes this information in the Community register of orphan medicinal products. For more information, see: https://www.ema.europa.eu/en/human-regulatory/post-authorisation/orphan-medicines/market-exclusivity-orphan-medicines.

parties to the joint R&D still should be allowed to cooperate while only one of the parties will gain exclusive access and exploitation rights. If the R&D cooperation for the development of orphan medicine is concluded with research institutes, academic bodies or undertakings which supply research and development as a commercial service without normally being active in the exploitation of results, the parties may agree to confine their use of the results for the purposes of further research and benefit from the exemption in the R&D BER (see current Article 3(2) of the R&D BER). More generally, such agreement could be exempted based on the finding that exclusive access is indispensable under Article 101(3) TFEU (see Horizontal Guidelines, paragraph 140). However, there is perhaps a need for a clearer and a more transparent exemption.

In reference to exclusive exploitation right often sought in the human medicine industry generally, and in the orphan drug sector in particular, it could be clarified that, when SMEs are part of a cooperative research, they could be restricted from actively exploiting the research results and the background know-how and confine their use of the results and background know-how acquired during the R&D cooperation for the purposes of further research only.[30] It should be stressed that Article 6(1)(b), concerning excluded restrictions (including the obligation not to grant licenses to third parties) could then be redrafted and clarify and apply in situations where the party that acquired the exclusive access and exploitation right under Article 3(2) and (3) stopped exploitation of the research result. The rule in Article 6(1)(b) could be a deterrent for killer situations (see discussion below).[31]

Specific industries – ICT – Telecom – Consumer Electronics

In network industries, such as telecom and consumer electronics, the goal of the collaboration is the creation of patents *and* technical standards and that may also cause SMEs to cooperate with the large firms that take part in developing the technical standard.[32]

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30 Previously, the rules was that research institutes, academic bodies, or undertakings which supply research and development as a commercial service without normally being active in the exploitation of results may agree to confine their use of the results for the purposes of further research. SMEs were not included.

31 Colleen Cunningham, Florian Ederer and Song Ma, Killer Acquisitions, *Journal of Political Economy*, 129(3) (2020), 649–702.

32 Yet, it should be noticed that according to the answers provided in the public consultation (CITI) also SMEs active in the pharmaceutical industry combined their R&D cooperations with standardisation agreements.

In network industries, large firms can engage an SME active in R&D to conduct paid for or outsourced R&D for the benefit of the large firm or for developing a joint technology standard. Under the US specific law for R&D collaboration, the National Cooperative Research and Production Act of 1993 ('NCRPA'), there is a requirement to notify so as to benefit from a more lenient treatment.[33]

Whether the NCRPA in fact is an exemption rather than stipulating a limited immunity is a question of degree and viewpoint.[34] There is indubitably little incentive for a private plaintiff to initiate proceedings against an R&D cooperation that benefits from the application of the act.

The immunity in the NCRPA for joint R&D against private third party litigation was created mainly by way of three limitations.

The first cornerstone of the exemption is the limitation whereby a successful private plaintiff would only be rewarded actual damages, not treble damages under the act.[35] This is in contrast with the prevailing US antitrust philosophy.

The second reason to prevent private litigation was that a defendant in some cases is able to win their litigation costs.[36] This is a concept alien to US antitrust law traditions.[37] It gives the defendant an incentive to prolong litigation, and it adds to the uncertainties facing a potential antitrust plaintiff. The difficulties

33 No further analysis is done. The notifications often include the cooperation agreements.

34 Members of the House of Representatives actually used the notion "immunity" from Federal and State antitrust laws, see Report from the House Committee on Science, Space, and Technology. H. Rpt. 98-571, pt 1. The notion that NCRPA creates limited immunity was acknowledged by representatives of the Justice Department, see speech by Masoudi, Gerald, 'Efficiency in Analysis of Antitrust, Standard Setting, and Intellectual Property', before High-Level Workshop on Standardization, IP Licensing, and Antitrust 2007, TILEC, University of Tilburg, http://www.usdoj.gov/atr/public/speeches/220972.htm.

35 See 15 U.S.C.A § 4303. Interestingly, states are allowed to recover total damages, see 15 U.S.C.A. § 4303 (b).

36 See 15 U.S.C.A § 4304 (a) (2), "if the claim, or the claimant's conduct during the litigation of the claim, was frivolous, unreasonable, without foundation, or in bad faith".

37 However, reimbursement for legal fees for the plaintiff is standard civil law procedure in civil law countries.

should also be seen in the light of the fact that the typical antitrust plaintiff has considerably less assets than the defendant.

The third restriction creating the exemption is the interaction between the rule of reason and the concept of "innovation market". The NCRPA states that only a rule of reason can be employed to find a violation. The restriction of the per se rule implies that the plaintiff needs to show either direct anticompetitive harm or likely anticompetitive effects with evidence of, or due to, substantial market power.[38] *Direct antitrust harm caused by collaborative research will be difficult to show, so a plaintiff needs to establish market power in a research, development or other relevant market to be successful. The third restriction does not only limit private parties but also the Justice Department and the FTC in their pursuit of alleged anticompetitive collaborations.*

In connection herewith, it should be mentioned that the US equivalent to comfort letters, business review letters, can be extracted from both DOJ and FTC and may be used to secure the R&D cooperation from being litigated by the Federal public authorities, while also making use of the different guidelines published by the Federal agencies. As a result, few, if any litigations have been brought against R&D collaborations that fulfil the requirements of the NCRPA.

From the public notifications under the NCRPA, it seems that several collaborations include many parties apart from the SME specialised in R&D. Little research has been done on this, yet officers at the US Justice Department have on two occasions analysed R&D agreements which had been filed under the NCRPA so as to enable the participants to gain access to the safe harbour.[39] From data consisting of 96 Joint R&D agreements, Suzanne Majewski *et al* concluded that several joint R&D agreements were entered into by product market competitors, i.e. vertically integrated firms. Some of the notified collaborations included all firms in an industry, i.e. they were industry wide. The aim was to create and to disseminate new technology standards. In

38 For a proposal of the rule of reason approach under the NCRPA, see T. Jorde & D. Teece, Innovation, Cooperation and Antitrust, *High Tech Law Journal* 4 (1989), 1, 62 *et seq*. with references.

39 S. E. Majewski, How Do Consortia Organize Collaborative R&D? Evidence from the National Cooperative Research Act (SSRN 2004), 12 et seq.; S. E. Majewski & D. V. Williamson, Endogenous Spillovers, Strategic Blocking, and the Design of Contracts in Collaborative R&D: Evidence from NCRA filings of R&D Joint Ventures (SSRN 2002), 20 et seq.

their agreements, the competing firms tended, according to the researchers, to adapt the collaboration based on the need to access foreground and background intellectual property rights and know-how, to shared costs and for the reduction in duplicative efforts. Interestingly, one of the main concerns identified by the DOJ officials was that joint R&D agreements often prevented spillovers or information sharing, something that they concluded might harm competition in innovation.[40] According to the researcher, spillover effects, i.e. transfer of knowledge between the parties, and between the parties and the public, was procompetitive.[41]

It should be pointed out that industry-wide R&D cooperation identified by the researchers involving SMEs can be very beneficial, both creating and disseminating knowledge and implementing new technologies. The SME can be the firm which get contracted to do the R&D (paid for or outsourced R&D) or may act as a coordinator. The set-ups may lead to the development of technical standards and patent pool building where a vehicle (e.g. an SME) will be holding the intellectual property rights, making use of the joint exploitation possibility of intellectual property rights under the R&D BER. Interestingly, R&D cooperation that includes several large firms and possibly some SMEs, aiming to create a new technology that will become a standard, can be exempted for at least seven years under the R&D BER as cooperation between non-competitors aiming to create innovation with a new demand.[42] In that situation if the

40 ibid.

