New EU R&D Agreements Regulation

Trumpets sound and angels sing in Heaven,
there's a new R&D Regulation for 2011!

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A week before Christmas, the new EU block exemption regulation for research and development ("R&D") agreements (the "new Regulation") was published in the Official Journal. The reference is *Commission Regulation (EU) No 1217/2010, OJ L335/36 (18.12.10)*. The previous regulation was due to expire; hence the need for a new Regulation. The new Regulation came into force on 1st January 2011 and will expire on 31st December 2022.

Agreements that contain anti-competitive terms may be void under Article 101 of the Treaty on the Functioning of the European Union and may cause the parties to be liable for fines. There may also be a risk of legal action by third parties who are adversely affected by the anti-competitive behaviour. Article 101 was previously known as Article 81 of the EC Treaty; older readers will remember that in an even earlier incarnation it was known as Article 85 of the Treaty of Rome. The new Regulation provides automatic clearance or "block exemption" from Article 101 for R&D-related agreements that fit within the terms of the Regulation. In US terminology it provides a "safe harbor" for such agreements.

The new Regulation has a similar look and feel to the old Regulation that it replaces. The main changes in the new Regulation can be summarised as follows:

- **R&D funding agreements are covered.** The new Regulation specifically includes agreements to fund R&D within its scope, as well as agreements for "joint" R&D. The previous regulation focused only on joint R&D. Arguably when one party merely pays for R&D to be performed, there is no joint R&D.

In our view, this is a welcome change.

- **Market share limits for R&D funding agreements.** As was the case under the old regulation, block exemption is not available under the new Regulation if the parties are competitors and their combined market share (in either the relevant product market or the relevant technology market) exceeds 25%. The new Regulation goes further and states that, in the case of R&D funding agreements, or joint exploitation arrangements arising from R&D funding agreements, this 25% cap applies to the combined market share of the funding party and all of the parties with which the funding party has entered into R&D agreements with respect to the same products or technologies.

In practice, the funded party may not have sufficient information about the other funded parties to make this calculation. In our view, this change is undesirable.

- **Exclusive licensing to one of the parties is permitted.** The previous regulation permitted certain restrictive terms where there was "joint" exploitation of the results of joint R&D. However, it was unclear whether an arrangement whereby one party received an exclusive, worldwide

commercialisation licence from the other party amounted to joint exploitation.[1] The new Regulation permits such exclusive licensing arrangements, subject to conditions including the right of each party to have access to the results for the purposes of further research.

In our view, this is an important and welcome change, which is long overdue.

- **Terms that must be included in the R&D agreement.** A surprising change in the new Regulation, which to the author's recollection does not feature in other block exemptions, is that if the agreement is to receive the block exemption, it must stipulate the following matters. The author interprets the word "stipulate" to mean that the agreement must include a specific clause or clauses stating the following matters:

    - **Access to the results.** The R&D agreement must stipulate that all the parties have access to the final results of the R&D, including any resulting IP, for the purposes of further research and development. In the case of contract research organisations, universities and similar bodies, they need only have access for research (ie not development). In principle the parties must also have access for further exploitation, but this is subject to several exceptions. The exceptions include where the parties have agreed that one is exclusively licensed, or where one party is a university or contract research organisation.

    - **Access to pre-existing know-how.** Where the R&D agreement provides only for R&D (ie not joint exploitation), it must stipulate that each party must be granted access to pre-existing know-how of the other parties, if this know-how is indispensable for the purpose of its exploitation of the results. This access can be on a fee-paying basis as long as this doesn't impede access.

In our view, these changes are undesirable. They indicate a prescriptive approach by the European Commission and leave a number of questions unanswered. For example, research agreements with universities often state that the university may use the results of the research, but only for academic or non-commercial research. Would such a limitation be permitted? Our best guess is "yes", but it would have been better to have made this clear. In relation to access to pre-existing know-how, EU Framework agreements anticipate that a party may declare some of its pre-existing know-how to be unavailable to the other members of the research consortium[2]. This does not seem to be permitted under the new Regulation, unless the consortium agreement also covers "joint exploitation" (which it will often do).

- **Changes to "hardcore" restrictions.** As with the old regulation, the new Regulation includes a list of restrictions (known as hardcore restrictions) which, if included in an R&D agreement,

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[1] See the author's detailed comments on this subject in Technology Transfer, 3rd edn (editor: Mark Anderson, Bloomsbury, 2010) at page 706, and in previous editions of that work.

