



Pursuant to Article 9, paragraph (2), of the Law on Protection of Competition ("Official Gazette of the Republic of Macedonia" No. 145/10 and 136/2011), the Government of the Republic of Macedonia, on its session held on 23.03.2012, adopted the following:

Regulation on the detailed conditions for block exemption of certain types of research and development agreements ("Official Gazette of the Republic of Macedonia" No. 41/2012)¹

Article 1

General provision

This Regulation regulates the scope of application of the block exemption, the detailed conditions in terms of market shares, conditions for exemptions, the restrictions and obligations that research and development agreements shall not contain and the conditions for the withdrawal of the block exemption.

Article 2

Definitions

(1) Certain terms used in this Regulation shall have the following meaning:

a) "Block exemption" means exemption of certain research and development agreements from the application of the provisions on prohibited agreements stipulated in Article 7 paragraph (1) of the Law on Protection of Competition (hereinafter: the Law)

b) "Research and development agreement" means an agreement entered into between two or more parties which relate to the conditions under which those parties pursue:

- Joint research and development of contract products or contract technologies and joint exploitation of the results of that research and development:

- 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:

- Joint research and development of contract products or contract technologies excluding joint exploitation of the results:

- Paid-for research and development of contract products or contract technologies and joint exploitation of the results of that research and development:

¹ This Regulation is harmonized with Commission Regulation (EU) No.1217/2010 of 14th December 2010 on the application of Article 101 (3) of the Treaty of functioning of the European Commission to certain categories of research and development agreements (Text with EEA relevance) OJ L 335, 18.12.2010, p.36-42, CELEX no.32010R1217



- 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 and/or

- Paid-for research and development of contract products or contract technologies excluding joint exploitation of the results:

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 and/or a service, including intermediary goods and/or services and final goods and/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 related rights:

i) "Know-how" means a package of non-patented practical information, resulting from experience and testing, which is secret, substantial and identified:

- "Secret", in the context of know-how, means that the know-how is not generally known or easily accessible:

- "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:

- "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:

i) "Joint", in the context of activities carried out under a research and development agreement, means activities where the work involved is:

-carried out by a joint team, organization or undertaking:

-jointly entrusted to a third party: or

-allocated between the parties by way of specialization in the context of research and development or exploitation:

k) "specialization 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:

l) "specialization 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 license granted by the other parties:

m) "paid-for research and development" means research and development that is carried out by one party and financed by a financing party:

n) "Financing party" means a party financing paid-for research and development while not carrying out any of the research and development activities itself:

o) "Competing undertaking" means an actual or potential competitor:

p) "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:

q) "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 3 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:

r) "Relevant product market" means the relevant market for the products capable of being improved, substituted or replaced by the contract products:

s) "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 purpose of this Regulation, the terms "undertaking" and "contracted parties" include their related undertakings.

Article 3

Scope of application of the block exemption

(1) Research and development agreements are exempt from the application of the provisions of Article 7 paragraph (1) of the Law if they meet the conditions stipulated in this Regulation, in accordance with article 7, paragraph (3) and Article 9 paragraph (1) point 2) of the Law.

(2) Block exemption shall apply if agreements set out in paragraph (1) of this Article contain restrictions on competition stipulated in Article 7 paragraph (1) of the Law.



(3) The exemption provided for in paragraph (1) and (2) 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 4

Detailed conditions in terms of market shares thresholds of research and development agreements

(1) Where the parties are not competing undertakings, the exemption provided for in Article 3 shall apply for the duration of the research and development. Where the results are jointly exploited, the exemption shall continue to apply for 7 years from the time the contract products or contract technologies are first put on the market in Republic of Macedonia.

(2) In case of research and development agreements listed in Article 2 paragraph (1) item b) line 1, 2 or 3 of this Regulation where two or more of the parties are competing undertakings, the exemption provided for in Article 3 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, the combined market share of the parties to a research and development agreement does not exceed 25 % on the relevant product and technology markets.

