

DG COMP proposals to amend the

R&D Horizontal Block Exemption Regulation:

A review on behalf of the

publicly funded Research Organisation (PRO)

& University sector

Final Report

Prepared by



EUROPEAN COMMISSION

Directorate-General for Competition *E-mail:comp-publications@ec.europa.eu*

European Commission B-1049 Brussels

DG COMP proposals to amend the R&D Horizontal Block Exemption Regulation: A review on behalf of the publicly funded Research Organisation (PRO) & University sector

Final report

Europe Direct is a service to help you find answers to your questions about the European Union.

Freephone number (*):

00 800 6 7 8 9 10 11

(*)The information given is free, as are most calls (though some operators, phone boxes or hotels may charge you).

LEGAL NOTICE

The information and views set out in this report are those of the author(s) and do not necessarily reflect the official opinion of the Commission. The Commission does not guarantee the accuracy of the data included in this study. Neither the Commission nor any person acting on the Commission's behalf may be held responsible for the use which may be made of the information contained therein.

More information on the European Union is available on the Internet (http://www.europa.eu).

Luxembourg: Publications Office of the European Union, 2022

Catalogue number: KD-07-22-075-EN-N

ISBN: 978-92-76-47646-7 DOI: 10.2763/630311

© European Union, 2022

Reproduction is authorised provided the source is acknowledged.

The reproduction of the artistic material contained therein is prohibited.

Authors:



- Malcolm Bain (Across Legal, Barcelona)
- Laura MacDonald
- Yolanda Martínez (Marimón Abogados, SLP, Barcelona)
- Bruno Vandermeulen

Contents

Abstract Executive Summary R&D Collaborations: Landscape from University/PROs Perspective Research Institutes and Academic Bodies Differences between research institutes and academic bodies	3 4 4
Overview of the nature of horizontal R&D cooperation agreements by researinstitutes and academic bodies (including downstream exploitation and utilisate of R&D results)	tion
The Role of Research institutes and Academic Bodies as originators of R&D implementers The different forms of R&D cooperation agreements with research institutes and academic bodies Three Options Considered Option 1: Baseline scenario (no policy change)	6 d/or 7 .10 .10
Option 2: the addition of further clarifications of the definition of competundertakings in case research institutes and/or academic bodies are involved in Fagreements	R&D . 12 emic . 12
Being active in the exploitation of the R&D results	. 13
Option 3: the exploration of whether the conclusion of R&D agreements that concluded with academic bodies and/or research institute and that are unlikely raise anti-competitive concerns and have beneficial effects on consumers can allowed by modifying (and potentially removing) the requirement(s) in the R&D of (a) Full access to the results and / or (b) access to pre-existing know-how	y to be BER .16
Access to pre-existing know-how	. 19
Methodology	. 21 . 21 . 21 . 21 . 21
Challenges	
Additional Topics	. 22
Compatibility of Terminology across the R&D BER and the Technology Transfer	
Annex A - LESI Les Nouvelles June 2019 Issue « Knowledge Transfer and IP : New Challenges » articles	the . 24
Allines D - Evaluties of Man Collaboration Terms and Trems	. 23

Abstract

This report assesses the ability of the proposed policy options to ensure that the rules of the R&D BER and the Horizontal Guidelines do not discourage the participation of research institutes and/or academic bodies in R&D cooperation agreements that do not raise competition concerns. The report welcomes proposals for added clarification in both an updated BER and its Guidelines as being necessary, such as around certain temporal and material aspects.

Executive Summary

This report focussed on the specific questions around the ability of the proposed policy options to ensure that the rules of the Research and Development (R&D) Block Exemption Regulation (BER) and the Horizontal Guidelines do not discourage research institutes and/or academic bodies from engaging in R&D cooperation agreements that do not raise competition concerns.

Feedback on each of the three official proposals from the Commission is set out, with justification including some experiences of the ASTP experts.

Option	Commission's Proposal	Feedback	
1	Baseline scenario (no policy change)	Feedback suggests that <u>making no change</u> would send the wrong signal to the community and that some amendments are needed to keep the R&D BER's up to date with current needs.	
2	Adding further clarifications to the definition of "competing undertakings" in the R&D BER's in case research institutes and/or academic bodies are involved in R&D agreements	Feedback proposes that some more <u>clarity on</u> <u>both temporal and material aspects</u> of the assessment would be necessary either in the R&D BER or the Horizontal Guidelines. These specifications may include, amongst others, the moment in which the competitive analysis must be undertaken.	
3	Exploring whether the conclusion of R&D agreements with academic bodies and/or research institutes that are unlikely to raise anti-competitive concerns and have beneficial effects on consumers can be allowed by modifying (and potentially removing) the requirement(s) in the R&D BER on:		
	full access to the results and/or	Our research revealed no major concern regarding the condition to provide full access to the R&D results. In general, parties see this as a <u>reciprocal compensation</u> of their respective intervention and contribution to the project. Therefore, removing this as a condition for the exemption may not have a significant effect on the contractual configuration of R&D projects in which such reciprocity in the access to results and/or delimitation in connection to respective exploitation seems to be the common rule.	
	access to pre-existing know- how in case such agreements	With regard to access to pre-existing know-how , there seems to be a common practice of making this available against payment. However, a clarification and confirmation of the interaction between Articles 3(2), 3(3) and 5(a) R&D BER would contribute to legal certainty.	

R&D Collaborations: Landscape from University/PROs Perspective

This report assesses the ability of the proposed policy options to ensure that the rules of the R&D BER and the Horizontal Guidelines do not discourage the participation of research institutes and/or academic bodies in R&D cooperation agreements that do not raise competition concerns.

This report provides some background information around the profiles of those research centre and the types of collaboration they frequently enter into, in order to give some insight into the prevailing trends and practices, before commenting on the 3 options.

Research Institutes and Academic Bodies

The reviewers considered the specific questions: Is there a difference(s) between academic bodies and research institutes or are these terms interchangeable?