[2] For example, Annex II to the standard European Commission funding contract (Framework 6) includes, at section II.35, the following wording:
"c) *Access rights* to *pre-existing know-how* shall be granted provided that the *contractor* concerned is free to grant them; d) A *contractor* may explicitly exclude specific *pre-existing know-how* from its obligation to grant *access rights*, by means of a written agreement between the *contractors* established before the *contractor* concerned signs the *contract* or before a new *contractor* joins the *project*..."

Similarly Annex II to the standard contract for Framework 7 includes, at Article II.31: "Without prejudice to their obligations regarding the granting of *access rights*, *beneficiaries* shall inform each other as soon as possible of any limitation to the granting of *access rights* to *background*, or of any other restriction which might substantially affect the granting of *access rights*."

would bring the agreement outside the block exemption. In practice, including hardcore restrictions presents a significant risk of breach of Article 101. The new Regulation includes a slightly modified list of hardcore restrictions, as well as introducing some additional exceptions to the hardcore restrictions. The latter are rather confusing "double negatives" in that they are clauses which don't amount to hardcore restrictions and therefore, by implication, are acceptable. The new exceptions (ie which we should probably assume are acceptable) include:

- **Non-compete:** Certain restrictions on the commercialisation of competing products during the period of joint exploitation

- **Price-fixing:** Certain restrictions on the price that may be charged to immediate customers and licensees, where the parties to the R&D agreement are jointly distributing or licensing the resulting products or technologies

In our view, these changes are largely welcome, as they indicate a more relaxed view by the Commission in relation to provisions that clients sometimes wish to include. It is noteworthy that the Technology Transfer Regulation does not permit such non-compete restrictions in licence agreements.

- **New grey list.** Consistent with other block exemptions (eg the Technology Transfer Regulation), but unlike the old R&D regulation, the new Regulation includes a short list of clauses that are not considered "hardcore" but which will not receive automatic exemption. In the old days, when hardcore clauses were known as black-listed clauses, these less bad clauses were sometimes referred to as grey clauses. A key difference between grey clauses and hardcore clauses is that including a grey clause in an R&D agreement does not disqualify the rest of the agreement from block exemption, unlike the position for hardcore clauses. The two new grey clauses are slightly tweaked versions of clauses that were considered hardcore in the old R&D regulation, namely:

    - **No challenge clauses.** Certain obligations not to challenge, after completion of the R&D, the validity of the other party's IP that is relevant to the R&D or the results of the R&D

    - **Prohibitions on licensing third parties.** Certain obligations not to license third parties to manufacture the contract products or apply the contract technologies

In our view, it is a welcome development that these restrictions have been shifted from the hardcore list to the grey list.

Concluding remarks

The above commentary does not describe all of the provisions of the new Regulation, as it focuses only on significant changes from the previous regulation that it replaces.

Most of the changes in the new Regulation are welcome. The main area where the changes are unwelcome is the requirement, in certain situations, to stipulate that access rights are given to the results and pre-existing know-how. This point should be considered in relation to both future and existing R&D agreements.

In relation to future R&D agreements, draftsmen may wish to prepare some standard "default" provisions for their R&D agreements to include the "stipulations" referred to above.

Parties should also consider whether existing R&D agreements need to be amended to include such stipulations. This would only be relevant to agreements that potentially breach Article 101 (as to which, see the final paragraph of this update) and will continue in force beyond 2012 (including in any commercialisation phase of the agreement).

In this context, Article 8 of the new Regulation should be noted. This Article provides that agreements that were in place at 31 December 2010 and that were exempted under the old R&D regulation will continue to receive exemption under the old regulation but only until 31 December 2012.

More generally, the coming into force of the new Regulation is a reminder that competition law issues do need to be considered when drafting and negotiating R&D agreements, and that the most efficient way of doing this may be to ensure that the agreement fits within the terms of the new Regulation.

In our experience, universities enter into many R&D agreements without considering whether the terms of the agreement fit within the R&D regulation. There are a number of reasons for this, including:

- An assumption that many R&D agreements are unlikely to include anti-competitive terms or are unlikely to be sufficiently large in scale to have an effect on EU competition
- Lack of reported cases where universities have been held to breach competition laws
- Lack of legal resource and/or lack of awareness of competition law issues
- The technical complexity of the block exemption regulations – they are not easy documents to read and understand

Whilst this approach is understandable, in our view university research contracts departments should consider (or obtain legal advice on) competition law issues, particularly if:

- The amounts of money involved are large;
- The parties have large market shares in the relevant products or areas of research; and/or
- The agreement contains restrictive provisions. Certain types of provision should "ring alarm bells" in the mind of the research contracts manager, including (and this is not a comprehensive list – study the new Regulation's list of hardcore restrictions for more examples):
    - Non-compete clauses (eg promises not to conduct similar research)
    - Prohibitions on using the results for further research
    - Price-fixing

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