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EUROPEAN COMMISSION

Brussels, 14.12.2010
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COMMISSION REGULATION (EU) No .../...

of 14.12.2010

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

SEC(2010) 1543 final
SEC(2010) 1541 final

COMMISSION REGULATION (EU) No .../...

of 14.12.2010

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

(Text with EEA relevance)

THE EUROPEAN COMMISSION,

Having regard to the Treaty on the Functioning of the European Union,

Having regard to Regulation (EEC) No 2821/71 of the Council of 20 December 1971 on application of Article 85(3) of the Treaty to categories of agreements, decisions and concerted practices¹,

Having published a draft of this Regulation,

After consulting the Advisory Committee on Restrictive Practices and Dominant Positions,

Whereas:

- (1) Regulation (EEC) No 2821/71 empowers the Commission to apply Article 101(3) of the Treaty on the Functioning of the European Union* by regulation to certain categories of agreements, decisions and concerted practices falling within the scope of Article 101(1) of the Treaty which have as their object the research and development of products, technologies or processes up to the stage of industrial application, and exploitation of the results, including provisions regarding intellectual property rights.
- (2) Article 179(2) of the Treaty calls upon the Union to encourage undertakings, including small and medium-sized undertakings, in their research and technological development activities of high quality, and to support their efforts to cooperate with one another. This Regulation is intended to facilitate research and development while at the same time effectively protecting competition.
- (3) Commission Regulation (EC) No 2659/2000 of 29 November 2000 on the application of Article 81(3) of the Treaty to categories of research and development agreements² defines categories of research and development agreements which the Commission regarded as normally satisfying the conditions laid down in Article 101(3) of the

¹ OJ L 285, 29.12.1971, p. 46.

* With effect from 1 December 2009, Article 81 of the EC Treaty has become Article 101 of the Treaty on the Functioning of the European Union ("TFEU"). The two Articles are, in substance, identical. For the purposes of this Regulation, references to Article 101 of the TFEU should be understood as references to Article 81 of the EC Treaty where appropriate. The TFEU also introduced certain changes in terminology, such as the replacement of "Community" by "Union" and "common market" by "internal market". The terminology of the TFEU will be used throughout this Regulation.

² OJ L 304, 5.12.2000, p. 7.

Treaty. In view of the overall positive experience with the application of that Regulation, which expires on 31 December 2010, and taking into account further experience acquired since its adoption, it is appropriate to adopt a new block exemption regulation.

- (4) This Regulation should meet the two requirements of ensuring effective protection of competition and providing adequate legal security for undertakings. The pursuit of those objectives should take account of the need to simplify administrative supervision and the legislative framework to as great an extent as possible. Below a certain level of market power it can in general be presumed, for the application of Article 101(3) of the Treaty, that the positive effects of research and development agreements will outweigh any negative effects on competition.
- (5) For the application of Article 101(3) of the Treaty by regulation, it is not necessary to define those agreements which are capable of falling within Article 101(1) of the Treaty. In the individual assessment of agreements under Article 101(1) of the Treaty, account has to be taken of several factors, and in particular the market structure on the relevant market.
- (6) Agreements on the joint execution of research work or the joint development of the results of the research, up to but not including the stage of industrial application, generally do not fall within the scope of Article 101(1) of the Treaty. In certain circumstances, however, such as where the parties agree not to carry out other research and development in the same field, thereby forgoing the opportunity of gaining competitive advantages over the other parties, such agreements may fall within Article 101(1) of the Treaty and should therefore be included within the scope of this Regulation.
- (7) The benefit of the exemption established by this Regulation should be limited to those agreements for which it can be assumed with sufficient certainty that they satisfy the conditions of Article 101(3) of the Treaty.
- (8) Cooperation in research and development and in the exploitation of the results is most likely to promote technical and economic progress if the parties contribute complementary skills, assets or activities to the cooperation. This also includes scenarios where one party merely finances the research and development activities of another party.
- (9) The joint exploitation of results can be considered as the natural consequence of joint research and development. It can take different forms such as manufacture, the exploitation of intellectual property rights that substantially contribute to technical or economic progress, or the marketing of new products.
- (10) Consumers can generally be expected to benefit from the increased volume and effectiveness of research and development through the introduction of new or improved products or services, a quicker launch of those products or services, or the reduction of prices brought about by new or improved technologies or processes.
- (11) In order to justify the exemption, the joint exploitation should relate to products, technologies or processes for which the use of the results of the research and development is decisive. Moreover, all the parties should agree in the research and development agreement that they will all have full access to the final results of the