Differences between research institutes and academic bodies

While both types of organization – academic bodies and research institutes – do exist in Europe, for the purposes of the applicability of the R&D BER it may be stated that the terms could be interchangeable. They identify organizations which may have different goals, funding models and preferred terms of engagement with industry. But the evolution of collaborations in R&D means that each type of organization is equally likely to be engaged in collaborations which fall under, or should fall under, the R&D BER – including both independent and/or paid-for research. To illustrate the above, we can refer to the fact that across Europe, there is a wide range of publicly and privately –funded, research–active centers that engage in R&D Collaborations:

- (a) traditional "blue sky" 1 or "basic" research universities (such as Charles University or Leiden University)
- (b) technical universities (such as TU Delft or TU Munich, Universitat Politécnica de Catalunya)
- (c) dedicated thematic research centers (such as IMEC or Wageningen Agricultural University, Barcelona SuperComputing Center, Centre for Genomic Regulation)

In our experience, there is little difference if any (and certainly not material to this study) between these types of entities regarding their approaches to R&D collaboration, compensation terms or exploitation of results through licensing or spinouts. With regard to differences in ability to achieve different levels of compensation, some suggestion is made as to whether or not access to legal or specialist knowledge-transfer advice makes a difference. The reviewers are not able to comment on any definitive such difference. However, there is much literature around the evolution and development of supporting knowledge transfer offices, such as the dedicated *Les Nouvelles* June 2019 volume (see Annex A). A strong trend in the collaboration landscape of joint problem-solving and co-creation is emerging as a result of sophisticated relationships between industry and academic research centres.

4

Blue sky research: research without immediate practical application. https://en.wikipedia.org/wiki/Blue skies research

Overview of the nature of horizontal R&D cooperation agreements by research institutes and academic bodies (including downstream exploitation and utilisation of R&D results)

In all of these different types of academic bodies and research centers, we find the full spectrum of collaborative relationships. These include

- (a) **blue sky research generation**: research into basic scientific knowledge, e.g. collaboration between different R+D centres that have complementary skills and knowledge in a given area, the results of which is further scientific knowledge without immediate practical or industrial application. Usually no limitation on downstream exploitation or on use for further research, unless the research results in patented knowledge, which is often not the case, as there are no products or methods specifically targeted.
- (b) **applied and/or contracted research or service work**: research aimed at achieving a specific technology or scientific knowledge with practical application, or even a proof of concept or other higher TRL² result. Usually clear exploitation terms (outbound licensing or assignment of IPRs to one of the parties, particularly the financing or industrial party) and strict limitation on use by other parties except for further R+D and teaching. IPRs in contracted research is nearly always assigned to the contracting party, while the R+D centre may reserve a right to ongoing research and academic use.
- (c) **complex large-scale consortia addressing basic or upstream research:** same as "blue sky", but carried out by larger consortia facing more complex problems (e.g. CERN Collider).
- (d) **complex large-scale consortia co-operating in the downstream application and development of the results**: same as applied work, but on a larger scale (e.g. Airbus back in the 80s, Project TeSLA³).

The question of whether either or both of these defined categories is likely to be engaged in exploitation or be acting in a more "commercial manner" is not dependent on which type of defined organization they are. Instead, we find that almost all are engaged in a broad spectrum of both research and exploitation activities.

TRL: technical readiness level: see for example:
https://ec.europa.eu/research/participants/data/ref/h2020/wp/2014_2015/annexes/h2020-wp1415-annex-g-trl_en.pdf

An Adaptive Trust-based e-assessment System for Learning https://cordis.europa.eu/project/id/688520

The Role of Research institutes and Academic Bodies as originators of R&D or implementers

The reviewers considered the following specific topics: The role of research institutes and/or academic bodies in the field of R&D, namely whether research institutes and/or academic bodies are R&D originators or implementers, which are the necessary resources (financial, scientific, IP, know-how etc.) necessary to ensure the participation of research institutes and/or academic bodies in R&D and at which stage of the R&D process the cooperation with research institutes and/or academic bodies takes place.

Research institutions and academic bodies are generally **originators** of R&D, in accordance with the aims and scope of their Research Groups. They are more and more involved in collaborative proof of concepts and pilot projects (which can be seen as "**implementers**") and indeed participate actively in the exploitation of the results of R&D through further research, licensing, or taking a participation in a spin-out. In collaborative R&D projects where industry (including in particular SMEs are involved), the most common scenario is that the research institutions provide the intellectual and scientific input, whereas industry more often than not provides a problem to be solved, the data and case studies that may be researched, and an environment for testing the results.

However, this is just a general rule, and there are collaborations where industry provides co-researchers and laboratories for scientific and intellectual input. Annex B also contains reference to templates applicable to a wide spectrum of collaborative relationships with examples from Ireland, Spain, Belgium and the Netherlands.

The main necessary resources to ensure participation of research entities are twofold: (a) that the research falls within the (scientific) scope of their Research Groups and is of scientific interest to the researchers (professors, post-docs, PhDs, etc.) and (b) there is available finance and material resources for carrying out the research. The research group brings its own know-how, but one of the reasons for cooperative R&D projects, especially among different research institutes, is the complementarity of (background) know-how and IPR that is brought to the collaboration, whereby the institution makes up for a lack of knowledge by bringing it in from other R&D institutes.

For R+D collaborations that take place at the earlier stages of Technology Readiness (levels 1 to 4 or 5): i.e. from basic and blue sky research and even applied research, up to product prototyping and proofs of concept, though rarely beyond that (the stages when industry takes over, with a license or other access to the results to implement the research in their industrial sector), it is often very difficult if not impossible for R&D centers to determine if they are "competing" in a market (other than the research and education market) as the product market, product functionality, and practical or commercial application of their results is rarely known at the time of entering into the R&D collaboration.