41 In a follow-up paper, Majewski, purport that often parties to R&D cooperation seek to avoid spill-over effects of having researchers from the firms interacting. R&D cooperation reflected specialization in the R&D value chain where each firm provided R&D covering its specialization or where the R&D is outsourced to third party. However, by avoiding scientists interacting, supposedly the goal of the US NCRPA for creating welfare-enhancing exchange of ideas (spillover or knowledge leaking) was not reached. In 2008, under the US DOJ Business Review Letter system, an example of a set-up which included joint R&D, standard-setting and patent pool building also in pharma. The pool concerned ten of the essential patents for the Gen-2 standard, which had been decided and issued by the private Standard Setting Organisation EPCglobal, Inc. The patents were provided by seven different patentees and the 10 patents did not consist of all of the essential patents for the standard. See RFID Business Review Letter from Thomas O. Barnett to William F. Dolan and Geoffrey Oliver, dated 21 October 2008, 1.

42 The R&D-only SMEs often thus sell their services and assign or licence patents, rather than have a business strategy of selling products in the market or for extracting (high) royalties from manufacturing-only or vertically integrated firms. It seems that SMEs do seldom challenge the large firms. They do not develop to become Patent Assertion Entities (PAEs). Instead, SMEs focusing on R&D

participating companies are non-competitors, the market share limitation in R&D BER is not applicable.

Intermediate conclusions

There are some similarities generally between human medicine industry and network industries. The large leading firms are engaged in costly public-private regulatory procedures, such as clinical testing for human medicine, or in semi-public private legislative procedures such as the standard-setting process.[43] They are engaging with SMEs to gain access to promising research and conduct R&D so to develop and test new technologies. The R&D result is then fed back in the regulatory procedures (e.g. the standard-setting effort conducted in the technical committees). In these circumstances, the standard-setting process must be understood as a form of collective innovation, and also collective R&D, where the end result is a standard that meets the demands of society.[44]

It is clear that SMEs benefit from the collaboration with large tech firms both in the human medicine industry and in network industries. They need to enter into joint R&D cooperation with large firms for gaining access to funding, background intellectual property rights, technology and markets. The structure of the industries makes it necessary for SMEs to cooperate with large firms, while similar synergies cannot be achieved by cooperating between SMEs.

The tests proposed in this report will encourage more cooperation and clarify for SMEs that R&D cooperation with large firms may fall inside the R&D BER.

(a) Firstly, it should be more clearly stated that R&D cooperation that aims to create entirely new demand and markets can benefit from the R&D BER irrespective of current market shares held by the parties.

(including biotech SMEs) proliferate more as service oriented R&D firms, to which large firms unilaterally outsource their research or find research result they can develop into technologies or products that can be marketed.

43 It should be mentioned that the patent process can be costly for SMEs. National validation and maintenance of European patents, including processing and translations that are still necessary in many Member States, are costly and burdensome for the patent holder. High costs may also preclude certain originator companies – especially SMEs – from having their patents protected in all Member States. See Pharmaceutical Sector Inquiry 2009 para. 1298.

44 Josef Drexl, Anti-competitive Stumbling Stones on the Way to a Cleaner World: Protecting Competition in Innovation without a Market, *Journal of Competition Law & Economics* 8 (2012), 507, 534.

(b) Secondly, tests that do not focus on market share could be implemented to address the situations in the human medicine and standard-driven industries, where SMEs or small firms need to cooperate with large firms in order to access funding, technology and markets. These tests will be discussed below.

(c) Thirdly, if the R&D BER is too difficult to understand, it needs to be clarified.

How to identify SMEs for the purpose of a possible exemption under the R&D BER

According to the research conducted for the review of the HBERs and Horizontal Guidelines, SMEs have difficulties *inter alia* understanding the definition of the exemption, the notion of competitor and calculating relevant market share.

In an effort to make the R&D BER more transparent and applicable, the question to pursue is whether a specific exemption under the R&D BER should be introduced for R&D agreements concluded by SMEs. The issue of what parameters should be used to identify an SME from a competition law perspective will be discussed below.

Existing definition for SMEs

Micro, small and medium-sized enterprises (SMEs) are defined as enterprises which employ fewer than 250 persons and which have an annual turnover not exceeding EUR 50 million, and/or an annual balance sheet total not exceeding EUR 43 million in other areas of EU law and administration.[45] The parameters are used in EU funding schemes for SMEs. The parameters are set at a level which include a great number of firms in the EU. It is not a small minority that would be encompassed by the definition, as in some Member States, up to 60-70 per cent of all firms are considered SMEs.[46]

It should however be mentioned that the absolute parameters above are connected to EU competition law in the sense that undertakings fulfilling the parameters for 'SME' are normally not capable of affecting trade between Member States; however, they may be able to do so when SMEs engage in cross-border economic activity.[47] SME are thus normally only exposed to Member States' competition law.

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45 Extract of Article 2 of the annex to Recommendation 2003/361/EC. There is definition of autonomous (from large firms and exemptions stipulated in the annex.

46 The size of the industry consisting of SMEs may vary, but often makes up the great majority of firms in certain Member States. See Financing SMEs and Entrepreneurs 2020: An OECD Scoreboard https://www.oecd-ilibrary.org/sites/061fe03d-en/1/3/3/index.html?itemId=/content/publication/061fe03d-en&_csp_=5d0be09b32d3f3a6aa507a1c266f5551&itemIGO=oecd&itemContentType=book#section-d1e38836

47 See the discussion in particular at point 50 of the Notice on effect of trade. https://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:52004XC0427(06)&from=EN

Challenges for using the existing definition of SMEs for the purposes of an exemption under the R&D BER

A challenge with a test based on absolute parameters is to judge undertakings with limited size yet with shareholders or owners that are larger firms. When is the SME autonomous? Under competition law, the single economic entity doctrine has been used to identify the undertaking and its turnover,[48] while in EU legal systems that uses absolute parameters for identifying SMEs often make use of other forms of tests.[49] In addition, the concept of "connected undertaking", defined in various block exemptions and notices, see for example Article 1(2) in R&D BER relies upon three basic principles related to the powers of the parent company to define "undertaking", namely: "(i) power to exercise more than half of the voting rights, or (ii) power to appoint more than half the members of the supervisory board, board of management or bodies legally representing the undertaking, or (iii) right to manage the undertaking's affairs."[50]

The single economic entity doctrine is broader and the possibility of exercising decisive influence, also exists in situations in which none of the above three principles is met, for example in joint ventures in which a minority shareholder has powers that go beyond those necessary for the protection of its financial interest and extend to decisions affecting strategic business decisions.[51] Presumably, the notion of "connected undertaking" was implemented to simplify the self-assessment needed to be conducted to form for example R&D cooperations, and perhaps that line of logic should be implemented when indirectly defining SMEs for the R&D BER.

SME may be active in nearly all markets and nearly all sectors of the economy. The forms of SME are therefore equally diverse, ranging from single proprietorship to a firm with hundred employees or an internationally known successful and leading

48 David Bailey, Okeoghene Odudu, The single economic entity doctrine in EU competition law, Common Market Law Review, 51(6) (2014), 1721-1757.