joint research and development, including any arising intellectual property rights and know-how, for the purposes of further research and development and exploitation, as soon as the final results become available. Access to the results should generally not be limited as regards the use of the results for the purposes of further research and development. However, where the parties, in accordance with this Regulation, limit their rights of exploitation, in particular where they specialise in the context of exploitation, access to the results for the purposes of exploitation may be limited accordingly. Moreover, where academic bodies, research institutes or undertakings which supply research and development as a commercial service without normally being active in the exploitation of results participate in research and development, they may agree to use the results of research and development solely for the purpose of further research. Depending on their capabilities and commercial needs, the parties may make unequal contributions to their research and development co-operation. Therefore, in order to reflect, and to make up for, the differences in the value or the nature of the parties' contributions, a research and development agreement benefitting from this Regulation may provide that one party is to compensate another for obtaining access to the results for the purposes of further research or exploitation. However, the compensation should not be so high as to effectively impede such access.

- (12) Similarly, where the research and development agreement does not provide for any joint exploitation of the results, the parties should agree in the research and development agreement to grant each other access to their respective pre-existing know-how, as long as this know-how is indispensable for the purposes of the exploitation of the results by the other parties. The rates of any license fee charged should not be so high as to effectively impede access to the know-how by the other parties.
- (13) The exemption established by this Regulation should be limited to research and development agreements which do not afford the undertakings the possibility of eliminating competition in respect of a substantial part of the products, services or technologies in question. It is necessary to exclude from the block exemption agreements between competitors whose combined share of the market for products, services or technologies capable of being improved or replaced by the results of the research and development exceeds a certain level at the time the agreement is entered into. However, there is no presumption that research and development agreements are either caught by Article 101(1) of the Treaty or that they fail to satisfy the conditions of Article 101(3) of the Treaty once the market share threshold set out in this Regulation is exceeded or other conditions of this Regulation are not met. In such cases, an individual assessment of the research and development agreement needs to be conducted under Article 101 of the Treaty.
- (14) In order to ensure the maintenance of effective competition during joint exploitation of the results, provision should be made for the block exemption to cease to apply if the parties' combined share of the market for the products, services or technologies arising out of the joint research and development becomes too great. The exemption should continue to apply, irrespective of the parties' market shares, for a certain period after the commencement of joint exploitation, so as to await stabilisation of their market shares, particularly after the introduction of an entirely new product, and to guarantee a minimum period of return on the investments involved.

- (15) This Regulation should not exempt agreements containing restrictions which are not indispensable to the attainment of the positive effects generated by a research and development agreement. In principle, agreements containing certain types of severe restrictions of competition such as limitations on the freedom of parties to carry out research and development in a field unconnected to the agreement, the fixing of prices charged to third parties, limitations on output or sales, and limitations on effecting passive sales for the contract products or contract technologies in territories or to customers reserved for other parties should be excluded from the benefit of the exemption established by this Regulation irrespective of the market share of the parties. In this context, field of use restrictions do not constitute limitations of output or sales, and also do not constitute territorial or customer restrictions.
- (16) The market share limitation, the non-exemption of certain agreements and the conditions provided for in this Regulation normally ensure that the agreements to which the block exemption applies do not enable the parties to eliminate competition in respect of a substantial part of the products or services in question.
- (17) The possibility cannot be ruled out that anti-competitive foreclosure effects may arise where one party finances several research and development projects carried out by competitors with regard to the same contract products or contract technologies, in particular where it obtains the exclusive right to exploit the results vis-à-vis third parties. Therefore the benefit of this Regulation should be conferred on such paid-for research and development agreements only if the combined market share of all the parties involved in the connected agreements, that is to say, the financing party and all the parties carrying out the research and development, does not exceed 25 %.
- (18) Agreements between undertakings which are not competing manufacturers of products, technologies or processes capable of being improved, substituted or replaced by the results of the research and development will only eliminate effective competition in research and development in exceptional circumstances. It is therefore appropriate to enable such agreements to benefit from the exemption established by this Regulation irrespective of market share and to address any exceptional cases by way of withdrawal of its benefit.
- (19) The Commission may withdraw the benefit of this Regulation, pursuant to Article 29(1) of Council Regulation (EC) No 1/2003 of 16 December 2002 on the implementation of the rules on competition laid down in Articles 81 and 82 of the Treaty³, where it finds in a particular case that an agreement to which the exemption provided for in this Regulation applies nevertheless has effects which are incompatible with Article 101(3) of the Treaty.
- (20) The competition authority of a Member State may withdraw the benefit of this Regulation pursuant to Article 29(2) of Regulation (EC) No 1/2003 in respect of the territory of that Member State, or a part thereof where, in a particular case, an agreement to which the exemption established by this Regulation applies nevertheless has effects which are incompatible with Article 101(3) of the Treaty in the territory of that Member State, or in a part thereof, and where such territory has all the characteristics of a distinct geographic market.