On the other hand, in situations where "contracted research or services" collaborations are entered into, often at higher TRL levels, it might be possible to anticipate the

Method for estimating the maturity of technologies in relation to their readiness to be industrially or commercially validated and exploited. See footnote 2 (ref to https://ec.europa.eu/research/participants/data/ref/h2020/wp/2014_2015/annexes/h2020-wp1415-annex-g-trl en.pdf)

downstream exploitation roles with anticipated clarity because the clear objective of the R&D collaboration is to design a specific solution to meet a specific market need, where the partners may have already been able to identify potential product market and product functionality. However, even in such cases, since the specific details (including the composition/materials/production challenges) relating to any ultimate product solution are unknown at the start of the project, understanding the market opportunity including the potential manufacturing supply and marketing roles remains information which can rarely be fully understood until achievement of actual results.

In both these situations, this renders it difficult for the partners not only to determine whether they are competitors but also to contractually commit to their downstream exploitation and production roles. As discussed later in this Report regarding typical contractual terms entered into, the balance of rights and obligations around commercial exploitation activities usually establishes a decision-making process triggered by generation of results, such that the parties can then decide which downstream roles they intend to play.

The different forms of R&D cooperation agreements with research institutes and/or academic bodies

The reviewers also considered the following specific topics: The different forms that R&D cooperation agreements with research institutes and/or academic bodies may take (including joint R&D and paid-for R&D agreements), the scope of the R&D cooperation agreements (for example whether the agreements are concluded with two or more research institutes and academic bodies, etc.) and any ancillary agreements linked to the R&D cooperation agreement (e.g. licensing, etc.).

The forms of R&D cooperation agreements are very broad. From a legal perspective, they are nearly all contractual, e.g., a mere contractual collaboration with reciprocal obligations (more common in small collaborations), to the creation of a contractual consortium with dedicated tasks, roles, voting rights, etc. Rarely will a legal vehicle be set up at the R&D stage of any research and innovation, the legal vehicle would only rarely be envisaged for joint exploitation of results.

R&D cooperation agreements are signed between anything between 2 and 50 or more parties. The most common (in our experience) is between 3-7 entities, with a mixture of R&D centres, larger industry partners and SMEs (promoted by R&D programmes of the European Union). The purpose of the collaboration is, as we have mentioned, to bring different know-how, skills and IP to the table, to share among participants during the performance of the R&D.

The R&D cooperation agreements themselves usually include the terms describing mechanisms to trigger licensing of IPRs (access to background, use of foreground⁵). However, when a specific IP asset is used (e.g an IT Platform, a dataset, materials) then often an ancillary license or material transfer agreement is entered into among the relevant parties, under the umbrella of the overall R&D cooperation agreements.

Access mechanisms usually involve decision-making stages as the progress of the project develops. Once results start to be generated, decisions about patenting and publication need to take place, often during the project. Contract terms set out how

7

Background IP: intellectual property rights and knowledge that have been previously generated and are brought by a party to the collaboration to be used during the research. Foreground IP: intellectual property rights and knowledge that is generated by and during the research project.

these are to made, usually enabling industrial partners to determine patent timing as long as publication routes are enabled without jeopardising patent priority dates. Exercising options to take commercial use rights (licensing or even ownership) is usually established with a time frame for industrial partners to decide. If they say no or choose a narrower commercial use field, often the university will retain responsibility to seek third party exploitation partners. Exclusive options are therefore the normal way to ensure R&D results are further developed either by the original R&D partners or an outside partner.

The reviewers further considered the following specific topics: The terms, conditions and duration of the different types of R&D cooperation agreements with research institutes and/or academic bodies, including the obligations that survive the end or termination of the R&D agreement (and their duration) such as full access to the final results, non-disclosure/non-use of know-how obtained from the other parties during the R&D agreement, compensation/royalty payments, non-compete and non-challenge clauses, etc.

R&D cooperation agreements usually set out 6 key items, although as with any contract, there are a number of general terms (applicable law, dispute resolution, etc.).

- 1. Purpose of the R&D, tasks of each member,
- 2. Financing
- 3. Planning and deliverables
- 4. Project governance
- 5. IPR, with access to background and use of foreground, reservation of rights
- 6. Confidentiality and Publications

The duration can be anything from a specific short terms paid-for R&D with concrete timetable, to long term blue sky research over a long period of years, with a variety of partners. The term is linked to the expected achievement of publishable or usable results (and the funding programme).

Most R&D cooperation agreements establish confidentiality of any accessed IPR (background or foreground) as the base rule, with exceptions for scientific publishing (which may also be embargoed if any IPR protection is being prepared). The agreement will define what background is being contributed and can be requested, and may subject such requests to specific licenses, restrictive use rights (specifically, only use for the performance of the project) and obligations on termination of the R&D (basically, return of all background to the owner).

Non-compete clauses are rare in the experience of the reviewers, because they are considered as a hard core restriction under article 5.a R&D BER. On the contrary, there is generally a practice that each partner may freely exploit its results, through internal use, licensing or spin-outs, and that if there are any joint results⁶, they are to be contractually agreed under joint ownership or joint exploitation models.

Joint results is a shorthand way of referring to results that are created jointly by two or more parties, such that more than one party has intellectual property rights or specific knowledge in or about the result. This means that under certain IPR laws such as e.g. copyright or software law, the authorization of all the (joint) co-owners of the results is required for exploitation (licensing, assignment) which would give each participant a blocking position and requires therefore an agreement between the parties on exploitation of these joint results. Such agreement may require

It is common practice for either joined ownership to vest contractually in one party with agreement concerning access and commercial use rights based on licenses to the other parties or alternatively for joined ownership to remain while contractual provisions establish the agreed range of non-exclusive or even exclusive commercial fields of use.

Non-challenge clauses (i.e. clauses that indicate that the parties will not challenge the validity of the IPRs of another party, e.g. issue legal or administrative proceedings to invalidate a patent), if any (they are not usual), generally apply to (a) another partner's contributed background and (b) results within the project, unless specific breach of a party's IPR can be shown. Parties to a collaboration enter into a form of "IPR peace" where they agree not to challenge the validity of background IP contributions, or the IPRs in other parties' results. Such clauses are useful to create the necessary trust and comfort between research partners so that they can exchange information with each other without the fear that such information could be used afterwards against them to invalidate an IPR.