49 See Article 3 of the annex to Commission Recommendation 2003/361/ EC.

50 See also for example point 12(2) of the Commission's Notice on agreements of minor importance.

51 See in this respect the Commission Consolidated Jurisdictional Notice under Council Regulation (EC) No 139/2004 on the control of concentrations between undertakings, paragraphs 62 to 73.

speciality supplier filling a niche market.[52] Given the differences in industries and sectors, it is however difficult to identify the typical SME from a competition law perspective.[53]

From a competition policy perspective, the block exemptions and the *de minimis* rules, generally cater to SMEs because they include market share thresholds or rather ceiling requirements, which to some extent reflect the relationship between the small and the large firms on the relevant market.[54]

Moreover, absolute parameters do not reflect difference in the size of the relevant market. A firm with an annual turnover of EUR 50 million may be regarded as medium-sized in a relevant market where some of the other firms have sales in the billion euro range. In another industry, with a different competitive structure and size, a firm having the same turnover figures is not necessarily to be considered small or medium-sized.[55] Its turnover could instead represent the entire market. From a market power perspective, the relevant definition would need to be based on the presence of large firms, as well as absolute parameters.

Exemptions for SMEs in other jurisdictions

German law includes a general exemption from competition rules for cooperation by SMEs. According to the German general exemption, the issue whether an undertaking is an SME cannot only be answered on the basis of absolute parameters (e.g. annual turnover, number of employees).[56] Rather, it depends on the relative size of the firms in the sector of the economy concerned. What is decisive for the concept of SMEs is above all their size in relation to the large enterprises in the industry concerned in relation to which the small firms' competitiveness is to be improved by means of the collaboration. [57]

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52 See OECD Report 1996 General Cartel Bans: Criteria for Exemption for Small and Medium-sized Enterprises, https://www.oecd.org/daf/competition/cartels/1920345.pdf

53 ibid.

54 For similar reasoning see OECD Report 1996 General Cartel Bans: Criteria for Exemption for Small and Medium-sized Enterprises, https://www.oecd.org/daf/competition/cartels/1920345.pdf

54 ibid.

55 ibid.

56 ibid.

57 The German exemption for all kind of collaborations between SMEs are therefore based on a notification system, where the parties need to notify there

According to German law, the exemption depends on competition not being significantly affected by the cooperation conducted by the SMEs.[58] This would be determined by an overall assessment of the effects of a cooperation agreement on the conditions of competition in any relevant market, where the parties need to provide the necessary information. The following main criteria have to be taken into account when assessing the effects on competition under the German law exemption for cooperation by SMEs: (i) the market positions, and in particular the market shares of the firms participating in the cooperation; (ii) the nature of the inter-company cooperation, particularly the extent to which competition is thereby restricted and (iii) any other existing cooperation in the market.

On the basis of its present administrative practice, the German Competition Authority (Bundeskartellamt) presumes that the critical threshold of a significant effect on competition as a rule is reached if the joint market share amounts to between 10 – 15%. Such a market share threshold certainly applies in the case of agreements on major competitive parameters such as the setting of sales prices, discounts or other pricing components. However, if the cooperation concerns qualitatively less significant parameters,[59] the parties' market share may be above the 15% threshold.[60]

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collaborations.
https://www.bundeskartellamt.de/SharedDocs/Publikation/EN/Merkblaetter/Leaflet%20-%20Cooperation%20for%20SMUs.pdf?__blob=publicationFile&v=3

58 It seems thus that the underlying idea is that cooperation by SMEs may affect competition, yet not significantly.

59 Research and development may be exempt under the European Block Exemption Regulation on research and development cooperation agreements under Section 2 (2) of the ARC. However, under the exemption above, i.e. Section 3 of the ARC also hardcore clauses may be exempted.

60 The text rules out cooperations between large firms alone. However, according to the rulings of the Federal Court of Justice, large firms may take part in a cooperation agreement along with SMEs in isolated cases.32 32 Federal Court of Justice WuW/E BGH 2321, 2325 "Mischguthersteller"; WuW/E DE-R 1087, 1090 "Ausrüstungsgegenstände für Feuerlöschzüge". In such cases, it is decisive whether the efficiency of small and medium-sized enterprises can only be improved by large enterprises also being involved in the cooperation. This may be the case if the purpose of a cooperation among small and medium-sized enterprises cannot be achieved without the participation of large firms or cannot be achieved with the same effectiveness, for example when one or several small and medium-sized enterprises obtain improved purchasing or sales opportunities through an agreement with a large firm. In such cases, however, special attention is to be paid to examining whether there is a substantial impairment of competition in the market. In particular, the participation of large firms is not

The German exemption for SMEs is based on a case-by-case analysis, and states that whenever business cooperation is likely to appreciably affect trade between Member States, Union law applies. Priority means that the application of German law may not contradict an outcome that would have been reached if European rules had been applied to the same facts. The German exemption is therefore only relevant if it has previously been ruled out that the cooperation is likely to affect trade between Member States or if it has been ruled out that the effect is "appreciable". Also, if the conditions for the R&D BER are met, the cooperation is deemed to be legitimate independently from the German Competition Act.[61]

In **Japan**, certain types of behaviour of SME are fully exempted from the Anti-Monopoly Act. They include cartels intended to prevent excessive competition, rationalisation cartels, while also joint economic businesses and special contracts. The legal basis of the exemption is the Small and Medium-Sized Enterprise Co-operative Act. The Act defines, *by industry*, which associations of firms may be exempted as SMEs. For example, in the case of activities in the fields of production, mining, transportation, the member firms' capital must not exceed Y [100] million and the number of staff must not exceed [300]. For wholesale companies the following thresholds apply: capital up to Y [30] million and a maximum of [100] employees, whereas in the retail trade and services the thresholds are Y [10] million and [50] employees.[62]

The **Canandian** general safe harbour for collanboration between competitors requires the undertakings to calculate market shares. The aim is to identify whether the collaboration has an impact on competition by comparing it to the general level of

possible when it involves additional restraints to competition that influence the market situation to a not inconsiderable extent to the advantage of the participating large firms.

61 The German exemption for all kind of collaborations between SMEs are therefore based on a notification system, where the parties need to notify there collaborations. https://www.bundeskartellamt.de/SharedDocs/Publikation/EN/Merkblaetter/Leaflet%20-%20Cooperation%20for%20SMUs.pdf?__blob=publicationFile&v=3

62 See OECD Report 1996 General Cartel Bans: Criteria for Exemption for Small and Medium-sized Enterprises, https://www.oecd.org/daf/competition/cartels/1920345.pdf. Masako Wakui, Antimonopoly Law: Competition Law and Policy in Japan (Second Edition) (October 20, 2018). Antimonopoly Law: Competition Law and Policy in Japan (Second Edition), 2018, Available at SSRN: https://ssrn.com/abstract=3270141

concentration on the market. The Canadian Commission will not challenge an agreement related to a coordinated exercise of market power by firms in the relevant market where the share of the four largest firms in the relevant market is less than 65%, or the share of the parties to the agreement is less than 10% of the relevant market.[63]

Under the **US Guidelines** for collaboration between competiting firms there is a safe harbour based on the number of R&D efforts. According to the US Collaboration Guidelines, the antitrust enforcement agencies should not challenge an R&D collaboration on the basis of its effect on competition in an *innovation market* in case there are three or more independently controlled close substitute research efforts, in addition to the effort under scrutiny.[64] Moreover, it is uncertain whether the safe harbour in the US Guidelines would be applicable should the collaborating parties be competitors and have a market share on a product market or service market of more than 20 %.

It seems clear that no jurisdiction has an exemption that is based on absolute parameters only.