³ OJ L 1, 4.1.2003, p. 1.

- (21) The benefit of this Regulation could be withdrawn pursuant to Article 29 of Regulation (EC) No 1/2003, for example, where the existence of a research and development agreement substantially restricts the scope for third parties to carry out research and development in the relevant field because of the limited research capacity available elsewhere, where because of the particular structure of supply, the existence of the research and development agreement substantially restricts the access of third parties to the market for the contract products or contract technologies, where without any objectively valid reason, the parties do not exploit the results of the joint research and development vis-à-vis third parties, where the contract products or contract technologies are not subject in the whole or a substantial part of the internal market to effective competition from products, technologies or processes considered by users as equivalent in view of their characteristics, price and intended use, or where the existence of the research and development agreement would restrict competition in innovation or eliminate effective competition in research and development on a particular market.
- (22) As research and development agreements are often of a long-term nature, especially where the cooperation extends to the exploitation of the results, the period of validity of this Regulation should be fixed at 12 years,

HAS ADOPTED THIS REGULATION:

Article 1

Definitions

1. For the purposes of this Regulation, the following definitions shall apply:
- (a) ‘research and development agreement’ means an agreement entered into between two or more parties which relate to the conditions under which those parties pursue:
 - (i) joint research and development of contract products or contract technologies and joint exploitation of the results of that research and development,
 - (ii) joint exploitation of the results of research and development of contract products or contract technologies jointly carried out pursuant to a prior agreement between the same parties,
 - (iii) joint research and development of contract products or contract technologies excluding joint exploitation of the results,
 - (iv) paid-for research and development of contract products or contract technologies and joint exploitation of the results of that research and development,
 - (v) joint exploitation of the results of paid-for research and development of contract products or contract technologies pursuant to a prior agreement between the same parties, or

- (vi) paid-for research and development of contract products or contract technologies excluding joint exploitation of the results;
- (b) ‘agreement’ means an agreement, a decision by an association of undertakings or a concerted practice;
- (c) ‘research and development’ means the acquisition of know-how relating to products, technologies or processes and the carrying out of theoretical analysis, systematic study or experimentation, including experimental production, technical testing of products or processes, the establishment of the necessary facilities and the obtaining of intellectual property rights for the results;
- (d) ‘product’ means a good or a service, including both intermediary goods or services and final goods or services;
- (e) ‘contract technology’ means a technology or process arising out of the joint research and development;
- (f) ‘contract product’ means a product arising out of the joint research and development or manufactured or provided applying the contract technologies;
- (g) ‘exploitation of the results’ means the production or distribution of the contract products or the application of the contract technologies or the assignment or licensing of intellectual property rights or the communication of know-how required for such manufacture or application;
- (h) ‘intellectual property rights’ means intellectual property rights, including industrial property rights, copyright and neighbouring rights;
- (i) ‘know-how’ means a package of non-patented practical information, resulting from experience and testing, which is secret, substantial and identified;
- (j) ‘secret’, in the context of know-how, means that the know-how is not generally known or easily accessible;
- (k) ‘substantial’, in the context of know-how, means that the know-how is significant and useful for the manufacture of the contract products or the application of the contract technologies;
- (l) ‘identified’, in the context of know-how, means that the know-how is described in a sufficiently comprehensive manner so as to make it possible to verify that it fulfils the criteria of secrecy and substantiality;
- (m) ‘joint’, in the context of activities carried out under a research and development agreement, means activities where the work involved is:
 - (i) carried out by a joint team, organisation or undertaking,
 - (ii) jointly entrusted to a third party, or
 - (iii) allocated between the parties by way of specialisation in the context of research and development or exploitation;