Obligations that survive termination include:

- (a) Confidentiality of background and results that are not scientifically published (e.g. datasets, software, formula, designs, inventions, compounds, etc.)
- (b) Non-use of other party's background (as the license to use it is limited to performance of the R&D), subject to access rights for exploitation / use which are often on RAND or similar terms (see below, discussion on Option 3).
- (c) Agreed exploitation plans
- (d) Reservation of rights to use results for (non-commercial) internal research and education, subject to confidentiality.

Agreement examples: in order to enable the Commission to see what type of R&D collaborations are being entered into, among academic centers and their partners, ASTP has made a call to its membership, particularly via its Legal Special Interest Group (SIG) asking for examples which may be added to the Report. Examples of agreements can be found in Annex B.

the authorization of all co-owners, or that any or all parties may exploit the joint results independently and without accounting for income (i.e no cross-licensing fees). Alternatively, the exploitation of joint results may be under economic terms such that each party has to account to the co-owners for their share of any income or profits.

Three Options Considered

Option 1: Baseline scenario (no policy change)

Our research was conducted via videoconferences with legal, R&D management and technology transfer practitioners working in (1) a few European academic institutions (2) a small biotech company spun off from a European university (3) a large European-based institution working with multiple partners in the electronics sector and (4) a variety of SMEs who have entered into R&D Cooperation agreements with research institutions and academic bodies.

The outcome of this research makes us conclude that making no change to the R&D BER would send the wrong signal to the community of professionals to whom the R&D BER is addressed. Because the R&D BER seems nowadays used at most as a reference to define best practices but not – or no longer - as an instrument for legal guidance when drafting R&D cooperation or specialisation agreements. The R&D BER is not, or very rarely, referred to in the literature or used as a tool by legal practitioners to check the legality of their draft R&D agreements. This evolution may be due to the fact that its applicability is subject to uncertain and evolving criteria such as market power and turnover, and to self-assessment by the concerned parties. Not changing anything to the R&D BER or to the accompanying Guidelines could increase that evolution.

We recommend paying attention to the topics that the Commission has identified already, and to clarify certain terms and definitions to show that this Regulation can evolve with time by taking into account certain practices that have grown in recent years. That is in our view the best way to make the R&D BER relevant for practitioners.

Collaborative R&D activities are core to all research institutes and academic bodies. Across Europe, national funding agencies encourage reporting of the level of such engagement as part of assessment processes to determine allocation of public funding to support all research-related activities of such centres. (Examples include recent developments in Italy as well as the longstanding model of reporting in the UK.) The Commission's Staff Working Document (SWD)⁸ pages 41-47 refers to several trends and areas of potential challenge with regard to the applicability and impact of the current Horizontal Block Exemption Regulations (HBERs) in terms of the nature of technologies and market opportunities emerging in the past 10 years. This report echoes support for the conclusions drawn there, that some amendments may be appropriate to add clarification and certainty, such that institutions and partners find it easier and are more willing to rely on the HBERs and proceed to enter into collaborations aimed at new innovation and solving problems. These amendments may even include a merging of the two HBERs into a single piece of legislation, since their respective scope is not always clear to practitioners. Given the increasing proliferation of collaborative R&D across a whole spectrum of relationships between academia and industry (embracing both "paid for" or contract research as well as co-creation R&D)

For instance, the special issue of "Les Nouvelles" of June 2019 (enclosed with this report) that deals with collaborations between industry and academic institutions across the world (including Europe) does not contain a single citation to the R&D BER. The same consideration applies to the Specialisation BER.

SWD(2021) 103 final https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=SWD:2021:103:FIN

one would expect legal guidance from a single and comprehensive source and not from two different BER's. ⁹

In response to requests for input and feedback to specific questions about any challenges experienced in practice arising from the application of the R&D BER, anecdotal evidence suggests that a significant proportion of the Knowledge Transfer community representing those research organisations frequently entering into R&D alliances, have experienced no problems as a result of the provision of the current R&D BER, if they paid attention to them at all. There can be several reasons for this, including lack of awareness of any compliance issues, reliance on the fact that commercial partners are unlikely to risk entering into non-compliant agreements and thus ensure everything is compliant, or reliance on the fact that technology markets evolve so rapidly and are so uncertain (in terms of product creation, evolution and commercialisation) that the anti-competitive impact of any objectional restrictive covenant in a collaborative R&D agreement is basically inexistant.

However, amongst certain sectors such as ICT there have been specific instances identified where the perception is strongly held that the current provisions are too vaguely structured or too uncertain to enable (easy) application to technological research and developments which cross market sectors, making it difficult to be certain about the applicability of the R&D BER. This was already highlighted by the respondents in the public consultation on the R&D BER during the evaluation phase and we endorse the views that some changes are needed instead of doing nothing.

11

⁹ ASTP Survey page can be found at: https://www.astp4kt.eu/about-us/surveys/

Option 2: the addition of further clarifications of the definition of competing undertakings in case research institutes and/or academic bodies are involved in R&D agreements

Concept of competing undertakings in case research institutes and/or academic bodies are involved

Our research revealed a certain degree of difficulty in determining the competitive situation (actual or potential) between the company and the academic body or research institute participating in an R&D project. Especially when it comes to potential competition in technology markets or in so-called R&D markets 10 , R&D contracting parties may have doubts on their own inclusion in a relevant market. When it comes to product markets or even technology markets (where licences are present), the presence and market shares of the parties may be easier to identify at a given point in time. In the case of R&D markets this assessment is less clear. Both the company and the research institution and academic bodies may be present in the R&D field, but since the "commercializable" product –or improved good or process- is yet to be identified or its success may be doubtful, an evaluation of each parties' market position seems complicated.

For instance, when a biotech company collaborates with a research institution which already owns specialized technology and data for electronic devices that can be implanted in the human body to administer a drug, that biotech company may consider that the research institution a potential competitor as soon as the research institution and academic bodies wishes to enter into a new project with another biotech company for the development of a device that can collect biological data in the human body. In the pharma sector, both the company and the research institutions are often active in R&D markets but it is difficult -if not impossible- to calculate market shares there or even to know who else in the industry is conducting research for the same line of potentially commercializable products.