Intermediate conclusion

In reference to R&D, a system based on absolute parameters only does not appear adequate as these may not identify relevant market power in reference to competition in innovation. Thus, where the research efforts aims at developing new products or will create a completely new demand, competition in innovation is not sufficiently assessed under the notion of actual or potential competition on existing markets, nor with the use of the absolute parameters. However, should the aim be to identify the small firms and the pro-competitive cooperations in reference to R&D only, the focus should be on the firms general ability to [significantly] affect competition taking into account the small firms ability, either acting alone or through others, to successfully commercialize innovations. For such an analysis some information regarding the structure of the competition needs to be obtained, while possible relevant parameters

63 Canadian Competitor Collaboration Guidelines, chapter 3.4. https://www.competitionbureau.gc.ca/eic/site/cb-bc.nsf/eng/04582.html#sec03-4

64 See also the IP Guidelines, 13, 23, which state four or more independent research efforts in addition to the scrutinized effort. For the discussion of innovation market with many references, cf. Gilbert, Richard and Sunshine, Steven, 'Incorporating Dynamic Efficiency Concerns in Merger Analysis: The Use of Innovation Markets', (1995) 63 Antitrust Law Journal 569.

to look for regarding the firm's ability to commercialise innovation would be (i) its access to financial support, (ii) access to intellectual property, (iii) skilled personnel, or (iv) other specialized assets.

In light of the above, the use of absolute criteria to define SMEs that may be subject to an exemption for R&D cooperation agreement under the R&D BER may be a good starting point. Possibly, some firms that hold market power on a relevant market will be included under the notion of SME using absolute parameters. However, the current market share test would also be required for the assessment of market power in particular when it comes to competition in innovation (the market share test used today does not catch the firm having market power in reference to competition in innovation). Therefore, to minimise the risk that market power is created and maintained as a result of R&D cooperation by SMEs, a combination of the tests can be envisaged.

Indeed, a small firm that meets the absolute parameters to qualify as an SME should also show that it is not one of the largest firms on the relevant market. To show that the undertaking is not one of the [two-three] largest firms, a number factors could be weighed in, such as access to financial support, access to intellectual property, skilled personnel, or other specialized assets.[65]

[65] A somewhat similar Canadian exemption provides that as a general rule, the Commissioner will not challenge an agreement under section 90.1 on the basis of: a concern related to a coordinated exercise of market power by firms in the relevant market where the share of the four largest firms in the relevant market is less than 65%, or the share of the parties to the agreement is less than 10% of the relevant market.

R&D cooperation agreements concluded by SMEs and the R&D Block Exemption Regulation and Horizontal Guidelines

A research and development exemption under EU Competition law can be traced back to a notice issued in 1968 where the Commission stated *inter alia* that pure R&D co-operations generally do not restrict competition, on the condition that the parties are free to pursue their own research, and if there is no restriction regarding the use of the R&D results.[66] Under the 1968 notice, third parties should also, normally, not be denied access to the results of joint research. The 1968 notice also stated that arrangements, solely between non-competitors, or arrangements between competitors that neither limit the parties' competitive behaviour nor affect the market position of third parties, should be deemed not to fall under the predecessor to Article 101(1) TFEU.[67]

The notice was applicable to all companies, irrespectively of their size and market share. Yet, it has been asserted that not limiting the notice to SMEs was a mistake, and the exemption was later narrowed down, in practice, to apply only to these kinds of firms.[68] A useful argument for such an assertion was that collaborations between large firms, or any collaboration involving those holding market power, would almost automatically affect the market position of third parties. Large collaborating enterprises therefore needed individual exemptions under the third paragraph, i.e. Article 85(3) EC Treaty, now 101(3) TFEU, to enter into R&D agreements.[69]

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66 1968 notice, 3 (Notice concerning agreements, decisions and concerted practises in the field of cooperation between enterprises, OJ C 75/3 27.7.1968 3 (hereinafter the 1968 notice). See also Commission, Report on Competition Policy 1971, 46.

67 1968 notice, 3, paras 3 et seq.

68 According to the Commission, Report on Competition Policy 1971, 45, the notice should be utilized with discretion and certain reservations when dealing with large enterprises. See also Hanns Ullrich, Competitor Cooperation and the Evolution of Competition Law: Issues for Research in a Perspective of Globalisation, in J. Drexl (ed.), *The Future of Transnational Antitrust From Comparative to Common Competition Law* (Kluwer Law International, 2003), 159, 188 et seq. See also Valentine Korah, *R&D and the EEC Competition Rules Regulation 418/85* (ESC Publishing Limited 1986), 13 fn. 2.

69 Hanns Ullrich, Competitor Cooperation and the Evolution of Competition Law: Issues for Research in a Perspective of Globalisation, in J. Drexl (ed.), *The Future of Transnational Antitrust From Comparative to Common Competition Law* (Kluwer Law International, 2003), 159, 188 et seq. with references. The

It should be stressed that the principle already mentioned in the 1968 notice that the collaborating parties should be free to pursue their own research, and that there is no restriction regarding the use of the R&D results after the termination of the R&D collaboration is unique for the EU. The US NCRPA does not stipulate a similar requirement. It shows that the EU is concerned with the outcome of the R&D collaboration, and that even though two firms may enter into a R&D collaboration as non-competitors, they will often exit the collaboration as competitors or potential competitors. The spillover or knowledge leaking a cooperation create between the parties places them on equal footing in competition in innovation.

On 29 November 2000, the first 'modern' block exemption for the application of Art. 101(3) to R&D agreements was adopted after the introduction of the so-called more economic approach.[70] This block exemption was just one in a series of new block exemptions published since 1999 until 2004 where the Commission implemented the more economic approach. The 2000 block exemption expired in 2010 and was replaced by the current R&D BER published on 14 December 2010.[71] Some clarifications were made to Article 3, which had indirectly a bearing on research institutes, undertaking that focused on giving research as a service, i.e. undertakings more likely to be SMEs. Inter alia the access right to background know-how was clarified. Otherwise, the changes made did not directly cater to SMEs.

According to the 2010 Horizontal Guidelines, R&D cooperation can restrict competition in various ways: "*First, it may reduce or slow down innovation, leading to fewer or worse products coming to the market later than they otherwise would. Secondly, on product or technology markets the R&D cooperation may reduce significantly*

possibility of individual exemption under Art 101(3) has now been abolished. See Council Regulation (EC) No 1/2003 of 16 December 2002 on the implementation of the rules on competition laid down in Arts 81 and 82 of the Treaty, OJ L 1, 04.01.2003, 1 et seq. (hereinafter Regulation 1/2003).

70 Commission regulation No 2659/2000 29 November 2000 on the application of Art 81(3) of the Treaty to categories of research and development agreements OJ L 304, 05.12.2000, 7 *et seq*. (defined earlier as the 2000 R&D BER). The previous R&D BER was enacted in 1985; Commission Regulation (EEC) No. 418/85 of 19 December 1984 on the application of Art 85 (3) of the Treaty to categories of research and development agreements (Hereinafter the 1984 or old block exemption.

71 Commission regulation No 1217/2010 14 December 2010 on the application of Art 101(3) of the Treaty on the Functioning of the European Union to certain categories of research and development agreements OJ L 335, 18.12.2010, 36 *et seq*. (defined earlier as the R&D BER).

competition between the parties outside the scope of the agreement or it may make anti-competitive coordination on those markets likely, thereby leading to higher prices. A foreclosure problem may arise in the context of cooperation involving at least one player with a significant degree of market power (which does not necessarily amount to dominance) for a key technology and the exclusive exploitation of the results."[72]

The above definition focuses on concentration in innovation, as a potential problem. The issue is whether R&D cooperation including an SME might cause such antitrust harm. It depends on the market power of the SME, but, generally, anticompetitive effect would not materialize should there be alternative sources of effective competition. Should there be alternative R&D efforts or firms already active on the relevant market and which would constrain the cooperation between SMEs, or even between SMEs and large firms, such cooperation would generally be benign irrespective of turnover and market share.

