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RESPONSE OF LICENCING EXECUTIVES SOCIETY INTERNATIONAL (LESI) TO EUROPEAN COMMISSION REVIEW OF CURRENT REGIME FOR THE ASSESSMENT OF HORIZONTAL CO-OPERATION AGREEMENTS

Commission Reference HT.1407 - Stakeholder input

1. Introduction

The Licensing Executives Society International (LESI) welcomes the European Commission (Commission) review of Regulation 2658/2000 on the application of Article 81(3) of the EC Treaty to categories of specialisation agreements (**Specialisation BER**) and Regulation 2659/2000 on the application of Article 81(3) of the Treaty to categories of research and development agreements (**RDBE**). The focus of LESI's submission relates to RDBE, as the Specialisation BER is of limited relevance to members of the LES practice group. As a preliminary point, the practical experience of the majority of LESI members in relation to the application of the RDBE is limited, with the result that the enclosed comments represent a more general holistic view of the interaction between the RDBE, the Horizontal guidelines as they impact upon licensing and patent activities of LESI members.

2. Background to LES

The Licensing Executives Society International (LESI) is a global, not-for-profit, professional association made up of 32 national and regional societies, representing 93 countries. The national LES societies count altogether 12,000 individual members (including 3,500 in Europe) involved in the licensing, transfer and management of intellectual property rights. It is the largest professional organisation in the intellectual property field. Its aims include:

- Setting and promoting consistent, high professional standards for licensing executives on a global basis; and

- Informing and interacting with global organisations and policy forums concerning the economic significance and importance of licensing and other transfer of technology and intellectual property rights.

LES members come mainly from business, ranging from large multi-national organisations to SMEs but also from universities, the public sector, consultants and law firms and patent attorneys. LESI therefore occupies a unique position in representing such a wide variety of interests rather than the special interest nature of many other industry and professional organizations.

It is important in particular to note that LESI does not exist to advance the interests of a particular sector, but rather seeks to promote greater innovation through research and development, and the associated requirement of promoting a properly functioning system of intellectual property protection, to protect the fruits of such innovation, and to ensure the continued investment by companies in R&D. Within LESI are various working groups composed of experts in their particular areas. Two of these groups are the European Committee and the Life Sciences Committee. LESI, through the national LES societies, includes members working in numerous innovative industries, including the pharmaceutical and energy sectors, where R&D is at the forefront of maintaining a continued dynamic and competitive development. The comments below set out the views of LESI as regards the functioning of the RDBE, the context in which LES members view R&D and a robust system of intellectual property rights protection as intrinsically linked, and suggested amendments to be incorporated into any future RDBE.

3. General Application of the RDBE

In light of the Lisbon strategy, the level of research development and innovation in the Community must increase in order to contribute to the sustainable growth and jobs of those living in the Community. The contribution of R&D and innovation to the growth of the Community in the current economic climate is now of fundamental import, given that it is precisely the innovation process, connecting knowledge and technology, which will enable growth through the exploitation of market opportunities for new and improved products, services and business processes. LES members are at the heart of this innovative process, and view the European Commission's regulatory framework

and its treatment of R&D agreements and aid thereto, as fundamental to ensuring the Community maintains its competitive advantage and facilitates growth.

As a general observation, LESI would query the utility of the RDBE, and whether this is an instrument that is actually required. On balance, collaborating on R&D should not be viewed as anti-competitive, but ordinarily has pro-competitive benefits (a fact recognised by the RDBE), in terms of the furthering the economic growth of the European Union. The main competition concern arising from such agreements, concerns the future exploitation of IP rights. This issue is already adequately dealt with under other block exemptions (namely the technology transfer block exemption and vertical restraints block exemption), which provide sufficient guidance on those restrictions that are permissible or not, in respect of exploitation rights.

Similarly, the co-existence of the RDBE with the other block exemptions, in particular the technology transfer block exemption, can lead to unnecessary confusion and complication of the analysis of the competitive implications of an agreement. For example, the impact of the seven year limitation contained in Article 4(1) of the RDBE, raises the question as to what the status of the co-operation is after seven years, relative to its effect on competition. The seven year period seems unnecessary, given that a similar limitation is not contained in the technology transfer block exemption, provided the market thresholds are complied with, even though licensing is a common element of exploitation of the RDBE.

Therefore, LESI would submit in the first instance, that the European Commission's review should give due consideration to whether the RDBE is actually necessary, in light of the other block exemptions. If the RDBE is held to be necessary, then its application must be made more transparent, and relevant in terms of how it interacts with other block exemptions. The observations that follow at Section 4 below are intended to assist with ensuring the RDBE's application becomes more transparent and effective.