(3) In case of agreements for research and development listed in Article 2 paragraph (1) item b) line 4, 5 or 6 of this Regulation when two or more of the parties are competing undertakings, the exemption provided for in Article 3 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, 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.

(4) 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.

(5) Market share of this Article shall be calculated on the basis of:

a) 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) data relating to the preceding calendar year:

c) if the market share of this Article is initially not more than 25 % but subsequently rises above that level without exceeding 30 %, the exemption provided for in Article 3 shall continue to apply for a period of two consecutive calendar years following the year in which the 25 % threshold was first exceeded:

d) if the market share of this Article is initially not more than 25 % but subsequently rises above 30 %, the exemption provided for in Article 3 shall



continue to apply for a period of one calendar year following the year in which the level of 30 % was first exceeded:

e) The exemption of point c) and d) of this Article may not be combined so as to exceed a period of two calendar years.

Article 5

Detailed conditions regarding provisions that agreements must contain for the application of the block exemption (conditions for exemption)

(1) The block exemption provided for in Article 3 of this Regulation shall apply if:

a) 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 specialize 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:

b) Without prejudice to the possibility for the application of item a), 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:

c) Parties charged with the manufacture of the contract products by way of specialization in the context of exploitation must be required to fulfill 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 Article 2 paragraph (1) item l) line 1 or 2 of this Regulation, or where the parties have agreed that only the party manufacturing the contract products may distribute them.

Article 6

Restriction that may not be included in research and development agreements (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:

- The setting of production targets where the joint exploitation of the results includes the joint production of the contract products:

- 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 Article 2 paragraph (1) item l) line 1 or 2 of this Regulation:

- Practices constituting specialization in the context of exploitation: and

- 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 license 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 Article 2 paragraph (1) item l) line 1 or 2 of this Regulation:

(d) the restriction of the territory in which, or of the customers to whom, the parties may passively sell the contract products or license 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 specialization 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 specialization in the context of exploitation, who would market the contract products in other territories within the Republic of Macedonia:

(g) The requirement to make it difficult for users or resellers to obtain the contract products from other resellers within the Republic of Macedonia.

Article 7

Obligations that must not be included in research and development agreements (excluded restrictions)

The exemption provided for in Article 3 of this Regulation 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 Republic of Macedonia 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 Republic of Macedonia 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 licenses 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 Republic of Macedonia vis-à-vis third parties.

Article 8

Detailed conditions for the withdrawal of the block exemption

Commission for Protection of Competition may withdraw exemption if in a proceedings initiated ex officio or upon request of a party determines that the research and development agreement which are subject to the exemption in Article 3 of this Regulation, have consequences that are not in accordance to the conditions laid down in Article 7 (3) of the Law, and particularly if:

- the existence of a research and development agreement substantially restricts the scope for third parties to carry research and development in the relevant field because of the limited research capacity available elsewhere;

- because of the particular structure of supply, the existence of research and development agreement substantially restricts the access of third parties to the market for the contract products or contract technologies;

- without any objectively valid reason the parties do not exploit the results of the joint research and development vis-a-vis third parties;

- the contract products or contract technologies are not subject, in the whole or in substantial part of the territory of the Republic of Macedonia, to effective competition from products, technologies or processes considered by users as equivalent in view of their characteristics, price and intended use and / or

- existence of a research and development agreement would restricts competition in innovation or eliminate effective competition in research and development on a particular market.

Article 9

Transitional period

All research and development agreements entered into under the Regulation on block exemption granted to horizontal research and development agreements ("Official Gazette of the Republic of Macedonia" No.91/2005) need to harmonize with the provisions of this Regulation no later than March 1, 2014



Article 10

Termination

On the day this Regulation enters into force the Regulation on block exemption granted to horizontal research and development agreements (“Official Gazette of the Republic of Macedonia” No.91/2005) shall cease to be valid.

Article 11

Entry into force

This Regulation shall enter into force on the eight day after its publication in the “Official Gazette of the Republic of Macedonia”.