Cooperations between SMEs and large firms are also generally procompetitive. As discussed above, there are certain industries were SMEs need to gain access to relevant funding and resources held by large firms. Human medicine is one such industry where R&D cooperation can be formed so that SME developed research can be exposed to clinical testing funded and organised by large companies. Also the industries that depend on the development of standards under standard-setting organisations and access to certain standard essential patents can present high barriers to entry. SMEs may need to cooperate so as to enable their R&D results to gain access to the relevant technology standards and markets. Indeed, SMEs in technology or standard driven industries benefit from cooperating with large firms.

Moreover, in the industries addressed above, the most relevant rivalry and competition takes place before the product market is established. In pre-market research competition it is impossible to identify future market share for the product or technology under development. In addition, another difficult issue is when and whether current market shares on an existing product market should be taken into consideration when the R&D cooperation for a future product or technology is scrutinized. Especially SMEs seem to find this issue challenging when analysing whether the R&D cooperation falls inside or outside the R&D BER.

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72 Horizontal Guidelines, para. 127.

In this report, new pathways to the R&D BER are presented for the purpose of further discussion. Given the above, one alternatie to market shares for exempting R&D cooperation under the R&D BER would be a requirement to show that there are other rival R&D efforts (poles)[73] or competing technologies in the industry. This test would allow for R&D cooperation between competing undertakings with more than 25 % combined market share on current relevant markets. They would benefit from the R&D BER since there are rival R&D efforts for the market. The new test benefits SMEs since they neither need to establish their own market share, nor whether the R&D would create a new market.[74]

It should be stressed that there are less and less differences between the US and EU on the question of competition in innovation. Both the US agencies and the European Commission have actively considered innovation in a series of recent merger cases. For example, these have involved exploring the possibilities that horizontal mergers would lead to a loss of innovation by eliminating a strong innovator already present in the market or that would have likely entered existing markets or that would have created entirely new value chains, thus preventing consumers from gaining increased choice and variety.[75] It could be argued that the same development can be detected in

[73] To identify competing R&D efforts, the parties need to consider, among other things, the nature, scope, and magnitude of the R&D efforts; their access to financial support; their access to intellectual property, skilled personnel, or other specialized assets; their timing; and their ability, either acting alone or through others, to successfully commercialize innovations.

[74] The test could be limited to SMEs that would be identified based on parameters (e.g. annual turnover, number of employees) as discussed above.

[75] US cases: Complaint, Amgen Inc., 134 F.T.C. 333, 337–9 (2002) (identifying a research and development market for inhibitors of cytokines that promote the inflammation of human tissue); Wright Med. Tech., Inc., Proposed Consent Agreement with Analysis to Aid Public Comment, 60 Fed. Reg. 460, 463 (Jan. 4, 1995) (identifying a research and development market for orthopaedic implants for use in human hands); Am. Home Prods. Corp., Proposed Consent Agreement with Analysis to Aid Public Comment, 59 Fed. Reg. 60,807, 60,815 (Nov. 28, 1994) (identifying a research and development market for, among other things, rotavirus vaccines). See also Statement of the Federal Trade Commission in the Matter of Nielsen Holdings N.V. and Arbitron Inc., File No. 131-0058, September 20, 2013; and FTC Press Release, 'FTC Puts Conditions on Nielsen's Proposed $1.26 Billion Acquisition of Abritron,' September 20, 2013. See DOJ press release of April 27, 2015, available at http://www.justice.gov/opa/pr/applied-materials-inc-and-tokyoelectron-ltd-abandon-merger-plans-after-justice-department. See DOJ Complaint, USA vs Bayer AG and Monsanto Company, May 29, 2018, paragraph 61.

the US case law.[76] Interestingly, the view that this represents a new direction is not accepted in a recent paper written by current and former chief economists of the US and EU competition authorities.[77] In this paper, Giulio Federico, Fiona Scott Morton

EU cases: COMP/M. 5675 – Syngenta/Monsanto's Sunflower Seed Business, Commission decision of 17 November 2010, para. 248 and paras 200 and 207 (finding that farmers would have suffered from reduced choice); COMP/ M.6166 – Deutsche Börse/NYSE Euronext, Commission decision of 1 February 2012, section 11.2.1.3.4, confirmed by Case T-175/12, Deutsche Börse AG v Commission, ECLI:EU:T:2015:148; Case No COMP/ M.7326, Medtronic/Covidien, Commission decision of 28 November 2014; Case No COMP/M.7275, Novartis/GlaxoSmithKline's oncology business, Commission decision of 28 January 2015; Case No COMP/ M.7559, Pfizer/Hospira, Commission decision of 4 August 2015 Case No COMP/ M.7278, General Electric/Alstom (Thermal Power-Renewable Power & Grid Business), Commission decision of 8 September 2015. CASE M.7932 – Dow/DuPont, Commission decision of 27 March 2017.

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

77 Giulio Federico, Fiona Scott Morton & Carl Shapiro, 'Antitrust and Innovation: Welcoming and Protecting Disruption, Innovation Policy and the Economy', National Bureau of Economic Research, 2019.

and Carl Shapiro seem to endorse that there is a general test for establishing whether innovation in the industry as a whole would decrease due to a merger. This is done, for example, by dividing horizontal pharma merger cases into different groups: (i) product-to-pipeline overlaps, (ii) pipeline-to-pipeline overlaps, and (iii) competition in innovation (e.g. overlap in innovation capabilities). The last group of cases is a result of a general approach where the lessening of innovation in the industry as a whole has been scrutinised.[78]

Indeed, this methodology should also be picked up in a new R&D BER, should a new threshold for when the BER is applicable be introduced based on the requirement that if the competing undertakings cooperating in R&D can show that there are other rival R&D efforts, then the R&D BER should be applicable. However, whether there are truly competing R&D efforts should be interpreted rather strictly. The identification of competition in innovation and overlapping capabilities need to be stringent so as to identify the sources that create relevant competitive pressure. Possible relevant parameters should be whether an R&D effort has similar:

(a) aim and strategy
(b) access to financial support
(c) access to intellectual property,
(d) skilled personnel,
(e) other specialized assets;
(f) timing; and
(g) general ability.

The tests above are based on self-assessment of the parties involved and the additional requirement should be viewed as a safety mechanism so as not to block exempt R&D cooperation that restricts competition.

78 ibid.

Access to research results and background know-how

Articles 3(2) and 3(3) of the R&D BER stipulate the following:

> *2. The research and development agreement must stipulate that all the parties have full access to the final results of the joint research and development or paid-for research and development, including any resulting intellectual property rights and know-how, for the purposes of further research and development and exploitation, as soon as they become available. Where the parties limit their rights of exploitation in accordance with this Regulation, in particular where they specialise in the context of exploitation, access to the results for the purposes of exploitation may be limited accordingly. Moreover, research institutes, academic bodies, or undertakings which supply research and development as a commercial service without normally being active in the exploitation of results may agree to confine their use of the results for the purposes of further research. The research and development agreement may foresee that the parties compensate each other for giving access to the results for the purposes of further research or exploitation, but the compensation must not be so high as to effectively impede such access.*
>
> *3. Without prejudice to paragraph 2, where the research and development agreement provides only for joint research and development or paid-for research and development, the research and development agreement must stipulate that each party must be granted access to any pre-existing know-how of the other parties, if this know-how is indispensable for the purposes of its exploitation of the results. The research and development agreement may foresee that the parties compensate each other for giving access to their pre-existing know-how, but the compensation must not be so high as to effectively impede such access.*