Any amendments to any future RDBE must continue to take account of the economic efficiency considerations and the contribution of R&D to consumer welfare in the economy at large. A shift in market demand towards new innovative products, resulting from R&D and innovation in particular in the energy and life sciences sectors, underpins the future growth of the Community. Companies active in the R&D field will only rationally invest in R&D to the extent that commercial opportunities resulting from such research will benefit them through commercialisation of the results achieved. As such, future amendments to the RDBE must recognise the need for the commercialisation of research results, arising from R&D projects, to be rolled out in the least restrictive manner possible. It is in this context that the robust protection of intellectual property rights must receive greater recognition in any future RDBE.

The removal of structural barriers restricting investment in R&D must also be addressed, which requires a holistic approach by the Commission, taking into account the aims underpinning the recently enacted State Aid General Block Exemption Regulation (GBER). As such, LESI submits that any future RDBE should consider its impact upon addressing structural barriers affecting the investment in R&D, in conjunction with the GBER. Such barriers might be reduced through the enablement of intellectual property rights favouring innovation, in order to attract investment into these markets, which could result in market failures being rectified.

4. Specific Comments on Regulation 2659/2000 and Suggested Amendments

4.1 *Article 1.2 and Ancillary Restraints*

Future amendments to the RDBE must also have due regard to the necessity for certain ancillary restraints in agreements, in particular economically indispensible exclusive access rights, given the scale of the investment required in order to exploit the rights of R&D and the risks associated with such an investment. At present, there is only cursory reference in the RDBE to ancillary restraints - at Article 1.2 - and this should be addressed through specific reference in any future RDBE. An opposite

comparison lies in the definition of "non-compete obligations" for the purposes of Article 5 of the Vertical Restraints Block Exemption (Regulation 2790/1999) as contained in Article 1 (b). The issue of non-competes is particularly pertinent to collaboration and in-licensing agreements encountered by LES members, which may contain conditions to restrict the ability of parties to engage in R&D outside a collaboration, in order to prevent the parties competing with the joint R&D project. Depending on the scope of such conditions, it is arguable that they incentivise the parties' collaboration, focusing resources and effort on creation of new technology and products. Such conditions are, therefore, pro-competitive. In the case of a far reaching condition, it may be anti-competitive owing to the dampening effect that such a clause might have on innovation. It is in the context of a far reaching collaboration agreement, whereby the parties agree to joint R&D and production or distribution that certain ambiguities arise under the RDBE. Whilst it is clear that a restriction on R&D is permissible during the initial R&D phase, a condition imposing a restriction for the term of the agreement may not be enforceable. This ambiguity in the current RDBE should be clarified as, although prohibiting post-term restrictions on R&D, it is not clear from the RDBE whether this is intended to refer to the duration of the entire agreement, including production of the product, or simply to the R&D term. It may be useful to define the scope of non-competes punishable under the RDBE.

A new RDBE could also include a list of "*Excluded*" clauses, as is the case in Article 5 of the Technology Transfer Block Exemption Regulation. At present the list of hardcore clauses in the RDBE is too restrictive and a certain number of these clauses might be included in the future block exemption as "excluded" clauses (See Article 5 below for further details). The resultant creation of "Excluded" clauses would mean that their inclusion in an agreement would not necessarily result in the entire agreement being void as a matter of law.

4.2 *Article 2.11 (c)*

Article 2.11 (c) defines what may be considered to be a "joint" exploitation of the results, exempted under article 1 (a) of the RDBE. This joint exploitation comprises an allocation between the parties by way of specialisation in production or distribution.

In many R&D collaboration agreements, it is standard contract policy to allocate the exploitation of the R&D results amongst the participating partners. The exploitation may, for example, either comprise free-for-all access rights; be subject to the authorisation of the proprietor of IP rights in the R&D results; jointly allocated to one party acting for the account of all; or shared amongst the parties in accordance with their respective business interests.

It is on the latter issue that conflicting interpretations have arisen, in particular whether this internal allocation of exploitation rights can reasonably be qualified as a "joint exploitation" under Article 2.11 (c), taking into account the definition of specialisation as provided by the Commission in the specialisation BER, i.e. a contractual agreement "whereby one (or each) participant gives up the manufacture of certain products or provision of certain services in favour of another participant". This issue is pertinent when Article 1 and 2.11 (c) are read in juxtaposition with Articles 2.3 and 5.1.

Joint exploitation of the R&D results through a specialized production and distribution agreement inevitably leads to diminished access rights for each party for the purposes of exploitation (Article 3.2), limitation of outlets (Article 5.1 (c)), a restriction of customers (Article 5.1 (e)), and a prohibition to make passive sales (Article 5.1 (f)). Hence the basic difficulty of reconciling a contractual policy based on a sharing of exploitation rights, with the (permissive) provisions of Article 1 on the one hand, and the (prohibitive) provisions of Article 5 on the other hand.

The two examples below illustrate the tension between the exemption and the prohibition. In order to illustrate the variety of cases that may be encountered, one example is based on a hypothetical co-operative agreement between a public authority and private company, and the second example is based on co-operation between two private companies.

