

Response to DG Competition's Consultation on the revised R&D Block Exemption Regulation and Horizontal Guidelines

Introduction

EFPIA welcomes the opportunity to provide its views on the proposals to revise the R&D Block Exemption Regulation ("BER") and the accompanying horizontal co-operation guidelines ("Guidelines").

At the outset, EFPIA would like to commend the Commission for undertaking such a comprehensive review of the existing framework governing R&D cooperation agreements and state that EFPIA is broadly supportive of the current rules. Most of the proposed amendments to the existing rules are to be welcomed as they eliminate many of the inconsistencies that render assessment of R&D agreements under the current rules difficult. However, there are a number of issues which EFPIA considers could benefit from further consultation and clarification and our comments below focus exclusively on these.

The review of the rules on horizontal cooperation are an opportunity to ensure that the principles of competition law enforcement are aligned with the broader policy objectives of the European Union, namely the Europe 2020 Agenda to stimulate economic competitiveness, innovation and growth and the Commission's Seventh Framework Programme which is designed to encourage increased R&D cooperation across all sectors.

1. Specialisation in Research and Development (Article 1(12) BER)

Article 1(12) of the draft R&D BER introduces a new definition of "specialisation in research and development" that raises concerns. The exclusion of agreements where one party either exclusively provides the financing or exploits the results but does not contribute to the actual R&D process is unhelpful and lacks any clear or convincing policy rationale. EFPIA is concerned that this provision will undermine the opportunities for pharmaceutical companies to fund important collaborative research initiatives with universities, research institutes and academic bodies. Given the enormous R&D costs involved in pharmaceutical innovation, the majority of academic and research institutions simply will not have the financial capability to undertake independent research on a significant scale and will often require a larger company to provide the necessary finance. EFPIA invites the Commission to remove this provision from the revised BER or, in the alternative, to clarify that in situations where one party provides not only financing but also contributes IP rights and know-how, this will also constitute specialisation in R&D, regardless of whether this party actively engages in the R&D process.

2. Specialisation in Exploitation (Article 1(13) BER)

Article 1(13) of the Block Exemption introduces a new definition of "specialisation in exploitation" of the results of the joint R&D, which requires that "each of the parties must carry out some of the exploitation of the results in the internal market."

EFPIA is concerned that this definition will jeopardise international R&D cooperation. By requiring each party to exploit the results of the R&D in the internal market, the proposed definition excludes agreements under which two companies jointly carry out R&D and agree that one company will exclusively market the results in the EU and that the other will only market the results elsewhere. While EFPIA understands that the Commission wants to avoid the artificial partitioning of the internal market along national lines, EFPIA believes that the proposed definition in its current draft goes too far and wrongly disregards the level of competition amongst competing R&D poles or competing products within the EU. International cooperation in R&D across global markets is common and an essential way to encourage dissemination of technology into and within the EU. Cooperation may only make commercial sense if one party focuses on the EU and the other on non-EU markets. Denying such agreements the benefit of the protection discourages R&D cooperation to the EU's disadvantage. This proposal should be deleted.

3. Upfront Disclosure of IP Rights (Article 3(2) BER)

The draft R&D BER at Article 3(2) would introduce a requirement that, prior to commencing the joint R&D efforts, all parties disclose any pre-existing and pending IP rights "in as far as they are relevant for the exploitation of the results by the other parties" and such disclosure must be "open and transparent". Failure to disclose such IP rights will result in the agreement automatically falling outside the scope of the BER.

The underlying rationale of this new condition appears to be a desire to avoid the situation where one party to the agreement can use its existing IP rights to "ambush" the other party and prevent them from exploiting the results of the joint R&D on the basis of previously unknown IP rights.

EFPIA considers that this is an unhelpful qualification which risks placing a significant administrative burden on parties and increasing the transaction costs involved. It also introduces a level of uncertainty since it will not always be clear what IP rights will be relevant to the final exploitation of the results at the outset of the R&D process.

It is also not clear why such a requirement is necessary since ordinary market forces can be relied upon to produce the desired level of disclosure. Depending on the commercial context, parties will be able to negotiate either upfront disclosure (if that can be practicably achieved) or an obligation on each party to licence such rights as the other may need to exploit the results in the relevant fields, or some variation of these two positions.

EFPIA recommends that this qualification be deleted. A further alternative might be to limit the scope of the condition to such IP rights that are not merely "relevant" but technically essential for the exploitation of the R&D results.

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