The antitrust harm protected by the access right in Article 3 of the R&D BER is somewhat unique. Historically, the access rules in Articles 3(2) and 3(3) in the R&D BER should, from a competition policy perspective, be regarded as protecting the competitive status the collaborating firms acquire during the collaboration. They protect the ex post competitive status of the firms, while ex ante they might not have been competitors when entering the collaboration. Indeed, it does take into consideration that the parties become competitors – or potential competitors - during the collaboration due to the transfer and creation of know-how and patents in the joint

project.[79] From an economic perspective, joint R&D stimulates spillover or knowledge sharing effects between the parties which imply that they become rivals and such spillover increases both competition in innovation and price competition.[80]

A drawback with taking the competitive status the parties acquire after the R&D cooperation is, however, that a limitation of access to research result or background know-how may amount to antitrust harm.[81] Such restrictions on the access to the results (or pre-existing know-how for the purpose of exploitation) then become similar to non-compete restrictions. However, on the other side of the coin, the compulsory access requirements may cause firms to refrain from entering into R&D cooperation that would be beneficial and disperse and disseminate knowledge between the parties.[82]

It should be noted that Article 3(2) of the R&D BER addresses inter alia access to the R&D results for joint R&D cooperation and paid for R&D cooperation, while Article 3(3) grants access to background know-how if this is indispensable for the purpose of exploitation and the parties only entered into an agreement for joint R&D or paid for R&D. Research institutes, academic bodies, or undertakings which supply research and development as a commercial service without normally being active in the exploitation

79 See generally Andreas Fuchs, *Kartellrechtliche Grenzen der Forschungskooperation* (Baden-Baden, Nomos Verlaggesellschaft 1989) and Hanns Ullrich, *Kooperative Forschung und Kartellrecht* (Heidelberg, Verlag Recht und Wirtschaft 1988).

80 See discussion supra.

81 Possibly, one could find one exemption, joint research which the parties cannot independently carry out. Here there is no restriction or anti-competitive effect ex ante / ex post the cooperation.

82 It should be acknowledged that the Pharmaceutical Sector Inquiry from 2009 found that about 81% of submitted agreements (47 of the 58 agreements) provided for some kind of exclusive relationship. 44 agreements contained an exclusive supply, an exclusive purchasing and/or an exclusive licensing provision. A non-compete clause was included in 27 agreements. Looking at the combination agreements one can observe that around half of the agreements that amongst other things focused on research and development (seven of the thirteen agreements) or manufacturing (nine of the 19 agreements) were entered into on a non-exclusive basis. This suggests that companies usually enter into exclusive relationships if they focus only on the commercialization of products. However, if they also include research and development and/or manufacturing in the agreements, they more often reserve themselves the right to freely enter into agreements with other third parties. See para. 1282.

of results may agree to confine their use of the results according to Article 3(2) for the purposes of further research (and therefore not for exploitation).

In reference to Article 3(3) of the R&D BER, which seems to cause some special ambiguity, it should be pointed out that the rules stipulate a right to access indispensable background *know-how* for exploitation of the research result. That only indispensable background know-how is accessible is clear, however, it seems that often parties claim that the right to access background know-how also includes other proprietary information.[83] It should be noted that a lot of the ambiguity for the SMEs seems to stem from the use of the model agreement that stipulates broader access rights, rather than from the actual wording of the R&D BER. Model terms and obligations originating from EU funding drafted for the benefit of research institutes or academic bodies often stipulate broader access rights, including access also to background proprietary information.[84]

Moreover, R&D cooperation in reference to human medicine industry, for example, for the development of orphan medicines, cannot commercially accept that both parties have access to research result. As discussed above, the market for the orphan medicine can sometimes only hold one supplier. The parties are then forced to do an individual analysis of Article 101(3) TFEU that may result in too much ambiguity. This, in turn may also mean that the R&D cooperation will not be conducted in the first place. As a solution to this problem, SMEs may be included alongside with "research institutes and academic bodies" in Article 3(2). It would therefore be left to the parties

83 It should here be acknowledged that the 2016 Trade Secret Directive may cause much of the background know-how to become trade or business secrets, implying that the right to access background know-how in Article 3(3) may be limited. See Directive (EU) 2016/943 of the European Parliament and of the Council of 8 June 2016 on the protection of undisclosed know-how and business information (trade secrets) against their unlawful acquisition, use and disclosure OJ L 157, 15.6.2016, p. 1–18

84 See for example FP7 Grant Agreement Annex II General Conditions II.1. Definitions and Part C Section 2 – Access Rights. https://ec.europa.eu/research/participants/data/ref/fp7/93289/fp7-ga-annex2_en.pdf. Such access rights may reflect the personal right to conduct research on the behalf of the researchers in question. Moreover, there is a right to conduct research under patents, see for example Art.27(b) UPCA: The rights of a patentee shall not extend to (…) acts done for experimental purposes relating to the subject matter of the patented invention. In national patent law the research exemption can be broader. Thus, broad access rights stems from other sources that the R&D BER.

to restrict the access to the final results for SMEs to further research only and therefore limiting the right to exploit the research result. The SMEs can be included in the enumeration and it could also be considered that the notion of "undertakings which supply research and development as a commercial service without normally being active in the exploitation of results" be deleted as it is difficult to fulfil. Indeed, undertakings which supply research and development as a commercial service normally exploit the result through licensing, and the definition is hence seldomly applicable.

It could therefore be clarified in Article 3(2) that, when SMEs, research institutes or academic bodies are part of cooperative research, they could be restricted from actively exploiting the research results and therefore they would confine their use of the results for the purposes of further research only.[85] The SMEs, research institutes or academic bodies would then also be obliged to give access to indispensable background know-how according to Article 3(3) R&D BER.

At the same time, the impact of such inclusion on the growth of SMEs should also be considered. Most R&D focused SMEs are likely gaining revenues from royalty streams from third parties based on exploitation right obtained by Article 3(2) in the R&D BER. The proposal is however to leave it to the contracting parties if they would limit their use and in a commercial negotiation it can be expected that SMEs for which the revenue streams from licensing are important may be unwilling to agree to limiting their exploitation rights.

Notwithstanding the above, a general exemption regarding exploitation could be envisaged. Under such exemption, parties to R&D cooperation could be restricted from actively exploiting the research results and confining their use of the results for the purposes of further research only. This could take to form of giving one party exclusive access and exploitation right to research results and the background know-how, under the condition that they can show that there are other rival R&D efforts or competing technologies in the market [86] The right to exploitation now stipulated in

[85] Previously, the rules was that research institutes, academic bodies, or undertakings which supply research and development as a commercial service without normally being active in the exploitation of results may agree to confine their use of the results for the purposes of further research. SMEs were not included.

[86] Inspired by the TT Guidelines and the equivalent safe harbour in the US Antitrust Guidelines for the Licensing of Intellectual Property, see example 3, p. 12.

Article 3(2) R&D cooperation would thus be limited as there are other R&D efforts in the industry and the concentration of the R&D field is low and where therefore there is little or no potential anticompetitive effects.[87]

It should be stressed that if access is restricted according to the above, there is a theoretical risk that large firms enter into R&D cooperation agreements to obtain promising competing research results so as to control, slow or even kill the development of the competing research result from even becoming competing products on the relevant market. This means that it would be necessary to redraft Article 6(1)(b) of the R&D BER so that it applies in situations where the party that exclusively acquired the access and exploitation right under Article 3(2) and (3) of the R&D BER stopped the exploitation of the research result. Thus, in these situations, the restriction for exploitation of the research result and *background know-how* for the SMEs, research institutes and academic should be lifted. These entities would then be able to exploit the research result including background know-how. Exploitation can be conducted through licensing of the patents and transfer of know-how to a competing firm. Such a rule would eliminate the risk of larger firms entering into R&D cooperation with promising SMEs, so as to 'kill off' or shelve the promising research result.[88] Possibly, this should be considered a hard-core restriction.