The scarce guidance on defining potential competition provided in precedents, the Notice on Market Definition 11 or the Guidelines on Horizontal Agreements 12 seems

Commission Decision of 27 March 2017, Case M.7932 — *Dow/DuPont*, OJ C 353, 20.10.2017, p. 9, at 15-18 and 50-58. See, in particular, paragraphs 346 to 348 of the decision:

[&]quot;(346) Research and development markets "consists of the assets comprising research and development related to the identification of a commercializable product, or directed to particular new or improved goods or processes, and the close substitutes for that research and development".

⁽³⁴⁷⁾ According to the Technology Transfer Guidelines, "innovation is a source of potential competition which must be taken into account when assessing the impact of the agreement on product markets and technology markets. In a limited number of cases, however, it may be useful and necessary to also analyse the effects on competition in innovation separately. This is particularly the case where the agreement affects innovation aiming at creating new products and where it is possible at an early stage to identify research and development poles. In such cases it can be analysed whether after the agreement there will be a sufficient number of competing research and development poles left for effective competition in innovation to be maintained".

⁽³⁴⁸⁾ When considering both the downstream product markets and the upstream technology markets, innovation should not be understood as a market on its own right, but as an input activity for both the upstream technology markets and the downstream [...] markets. This however does not prevent the Commission to assess the impact of the Transaction at the level of innovation efforts by the Parties and its competitors".

¹¹ Commission Notice on the definition of relevant market for the purposes of Community competition law, OJ C 372, 9.12.1997, p. 5, at 24.

insufficient and does not lead to legal certainty when concluding R&D Agreements. Such scarce guidance suggests that defining material elements proving realistic possibilities to compete is necessary as opposed to hypothetical possibilities in a broad innovation or technology market. For instance, how much time should it take a public institution working with a telecom operator for the development of software and algorithms to be used in a mobility app that helps users to find their best way of transportation in a city, to be considered a "competitor" when it engages a year later in a similar project with another telecom operator? Vague concepts such as "short period of time" or "based on realistic grounds" (see Horizontal Guidelines, at 10 and footnote 6; or Article 1(t) R&D BER) without further specification do not contribute to legal certainty. Even the 3-year orientation seems insufficient in this regard as it requires a prospective evaluation that is often unclear at the beginning of the R&D project.

Very specifically, our research revealed that the problem arises, in particular, when, after a successful R&D project, the academic body or research institute subsequently plans to set up a spin-out. A spin-out is any new company containing IPR originally owned by the academic body or research institute. That is for instance the case when, in the two examples given above in relation to biotechnological research and mobility apps, the research institution and academic bodies would not engage in a second collaboration with a company but would instead create a spin-out that would operate as a wholly independent and commercially oriented company -whichever the corporate configuration or shareholding structure-, specialized in the development and commercialization of, respectively, medical devices that are inserted into the human body, or mobility software for users driving in particular cities. Such a spin-out would typically be created after the R&D project and would receive access to the created technology, or receive the created technology as an asset upon its incorporation, and/or be staffed with persons who previously worked on the R&D project. We identified some concern that potential competition could be found to pre-exist even if the spin-out project was not foreseeable when the R&D agreement was concluded. Particular guidance as regards the assessment of this kind of situation was requested during our interviews.

To sum up, some more clarity on both temporal and material aspects of the assessment would be necessary either in the R&D BER or the Horizontal Guidelines. These specifications may include, amongst others, the moment at which the competitive analysis must be undertaken (e.g. conclusion of the agreement and/or production of results), which lapse of time is to be considered, the entities to be taken into account, how to assess beforehand the realistic possibilities to become a potential competitor and/or how to calculate market shares in R&D markets or technology markets where research conducted by third parties (and, thus, the size of the market or the innovation space) may be completely unknown. All these would contribute to legal certainty.

Being active in the exploitation of the R&D results

The reviewers considered the specific questions on exploitation: What is the meaning and scope of "being active in the exploitation of R&D results" and how this has been interpreted and put in practice in horizontal R&D cooperation agreements involving academic bodies and/or research institutes?

Guidelines on the applicability of Article 101 of the Treaty on the Functioning of the European Union to horizontal co-operation agreements Text with EEA relevance, OJ C 11, 14.1.2011, p. 1, at 10.

The determination of whether they are "competitors" at the start of the project can often be difficult to determine. Rather an understanding downstream of the nature of the potential utilisation and valorisation of the results can better determine whether such activity is competitive, (as opposed to the parties being direct competitors from the start). Exclusive access to exploitation rights can be used to minimise competitive behaviours and often upfront terms within the collaboration agreements will prearrange that certain fields will be exclusively exploited by the partners, whether in the form of new spin-out companies or via licensing arrangements. In some cases, there can be an operational commercial activity retained by the research centres, such as supplying on demand certain materials, providing analytical services around research expertise and results. All of which are commercial activities which could have been carried out by a commercial partner. The question which arises is if this makes them competitors at the point the agreement is entered into.

In the circumstances where the research centres retain ownership of certain arising foreground results from such collaborations along with the attendant obligation (and responsibility) to ensure there is effective utilisation of such results post the project completion, then they could be seen as potential competitors with the commercial partners.

However, disregarding for the moment the R&D services market and the education market, it seems that research institutions and academic bodies only consider themselves to be potentially in "actual or potential competition" in a market through their (actual or future) IPR licensing or spin-out activities (i.e. use of the results), or the provision of know-how based services (professors, researchers, post-docs) to private industry in that market, and other technology transfer activities.

At the time of entering into the R&D agreement, the evaluation of whether the research institute is "actually or potentially competing" with another R&D partner is extremely uncertain due to:

- (a) the lack of then existing knowledge about specific licensing or technology transfer activities that will actually occur in the future, and potentially mean that it may be in a competitive position with the participants in the R&D project in the future;
- (b) the (lack of) identification of which markets are or will be involved and are to be taken into consideration (i.e. "relevant product markets") – even more so for basic research, where the potential uses of the results of the research are either very uncertain or very wide for a number of markets;
- (c) the rapid evolution of any specific market that is/may be identified as being of concern at the start of the project, such that by the time the results are achieved, the scope and situation of the market may have radically changed; and
- (d) the consideration of what type of (future) technology transfer activities, and with which intensity, will mean that they could be considered actual or potential competitors in the relevant product market.
- (e) exactly the same issues arise even if a pre-defined product is the objective. Because even in that case it is not known which features or composition or manufacturing process etc. will emerge, all of which might affect the role and identity of competitors in the field.