- (n) 'specialisation in the context of research and development' means that each of the parties is involved in the research and development activities covered by the research and development agreement and they divide the research and development work between them in any way that they consider most appropriate; this does not include paid-for research and development;
- (o) 'specialisation in the context of exploitation' means that the parties allocate between them individual tasks such as production or distribution, or impose restrictions upon each other regarding the exploitation of the results such as restrictions in relation to certain territories, customers or fields of use; this includes a scenario where only one party produces and distributes the contract products on the basis of an exclusive licence granted by the other parties;
- (p) 'paid-for research and development' means research and development that is carried out by one party and financed by a financing party;
- (q) 'financing party' means a party financing paid-for research and development while not carrying out any of the research and development activities itself;
- (r) 'competing undertaking' means an actual or potential competitor;
- (s) 'actual competitor' means an undertaking that is supplying a product, technology or process capable of being improved, substituted or replaced by the contract product or the contract technology on the relevant geographic market;
- (t) 'potential competitor' means an undertaking that, in the absence of the research and development agreement, would, on realistic grounds and not just as a mere theoretical possibility, in case of a small but permanent increase in relative prices be likely to undertake, within not more than three years, the necessary additional investments or other necessary switching costs to supply a product, technology or process capable of being improved, substituted or replaced by the contract product or contract technology on the relevant geographic market;
- (u) 'relevant product market' means the relevant market for the products capable of being improved, substituted or replaced by the contract products;
- (v) 'relevant technology market' means the relevant market for the technologies or processes capable of being improved, substituted or replaced by the contract technologies.

2. For the purposes of this Regulation, the terms 'undertaking' and 'party' shall include their respective connected undertakings.

'Connected undertakings' means:

- (a) undertakings in which a party to the research and development agreement, directly or indirectly:
 - (i) has the power to exercise more than half the voting rights,

- (ii) has the power to appoint more than half the members of the supervisory board, board of management or bodies legally representing the undertaking, or
 - (iii) has the right to manage the undertaking's affairs;
- (b) undertakings which directly or indirectly have, over a party to the research and development agreement, the rights or powers listed in point (a);
 - (c) undertakings in which an undertaking referred to in point (b) has, directly or indirectly, the rights or powers listed in point (a);
 - (d) undertakings in which a party to the research and development agreement together with one or more of the undertakings referred to in points (a), (b) or (c), or in which two or more of the latter undertakings, jointly have the rights or powers listed in point (a);
 - (e) undertakings in which the rights or the powers listed in point (a) are jointly held by:
 - (i) parties to the research and development agreement or their respective connected undertakings referred to in points (a) to (d), or
 - (ii) one or more of the parties to the research and development agreement or one or more of their connected undertakings referred to in points (a) to (d) and one or more third parties.

Article 2

Exemption

1. Pursuant to Article 101(3) of the Treaty and subject to the provisions of this Regulation, it is hereby declared that Article 101(1) of the Treaty shall not apply to research and development agreements.

This exemption shall apply to the extent that such agreements contain restrictions of competition falling within the scope of Article 101(1) of the Treaty.

2. The exemption provided for in paragraph 1 shall apply to research and development agreements containing provisions which relate to the assignment or licensing of intellectual property rights to one or more of the parties or to an entity the parties establish to carry out the joint research and development, paid-for research and development or joint exploitation, provided that those provisions do not constitute the primary object of such agreements, but are directly related to and necessary for their implementation.

Article 3

Conditions for exemption

1. The exemption provided for in Article 2 shall apply subject to the conditions set out in paragraphs 2 to 5.
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.
4. Any joint exploitation may only pertain to results which are protected by intellectual property rights or constitute know-how and which are indispensable for the manufacture of the contract products or the application of the contract technologies.
5. Parties charged with the manufacture of the contract products by way of specialisation in the context of exploitation must be required to fulfil orders for supplies of the contract products from the other parties, except where the research and development agreement also provides for joint distribution within the meaning of point (m) (i) or (ii) of Article 1(1) or where the parties have agreed that only the party manufacturing the contract products may distribute them.

Article 4

Market share threshold and duration of exemption

1. Where the parties are not competing undertakings, the exemption provided for in Article 2 shall apply for the duration of the research and development. Where the results are jointly exploited, the exemption shall continue to apply for seven years from the time the contract products or contract technologies are first put on the market within the internal market.
2. Where two or more of the parties are competing undertakings, the exemption provided for in Article 2 shall apply for the period referred to in paragraph 1 of this Article only if, at the time the research and development agreement is entered into:

- (a) in the case of research and development agreements referred to in point (a) (i), (ii) or (iii) of Article 1(1), the combined market share of the parties to a research and development agreement does not exceed 25 % on the relevant product and technology markets; or
 - (b) in the case of research and agreements referred to in point (a), (iv), (v) or (vi) of Article 1(1), the combined market share of the financing party and all the parties with which the financing party has entered into research and development agreements with regard to the same contract products or contract technologies, does not exceed 25 % on the relevant product and technology markets.
3. After the end of the period referred to in paragraph 1, the exemption shall continue to apply as long as the combined market share of the parties does not exceed 25 % on the relevant product and technology markets.