87 Inspired by the TT Guidelines and the equivalent safe harbour in the US Antitrust Guidelines for the Licensing of Intellectual Property, see example 3, p. 12.

88 See in analogy, Colleen Cunningham, Florian Ederer and Song Ma, Killer Acquisitions, *Journal of Political Economy*, 129(3) (2020), 649–702.

SMEs in R&D - some more examples of R&D collaborations

The examples have been drafted with inspiration from real situations, however, they do not reflect actual events or cases.

Example A

Z's *Anfano*, an anti-CTLA4 antibody and potential new medicine, have both been granted Orphan Drug Designation (ODD) in the EU for the treatment of hepatocellular carcinoma (HCC), the most common type of liver cancer. Z is a large pharmaceutical company constantly on the search for new promising research results. Z also provide a medicine for liver cancer, Zebac which is the third most sold drug globally for the treatment of liver cancer, out of 10 + different medicines currently marketed.

The EU grants ODD to medicines intended for the treatment, diagnosis or prevention of rare diseases or disorders that affect not more than five in 10,000 people in the European Union.

Liver cancer is the third leading cause of cancer death worldwide and for patients with unresectable or advanced disease, only 13 per cent are alive five years after diagnosis. The *Anfano* currently in phase II trials, are the only medicine in pipeline for certain forms of liver cancer. It is promoted as the first in a new generation of liver cancer medicines.

Peter Senecek, Executive Vice President of OC R&D, the R&D specialized firm that originally identified and conducted the necessary research in collaboration with Z, said: "Many patients with liver cancer are diagnosed and treated only after the disease is advanced, and there is an urgent need for new effective and tolerable treatments. We are eager to bring new potential options to these patients and look forward to the results of our ongoing Phase III". OC R&D is a small R&D only firm. A spin off from D Medical College, Peter is the main investor, inventor and researcher. OC R&D employ a further 35 researchers (55 employees all-in-all) yet has no product sale turn-over. Z has provided considerable funding and know-how for product development, and will invest in marketing for future access to the markets. Z is under the R&D cooperation granted a licence for the exclusive production and distribution of the resulting product for the duration of the patent, while the agreement also requires that OC R&D stops any R&D in the concerned field

of research for liver cancer. OC R&D will receive substantial payments under the royalty scheme provided in the R&D cooperation agreement.

The Phase III trial is testing *Anfano* in patients with unresectable, advanced cancer who have not been treated with prior systemic therapy and are not eligible for locoregional therapy (treatment localised to the liver). It is the first trial to test dual immune checkpoint blockade in the 1st-line advanced cancer setting. *Anfano* is not currently approved to treat liver cancer in any country. It is expected that the product could be brought to market in three to five years.

Analysis: Z and OC R&D might be competitors. It depends on the identification of the relevant market and the analysis of the overlaps in product-to-pipeline, and competition in innovation (cf. discussion above). The current R&D BER is most likely not applicable. It depends, firstly, on whether Z current medicine in the market could be viewed a competing medicine to the not yet developed *Anfano,* and on Z market share. This is a can be difficult analysis. OC R&D would most likely need to purchase such an analysis from third party or relay on information provided by Z. However, secondly, the exclusive exploitation right including the restriction on OC R&D not to conduct R&D in the same field of research after the terminate of the cooperation would most likely have caused the R&D cooperation to fall outside the R&D BER. The parties need then to make an individual analysis under 101(3) TFEU. Is the exclusive right including the restriction on OC R&D indispensable for the establishment of the R&D cooperation? If Z can agree to only obtain exclusive exploitation right, while OC R&D would still be allowed to specialize in R&D, the R&D BER could become applicable. Moreover, would the R&D cooperation continue during the life of the patent, OC R&D may be restricted to conduct R&D in the field connected to the joint research, se Article 4 R&D BER.

According to the proposal in this Report, OC would likely be regarded as an 'SME'. The R&D BER would then be applicable and the parties would not need to make an analysis of the relevant market, or conduct an analysis of the overlaps in product-to-pipeline, and competition in innovation. The exclusive exploitation right for Z would have been encompassed by the R&D BER according to the revision of R&D BER proposed in the report. Such right to exclusive exploitation is based on the identification of OC R&D as an SME. OC R&D not being able to conduct R&D will cause the cooperation to fall outside the R&D BER.

Example B

G is a globally active 50/50 joint venture between A and TL. It was established in 1985 and is domiciled in Belgium. It employs 200 individuals and has an annual turn-over of 500 MEUR (based on sales to parents) and total assets of 40 MEUR. A is a food and drink processing conglomerate corporation that qualifies to the list of the world's top 100 largest public companies. TL is the global leading cosmetics company and has developed activities in hair colour, skin care, sun protection, make-up and, perfume, and hair care.

G is a pharmaceutical company specializing in the research, development and marketing of therapeutic, corrective and aesthetic solutions for skin, hair and nail conditions. G's products treat a range of dermatological conditions including: acne, rosacea, fungal nail infections, psoriasis and steroid-responsive dermatoses, pigmentary disorders, skin senescence and skin cancer. In the field of products for treatment of skin senescence, G markets an injectable botulinum toxin product named B for the use in aesthetic medicine, in particular the treatment of facial lines and wrinkles. B has been the leading injectable botulinum toxin product for years and represent 60 + per cent of the sale of injectable botulinum toxin products.

K-Med is a company listed on Nasdaq OMX Frankfurt. It has less than 200 employees, turnover of 48 MEUR and total assets of 76 MEUR. K-Med develops, manufactures, markets, and sells high quality medical products for medical use. The majority of K-Med's products are based on the company's previously patented non-animal-based, stabilized, hyaluronic acid ("NOSHO") technology. The NOSHO is now off patent. Its main activity is the supply of injectable treatments where its product portfolio includes R. R was developed to treat lack of voluntary control over urination, incontinence. However, the new research focus is that R can be used for aesthetic treatment, for filling lines and folds, contouring and creating volume in the face. It is a so called 'derma filler'.

In the area of injectable aesthetic treatment there is little regulatory control and no requirements for clinical testing. Competition is fierce and there are at least four other R&D projects driven by either large cosmetic or pharmaceutical companies.

G and K-Med enter into an R&D cooperation, to be terminated after two years, for the development of an aesthetic treatment, for filling lines and folds, contouring and creating volume in the face based on the hyaluronic acid for R. The aim is to develop a new treatment and have it tested with successful result, and in the end, hopefully,

have the hyaluronic acid for R patented for this new use. Both firms agree to invest 50/50 in the R&D needed for the development of the new treatment. K-Med agree not to enter the aesthetic industry with its own line of products/treatments should the patent strategy be successful.

Analysis: Under the current block exemption, the scenario above could imply tricky analysis of the relevant market. Firstly, should R and B be considered (potential) competing products? Secondly, what about the business of parent company TL, should for example skin cream also be included in the relevant market?

Also an analysis of whether G and K-Med are SMEs, based on static parameters such as turn-over is challenging: should the parents' turnover of G be assigned to G, or not? It depends what should be included in the notions of undertaking and SME. Under the notion of connected undertaking the parents turnover would probably not be included, while under the doctrine of economic unity the parents turnover may very well be included. What about K-Med? Should the fact that the undertaking is publicly listed be included in the analysis of whether it is an SME, or not? Through its public listing it should have easier access to funding, while this is not taken in to consideration under the test for establishing SMEs.