Moreover, potential competition is not taken into account when defining markets, since the conditions under which potential competition will actually represent an effective competitive constraint depend on the analysis of specific factors and circumstances related to the conditions of entry. If required, this analysis is only carried out at a subsequent competitive assessment stage, in general once the position of the companies involved in the relevant market has already been ascertained, and when such position gives rise to concerns from a competition point of view. This in turn means that it cannot inform the parties at the time of signing the R&D cooperation agreement.

Taking this into account, the need to apply an analysis of "potential or actual competitors" entails significant transaction costs (legal fees, consultancy fees, search for market data, internal management time) which is discouraging for entering into R&D agreements. The more <u>clarity</u> and <u>flexibility</u> that R&D Centers are granted in this respect in the R&D BER and its interpretation/application (guidelines) the less barriers there will be to entering into R&D collaborations, in particular those that raise few if any competitive concerns.

Option 3: the exploration of whether the conclusion of R&D agreements that are concluded with academic bodies and/or research institute and that are unlikely to raise anti-competitive concerns and have beneficial effects on consumers can be allowed by modifying (and potentially removing) the requirement(s) in the R&D BER of (a) Full access to the results and / or (b) access to pre-existing know-how

To comment on this option, we have set out what is understood by (and the doubts about) "full access to results and/or pre-existing know-how" and then discuss if modifying or removing this requirement for the R&D BER exception will encourage research institutions and academic bodies to enter more readily into R&D collaborations.

We note that the current version of the R&D BER already has a limitation to this condition that is available for research institutions and academic bodies, such that they may limit this access to further research purposes only (Art. 3.2): The current R&D BER foresees an **exception for the requirement of full access** (see recital 11 and Article 3.2 R&D BER: "[...] 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**."). This corresponds with the legal principle enshrined in most European patent laws that tests for non-commercial and scientific purposes are exempted from patent infringement.

Full access to the results

The reviewers considered the following specific questions: What is the meaning of "full access to the results", the scope of this requirement and how it has been put in practice in horizontal R&D cooperation agreements involving academic bodies and/or research institutes?

The requirement for "full access to results" raises at least two doubts: which results, and what is "full access".

"Results": In practice, the concept of "project results" may give rise to uncertainty, because often collaborative projects will have two types of results in terms of ownership (and thus, giving access): individual results of a partner, or joint results of two or more partners. When the results of a collaborative project are individualized, then the research institute that is sole owner of its results is more reluctant to provide "full access" to the other parties to that institution's results, especially given the lack of definition in the R&D BER as to the meaning of "full access"- i.e. what rights (under intellectual property law) are to be granted to the other parties and whether there is compensation or not, as we discuss next. The understanding for the application of the condition for the exemption is that all results (of all partners, whether individual or joint) must be made available to all other partners.

"Full Access": Access is not a legally defined term (especially in the context of intellectual property), though understood in practice to mean (a) tangible or intangible access to the all the results (or background know-how) and (b) certain (if not "all", as implied by the word "full") rights to <u>use</u> those results for determined <u>purposes</u> (otherwise, access by itself has no meaning). However, the current draft of the R&D BER does not specify what is meant by "full" access (use for any purpose? independent commercialization too?) as opposed to a mere "access". Accordingly a <u>modification</u> of this term would provide greater clarity if it defined the minimum scope

of subsequent use required by the R&D BER. Generally speaking, use rights for further non-commercial research is usually understood and granted (as indicated in the recital and promoted by the exception in Art. 3.2), but use rights to incorporate into technology transfer and downstream licensing, or further commercial research, that are not specifically negotiated, usually gives rise to problems if they are not part of a joint or at least "agreed" exploitation.

While R&D agreements vary enormously, standard provisions regarding "access" include limited licenses to use for specified purposes. (Free) use for performance of the R&D is a given, and usually specified as royalty free. (Free) use for exploitation of the results of the R&D is NOT given, and is either reserved for an agreed exploitation plan (or vehicle) but is often granted for reasonable compensation (FRAND or RAND 13 or even preferential terms).

Full access to all results is wider than the usual practice, which is to limit access to (a) results (and background) that is <u>needed</u> either for the performance of the project, or for exploitation and, failing that (b) only for research purposes (as discussed). In large projects where there are a number of sub-projects or research lines, there is usually an understanding that partners only need to access those results and background for those work packages where they are involved. Requiring the grant of "full" access to all project results, irrespective of work packages, may be more onerous. The same applies where a partner is only interested in a part of the results of a project, and not concerned or related to other parts. Note, however, the practice we comment on below.

Also note that with regard to joint results, the terms of IP ownership usually provide for full access, on RAND or RF-RAND terms, to other parties that need the result (or background) for exploitation of their own results.

Our research among research institutions and academic bodies has in fact revealed no major concern regarding the condition to provide "full access" to the R&D results to R&D project partners, especially since there is already an exception made available to research institutes and academic bodies to limit access for further R&D. In general, parties see this as a reciprocal compensation of their respective intervention and contribution to the project.

While we think that removing or modifying the condition will not have a significant effect on the contractual configuration of R&D projects in which reciprocity in the access to results and/or a delimitation in connection to respective exploitation seems to be the common rule, it does however provide significant comfort to Research institutions and academic bodies that they can thus limit access, especially reducing risks of propagation of results or know-how downstream in other research projects, or breach of confidentiality provisions and usage rights through sharing with other (non-research) parties.