Article 5

Hardcore restrictions

The exemption provided for in Article 2 shall not apply to research and development agreements which, directly or indirectly, in isolation or in combination with other factors under the control of the parties, have as their object any of the following:

- (a) the restriction of the freedom of the parties to carry out research and development independently or in cooperation with third parties in a field unconnected with that to which the research and development agreement relates or, after the completion of the joint research and development or the paid-for research and development, in the field to which it relates or in a connected field;
- (b) the limitation of output or sales, with the exception of:
 - (i) the setting of production targets where the joint exploitation of the results includes the joint production of the contract products,
 - (ii) the setting of sales targets where the joint exploitation of the results includes the joint distribution of the contract products or the joint licensing of the contract technologies within the meaning of point (m) (i) or (ii) of Article 1(1),
 - (iii) practices constituting specialisation in the context of exploitation, and
 - (iv) the restriction of the freedom of the parties to manufacture, sell, assign or license products, technologies or processes which compete with the contract products or contract technologies during the period for which the parties have agreed to jointly exploit the results;
- (c) the fixing of prices when selling the contract product or licensing the contract technologies to third parties, with the exception of the fixing of prices charged to immediate customers or the fixing of licence fees charged to immediate licensees where the joint exploitation of the results includes the joint distribution of the

contract products or the joint licensing of the contract technologies within the meaning of point (m) (i) or (ii) of Article 1(1);

- (d) the restriction of the territory in which, or of the customers to whom, the parties may passively sell the contract products or licence the contract technologies, with the exception of the requirement to exclusively license the results to another party;
- (e) the requirement not to make any, or to limit, active sales of the contract products or contract technologies in territories or to customers which have not been exclusively allocated to one of the parties by way of specialisation in the context of exploitation;
- (f) the requirement to refuse to meet demand from customers in the parties' respective territories, or from customers otherwise allocated between the parties by way of specialisation in the context of exploitation, who would market the contract products in other territories within the internal market;
- (g) the requirement to make it difficult for users or resellers to obtain the contract products from other resellers within the internal market.

Article 6

Excluded restrictions

The exemption provided for in Article 2 shall not apply to the following obligations contained in research and development agreements:

- (a) the obligation not to challenge after completion of the research and development the validity of intellectual property rights which the parties hold in the internal market and which are relevant to the research and development or, after the expiry of the research and development agreement, the validity of intellectual property rights which the parties hold in the internal market and which protect the results of the research and development, without prejudice to the possibility to provide for termination of the research and development agreement in the event of one of the parties challenging the validity of such intellectual property rights;
- (b) the obligation not to grant licences to third parties to manufacture the contract products or to apply the contract technologies unless the agreement provides for the exploitation of the results of the joint research and development or paid-for research and development by at least one of the parties and such exploitation takes place in the internal market vis-à-vis third parties.

Article 7

Application of the market share threshold

For the purposes of applying the market share threshold provided for in Article 4 the following rules shall apply:

- (a) the market share shall be calculated on the basis of the market sales value; if market sales value data are not available, estimates based on other reliable market

information, including market sales volumes, may be used to establish the market share of the parties;

- (b) the market share shall be calculated on the basis of data relating to the preceding calendar year;
- (c) the market share held by the undertakings referred to in point (e) of the second subparagraph of Article 1(2) shall be apportioned equally to each undertaking having the rights or the powers listed in point (a) of that subparagraph;
- (d) if the market share referred to in Article 4(3) is initially not more than 25 % but subsequently rises above that level without exceeding 30 %, the exemption provided for in Article 2 shall continue to apply for a period of two consecutive calendar years following the year in which the 25 % threshold was first exceeded;
- (e) if the market share referred to in Article 4(3) is initially not more than 25 % but subsequently rises above 30 %, the exemption provided for in Article 2 shall continue to apply for a period of one calendar year following the year in which the level of 30 % was first exceeded;
- (f) the benefit of points (d) and (e) may not be combined so as to exceed a period of two calendar years.

Article 8

Transitional period

The prohibition laid down in Article 101(1) of the Treaty shall not apply during the period from 1 January 2011 to 31 December 2012 in respect of agreements already in force on 31 December 2010 which do not satisfy the conditions for exemption provided for in this Regulation but which satisfy the conditions for exemption provided for in Regulation (EC) No 2659/2000.

Article 9

Period of validity

This Regulation shall enter into force on 1 January 2011.

It shall expire on 31 December 2022.

This Regulation shall be binding in its entirety and directly applicable in all Member States.

Done at Brussels, 14.12.2010

For the Commission
The President
José Manuel BARROSO