According to the proposal in this Report, K-Med is an SME and not part of the [two-three] largest firms on the relevant market, yet is it planing to cooperate with one of the largest competing firms on the relevant market (G)? It depends on the how to delinate G and TL (see discussion regarding economic entity doctrine and connected undertaking above). Possibly, K-Med and G can both be considered SMEs. The R&D BER would become applicable even though G holds 60 per cent market share in the market of injectable botulinum toxin products.

Notwithstanding the above, given the rivalry and competition for new forms of derma fillers, the proposed test which is based on the identification of other rival R&D efforts could also be used in this example. Their R&D effort would fall inside the R&D BER irrespective of market share, while possibly also the exclusive exploitation right could pass the (new) Article 3 hurdle.

Conclusion

The issue addressed in this report is whether SMEs should be granted special status in the R&D BER to promote their involvement in horizontal R&D cooperation agreements.

R&D cooperation agreements with other SMEs or with large firms may provide SMEs with access to funding, knowledge and other necessary resources. In several industries such as human medicine and technology-driven industries, SMEs are often obliged to cooperate with large firms so as to enable their research result to develop into marketed products. Compliance uncertainty in relation to a potential R&D cooperation may lead to the cooperation being abandoned with the consequence of missed opportunities and delays in innovation.[89] Therefore, efforts should be made to promote SMEs to engage in pro-competitive R&D cooperation agreements. For example, limiting the regulatory burden for SMEs may promote SMEs to join pro-competitive R&D cooperation agreements.

Considering the above and in the context of the review of the HBERs, the purpose of this report is to analyse whether the R&D BER should:

(a) include a specific category of R&D agreements covered by the exemption of the R&D BER when such agreements are concluded by SMEs; and/or
(b) modify (and potentially remove) in the R&D BER the requirements of full access to the final results and/or access to pre-existing know–how when the horizontal R&D cooperation agreements are concluded by SMEs.

Exempting SMEs under the R&D BER

The first question requires to determine how to identify SMEs that could be subject to an exemption (in addition to the generally used definition for SMEs), for instance by ascertaining the existence and power of other large companies. To some extent, the HBERs and the *de minimis* rules, generally cater to SMEs due to the level of the market share threshold. It may however be difficult for SMEs to identify their relevant markets, competitors and market shares, in particular when pre-market activities are

89 Regulatory burdens remain an obstacle for SMEs as these firms tend to be poorly equipped to deal with them. Policy makers must ensure that compliance procedures associated with, e.g. R&D and new technologies, are not unnecessarily costly, complex or lengthy. See the Commission's Staff Working Document, paragraphs 48 and 61.

assessed. Therefore, there might be other parameters to identify pro-competitive R&D cooperation agreements concluded by SMEs.

The report therefore proposes three new additional tests to identify pro-competitive horizontal R&D agreements concluded by SMEs that should trigger the applicability of the exemption under the R&D BER.

Firstly, a test[90] for **competition in innovation**. A new threshold could be introduced in the R&D BER based on the existence of other rival R&D efforts or competing technologies. The requirement would therefore be that, if the competing undertakings cooperating in R&D can show that there are other rival R&D efforts[91] or competing technologies already in the market or perceived to soon enter the market, their R&D cooperation agreement could benefit from the exemption under the R&D BER because there would still be a sufficient level of competition in innovation. Recent merger cases at EU level could provide further guidance on the criteria to identify rival or competing R&D efforts. While such a safe harbour has not been implemented before under the R&D BER, it should be acknowledged that at least one other jurisdiction, the U.S., has a similar safe harbour.[92]

Secondly, an additional test based on the **definition of an SME** is discussed in the report. SMEs are defined in the Annex to Commission Recommendation 96/280/EC based on absolute parameters, i.e. as enterprises which employ fewer than 250 people and which have an annual turnover not exceeding EUR 50 million, and/or an annual balance sheet total not exceeding EUR 43 million. The exemption would be applicable to undertakings that fall within such definition. A similar type of test is used in other areas of Union law such as when the administration may provide funding. However, creating a specific exemption for SMEs catering to all industries based on absolute parameters (e.g. annual turnover, balance sheet, number of employees) is a challenge since industries and markets are different in reference to size, turnover and structure. Therefore, the definition of SMEs based on absolute

90 See Article 4 R&D BER for the current applicable test.

91 The number of rival R&D efforts could be discussed.

92 For the US equivalent, compare Collaboration Guidelines, 26 et seq. stating the antitrust enforcement agencies should not challenge an R&D collaboration on the basis of its effect on competition in an innovation market in case there are three or more independently controlled close substitute research efforts, in addition to the effort under scrutiny; and IP Guidelines, 13, 23, which state four or more independent research efforts in addition to the scrutinized effort.

parameters can be a first prong in the test, and thus a useful starting point. It should be acknowledged that a definition of SMEs based on absolute parameters is already used under EU Competition law. For example, the Notice on Effects on Trade[93] indicates that SMEs, as defined in the Annex to Commission Recommendation 96/280/EC, are normally not capable of affecting trade between Member States; however, they may be able to do so when they engage in cross-border economic activity.[94] The Annex to Commission Recommendation 96/280/EC defines SMEs based on absolute parameters.

Thirdly, another test could be to require SMEs entering into a R&D cooperation agreement to provide information indicating that they **are not part of the largest firms on the relevant market** (e.g. top 2 or top 3). This third test can be either stand-alone test or work as the second prong (for example in combination with the second test) to identify horizontal R&D cooperation agreement concluded by SMEs that should be exempted under the R&D BER. To show that the undertaking is not part of the [two or three] largest firms on the relevant market, a number of factors could be weighed in, such as access to financial support, access to intellectual property, skilled personnel, or other specialized assets.[95]

Modifying or removing the conditions of full access and/or access to pre-existing know–how

In reference to Article 3(2) of the R&D BER, the rules stipulate a right to access the research results for all parties of the R&D cooperation agreement.[96] With regard to

93 Commission Notice — Guidelines on the effect on trade concept contained in Articles 81 and 82 of the Treaty, OJ C 101, 27.4.2004, p. 81–96 (the 'Notice on Effect on Trade').

94 See point 50 of the Notice on Effect on Trade.

95 A somewhat similar Canadian exemption provides that as a general rule, the Commissioner will not challenge an agreement under section 90.1 on the basis of: a concern related to a coordinated exercise of market power by firms in the relevant market where the share of the four largest firms in the relevant market is less than 65%, or the share of the parties to the agreement is less than 10% of the relevant market.

96 There are binding exemptions concerning intellectual property rights (IPRs) and their use for research purposes under national and European patent legislation. For example, according to Article 27(b) UPCA: "*The rights of a patentee shall not extend to (…) acts done for experimental purposes relating to the subject matter of the patented invention*". Under national patent law, the research exemption

SMEs, it could be considered whether the exception foreseen in Article 3(2) R&D BER for research institutes and academic bodies could also be made available to SMEs that are part of a horizontal R&D cooperation agreements. This exception allows to limit the requirement of full access to the R&D results so that such results can only be used for the purposes of further research.[97]

It should however be acknowledged that such modification may potentially restrict growth for SMEs in the EU since R&D-focused SMEs are likely gaining revenues from royalty streams derived from the exploitation rights obtained through Article 3(2) in the R&D BER. The proposed modification could thus be allowed only in situations in which there are other R&D efforts in the industry and the level concentration in the relevant R&D field is low.

In reference to Article 3(3) of the R&D BER, the requirement of access to pre-existing know-how could benefit from further clarity but no significant changes seem necessary.

can be broader. Indeed, the exception foreseen in Article 3(2) R&D BER should been seen as a clarification.

97 The current rule is that research institutes, academic bodies, or undertakings which supply research and development as a commercial service without normally being active in the exploitation of results may agree to confine their use of the R&D results for the purposes of further research. SMEs are not currently included unless they fall under the third category.

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