However, given the presupposition for this scenario of Option 3, that this option is for collaboration agreement are "unlikely to raise anti-competitive concerns and have beneficial effects on consumers", then requiring the research institution to give full access to results (and all the more so, reserved background, even if it is limited to

-

⁽Fair) Reasonable and Non Discriminatory. See for example "Fair, Reasonable and Non-Discriminatory (FRAND) Licensing Terms" Yann Ménière, JRC Science and Policy Report. EU Commission, 2015.

research) could be seen as unnecessary and a burden on the research groups, and thus supports the proposal to <u>remove</u> such requirement for exemption in this scenario. Besides, Article 3(2) R&D BER already provides for sufficient flexibility, inasmuch as specialization in the context of exploitation -and related access to results- is expressly permitted and can be modelled on a case-by-case basis.

As regards the exception for joint R&D or paid-for research foreseen in Recital 11 and Article 3(2) R&D BER^{14} we did not identify particular concerns either, and we may therefore assume that the exception is useful and regularly used without trouble.

We did perceive, in relation to the last sentence of Article 3(2) R&D BER, 15 that compensation for full access to results for exploitation purposes seems to be the rule rather than the exception. Parties and, in particular the industry, seem to have no trouble with providing full access to results provided this is negotiated and economically compensated (whether RAND, preferential terms, or not). This is either as a separate license (technology transfer agreement) to the party requiring access (partner or industrial licensee) or under the terms of the exploitation plan agreed by the parties.

On another note, in connection with our comments to option 2 above, the Commission may want to consider further clarifying the reasons for the exception foreseen in this Article 3(2). Indeed, if the academic body or research institute is only active in joint R&D or paid-for research, but if is neither active in the product nor in the technology markets, and provided of course that other conditions in the R&D BER are met, parties should be reasonably certain that their agreement does not give rise to competition concerns.

[&]quot;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". This is a hint that this applies when these institutions and bodies are not competitors or potential competitors in the product/technology market, as they are "not active in exploitation".

[&]quot;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".

The reviewers also considered these other specific questions: What is the meaning of "use of the results for the purposes of further research", the scope of this exception and how it has been put in practice in horizontal R&D cooperation agreements involving academic bodies and/or research institutes?

In some countries this amounts to nothing more than the contractual confirmation of the legal principle enshrined in the patent laws that tests for non-commercial and scientific purposes are covered by the legal exemption of experimental use. Similar exceptions exist for access to copyrighted works, data bases (and under the Single Digital Market directive, datamining) but have been transposed in a variety of manners, and research institutions and academic bodies are reluctant to rely on legal exceptions to carry out R&D when they have the opportunity for contractual clarity and licensing terms.

So it is useful (and thus more encouraging for participation in collaborative research) to have <u>more freedom</u> to be able to contractually circumscribe access and use of what can be essential IPRs of the institution.

Access to pre-existing know-how

The reviewers considered the following specific questions: What is the meaning of "access to pre-existing know-how", the scope of this requirement and how it has been put in practice in horizontal R&D cooperation agreements involving academic bodies and/or research institutes?

At least in one case a question arose as regards the combination of Articles 3(2) of the R&D BER-full access to final results- and Article 3(3) of the R&D BER -access to pre-existing know how- with Article 5(a) of the R&D BER- -which excludes from the exemption of the R&D BER, subject to certain conditions, R&D agreements that have as their object the restriction of the parties' freedom to carry out R&D (independently or in cooperation with third parties) in an unconnected field or, once the R&D is finalized, in the same field or in a connected one R&D BER.

The parties feared that such combined provisions could eventually lead competitors to get access to pre-existing know-how through a hypothetical subsequent agreement with the same academic institution. Such a result would have impeded the agreement. Therefore, to avoid this type of situation (and disincentive to participate in an R&D project), more clarity would be welcomed on which restrictions may be legitimately placed on the use of pre-existing know-how to which "access" is granted (such as confidentiality provisions – see next; or a category of defined permitted field of use or prohibited field of use). In this respect, the concept of "(un)connected" in Art 5(a) is very difficult to determine.

It is our opinion that Article 3(2) R&D BER acts as a limit to the prohibition established in Article 5(a). When R&D agreements are entered into with academic bodies or research institutes, clauses guaranteeing the exclusivity of one of the parties in the exploitation of results, as well as of the intellectual property rights or know-how contributed to and/or derived from the research, are lawful. Therefore, even if Article 5(a) prohibits a commitment from the research institute not to conduct further R&D in the same field with another undertaking (even a competitor), the use of the results or pre-existing know-how of the first project could well be prohibited. Validated confidentiality clauses in some relatively old precedents would confirm that approach (e.g. case IV/32009 – Elopak/Metal Box – Odin, at 32; case IV/32306 – Olivetti/Canon, at 49; case IV/31340 – Mitchell Cotts/Sofiltra, at 10).

The above understanding seems highly reasonable since it aims at guaranteeing that the R&D project is not used to gain access to previous know-how that would otherwise not be accessible. A clarification and confirmation of this interaction between Articles 3(2), 3(3) and 5(a) R&D BER would contribute to legal certainty.

From a practical point of view, as for "(a) access to results", there seems to be a practice to allow such access to background (for exploitation) only against payment. This is all the more so in that **pre-existing know-how** is often stated as "know-how of the research group", which means that any access to such **pre-existing know-how** means time and dedication of the group's researchers. It is not limited to documented materials that can be easily shared at low cost or effort of the research institution. Time and dedication which often is a revenue stream for R&D consulting for the research institution. Compensation is indeed foreseen as a possibility in the last sentence of Article 3(3). Practice suggests that it is the rule rather than the exception.

Further Case Examples: where possible specific examples are shared in Annex B.

The cases illustrate how research institutes and/or academic bodies make or have made use of the rules and exceptions under the R&D BER and the Horizontal Guidelines and how these rules/exceptions have contributed to or discouraged the participation of research institutes and/or academic bodies in R&D agreements that do not raise competition issues.

Methodology

Materials shared

A shared Teams Project was created so that the three ASTP experts (plus Professor Björn Lundqvist) (together, the "Experts") are all able to manage access to the background materials as well as regular calls to exchange opinions. These include:

- (a) The European Commission published the staff working document SWD(2021) 103 final ("SWD") which summarised the findings of the evaluation of Commission Regulation (EU) No 1217/2010, i.e. the Research and Development ("R&D") Block Exemption Regulation ("R&D BER"). Guidelines on the applicability of Article 101 of the Treaty on the Functioning of the European Union to horizontal cooperation agreements.
- (b) Inception Impact Assessment ("IIA", Ref. Ares(2021)3714309).
- (c) Overview of the initial results of the public survey CATI Results August 2021.

Logistics

Co-ordination among the experts, plus Professor Björn Lundqvist and other volunteers is being encouraged, in order to provide as much meaningful content to the Report(s) as possible. Ongoing updates with the DG Comp team will be provided by ASTP, including the opportunity to join any of the weekly Expert Team calls on request of the DG Comp team. Draft Report preparation is being supported by ASTP directly, in order to ensure the short timescales can be adhered to.

Weekly calls

These have been established, including Professor Björn Lundqvist as the Commission's other Expert looking at the experiences of SMEs to produce his separate report.

Consistency

Given the potential cross-over of content from the SME and academic communities, open communication amongst all the Experts is being facilitated. Already there can be seen a need to identify examples of collaboration agreements, where project partners may be a mix of SMEs and academic centres.

Background/Follow-up Local Information

As mentioned above, the briefing document provided to the experts enabled them to determine what kind of background information they need. Through ongoing contacts/communication with the added volunteers, the experts have been enabled to access wider examples of specific cases where the R&D BER has been relied on in the past. It also gives the opportunity for feedback on the extent to which the sectors feel that their activities are likely to fall under the revised R&D BER.

Co-ordination of added input

A small group of additional volunteers will continue brainstorming with the Experts to add information around any specific amendments (based on their own experiences), feedback on the EC current proposals as well as providing potential case examples. These added volunteers are drawn from research centres across Europe with direct experience of the R&D BER (Sweden/Germany/Italy/the Netherlands) while the wider network of ASTP's National Associations committee is also being given the chance to share example agreements.

Challenges

The experts are all enthusiastic about being able to share their own experiences in this Report, although the short timescale perhaps will make it difficult to secure consent to share tangible cases in detail. Given a longer time (such as post-submission of the report) it may be possible to continue to seek any relevant consents from clients and partners to share specific case details with the Commission.

The Report should enable added practical perspectives to be included in the planning stage for the formal amendment wording to the R&D BER that the Commission will propose.

Additional Topics

Based on practical experiences of each Expert some added issues are included to the extent that the current BER offers hindrances to effective participation of research institutes and academic bodies in R&D collaborations. These examples also highlight the interaction of applicability of the R&D BER with other regulations which also impact on the innovation relationships.

Use of the definitions of "Trade Secrets" and "Know How"

Should there be consistency across these different legal terms? This is a highly relevant topic since the term "Trade Secrets" is a Union term from the 2016 Trade Secret Directive (TSD) that encompasses the narrower but well-known Union term "Know How" from the Horizontal Block Exemption Regulations. Our interviews show that the term "Know How" is still being used in technology transfer and research agreements despite the entry into force of the TSD because companies and academic institutions have difficulties in demonstrating the requirements of "commercial value" and "efforts to keep the secret" for a trade secret and prefer to continue working with the notion of know-how by defining this concept themselves in their agreement instead of relying on the broader but more difficult to achieve definition of the Trade Secret Directive. The fact that a contractual relationship and line of communication exists between the R&D participating entities helps in defining the relevant know-how on a case-by-case basis and justifies maintaining this legal term in the R&D BER. But to avoid confusion, or the false assumption that the Union term "trade secret" has replaced the older term "know-how" it is recommended that the comments above appear in the BER Guidelines.

Sustainability

If sustainability is a standard to be measured- what guidance can be given which will enable this to be understood and applicable? While acknowledging that sustainability is a broader subject, probably relevant for several -if not all- Competition Law areas, our discussions revealed an increasing interest on the concept and how is it going to be defined and measured when confronted to R&D agreements. Incentives to produce sustainable results and/or share results (to avoid unnecessary repetition leading to sustainability concerns) should be carefully analysed. Attention was also drawn to the value of "negative sustainability data" and the importance to keeping access to them, just as is already the case for data about unsuccessful clinical trials.

Data on sustainability can have great commercial value (our interviews revealed the example of a dataset about the working of a "fab" that can have a considerable impact on the environment) and they may not be easily subjected to "free access" by some industry actors.

At the very least, a distinction should be made between "sustainability data" on one hand that could be made available for free, and the methods for crunching and analyzing such data on the other hand, that should remain proprietary to their developers.

In the context of R&D projects, while acknowledging that full access by third parties cannot be imposed on the parties, incentives to produce and/or share sustainable results or data that cause such sustainable results so that no R&D efforts are unnecessary repeated, may be explored. This may also be analyzed in connection to open data obligations that may legally bind academic bodies or research institutions.

A final issue revealed during our research concerned access to results by third parties, either because the parties had an interest in allowing or, to the contrary, expressly precluding such access to any third party. This issue is not covered by the R&D BER, other than when it refers to further R&D projects concluded in the future (Article 5). We refer, conversely, to incentives or consideration given to access to results to third parties irrespective of their involvement in other R&D projects

Compatibility of Terminology across the R&D BER and the Technology Transfer BER

While the Experts will try to share the past, current and emerging trends in the relationships entered into, it is already clear that the expansion of longer term, expansive strategic relationships amongst partners makes it more difficult to see an agreement as falling under only one of the BERs. Upstream R&D arrangements are often combined with complex downstream arrangements- thus rendering it critical that the two key BERs (R&D & TT) be fully compatible per definitions and scope of applicability. Or even better: are merged into a single legal instrument.

Annex A - LESI Les Nouvelles June 2019 Issue « Knowledge Transfer and IP : the New Challenges » articles

Please see the separate document of Annex A.

Annex B - Examples of R&D Collaboration Terms and Trends

Please see the separate document of Annex B.







ISBN: 978-92-76-47646-7