Example 1: An industrial company works with a public entity (e.g. an R&D centre or a university) on the joint development of a process for CO2 capture. They share the exploitation rights as follows: 1) product market (= industrial application of the process within the group of companies controlled by the industrial company) allocated to the industrial company; 2) technology market (= technology transfer of the process to third parties outside the group of companies controlled by the industrial company) allocated to the public entity. According to the logic of this specialisation, (a) the public partner forgoes or "renounces" the exploitation of the results on the product market - although this renunciation is in name only, in light of the corporate research mission of the public entity and the absence of the manufacturing and distribution means that would be required to exploit the process on the product market; and (b) the industrial partner forgoes or "renounces" the exploitation of the results on the technology market, otherwise the cost-benefit balance of the cooperation would be disturbed, with the industrial partner deriving a disproportionate commercial advantage from the exploitation of the results.

This schedule would likely be considered a "specialisation in...production and distribution" under Article 2.11 (c) of the RDBE, corresponding to the mutual interests of each party in consideration of the investments that each has committed to the R&D program, i.e. full and unlimited industrial exploitation of the results attributed to the industrial partner, in accordance with its industrial interests to exploit an innovative technology, and full and unlimited commercial exploitation of the results attributed to the public partner, in accordance with its mission to disseminate innovative technologies on the marketplace.

The relationship can be considered to be between non-competing parties on the product market, and between competing parties on the technology market. An evaluation of the parties' cumulative market share at the time the R&D agreement is entered into should therefore be carried out.

If the market share is above 25%, a competition analysis under Article 81(3) may be necessary. If the market share is below 25%, the agreement should be exempted under Article 1 - although this specialisation is intrinsically based upon a restriction of the customers that each participating undertaking may serve, whether before or beyond the end of seven years from the time the contract products have been put on the market (cf. Article 5.1 (e) of the RDBE).

The latter restriction (= continuation of the specialisation beyond seven years) may be necessary in order to maintain the economic equilibrium between parties that are not active on the same business level - since the public entity does not have the same corporate purpose as its private partner and also, does not have the corresponding industrial means of exploitation of the results, the decision to enter into a joint R&D program with the industrial partner will be closely correlated to the exclusive license rights that the public entity acquires for the results, taking into account the investments that have been committed and the reasonable expectations of a return on investment when the exploitation of the results becomes a reality.

This extension of the specialisation regime beyond seven years does not seem to raise particular competition concerns, as the technology transfer block exemption covers exclusive exploitation rights for the duration of the validity of the IP rights (see LESI comment at Section 3 above). LESI submits that, in general, such specialisation regimes or agreements are more appropriately viewed as technology transfer transactions, with each party granting particular exploitation rights to the other party for a particular field.

Example 2: a pharmaceutical company interested in developing a particular compound for allaying heart diseases, wishes to collaborate with a chemical company, pursuant to a commercial agreement whereby the pharmaceutical company will have exclusivity rights to use the compound for cardiologic applications, and the chemical company will have exclusive sales rights for other medical applications. Since the other medical applications are considered to be marginal, the pharmaceutical company agrees to finance 75% of the R&D budget of the work conducted by the chemical company. The pharmaceutical company will be primarily responsible for the direction and orientation of the R&D works.

This specialisation in production and distribution inevitably leads to a contractual agreement which may trigger the various prohibitions under Article 5.1 (c) to (g). The "joint exploitation" of the results exempted under Article 1 will not be possible (commercially viable) unless the parties agree to certain restrictions of competition, i.e. mutually restrictive obligations to limit sales and mutual restrictions on customer solicitation, whether actively or passively (the chemical company renouncing to the cardiologic market and the pharmaceutical company renouncing to the other medical markets).

The deal is justifiable on the grounds that the pharmaceutical company finances the majority of the R&D work program, the consideration for which is the commercially legitimate demand of certain exclusive exploitation rights on the medical application. Again, this is not radically different from a situation under which the chemical company, in a standard licence agreement, would grant exclusive exploitation rights of its IP rights to the compound to the pharmaceutical company for the cardiologic market under the TTBE (Article 4.1 (c)(ii)).

Having regard to the above examples, Article 2.11 (c) should be clarified to address, in more precise terms, the definition of joint exploitation, both through a better definition of what is covered by "joint exploitation", and through a clarification of the relationship

between Article 1 with the prohibited clauses of Article 5.1 that often are incompatible with the contractual structure of a joint exploitation regime.

4.3 *Article 3.2*

This paragraph stipulates that "all the parties must have access to the results of the joint research and development for the purposes of ... exploitation".

LESI proposes to add the addition of "without prejudice to the restrictions inherent to a joint exploitation of the results", in order to address the interpretation difficulties discussed above in the context of Article 2.11 (c).

Similarly, this paragraph should apply only in circumstances where a party participates in the joint R&D effort for the full term of the R&D agreement. While LESI adheres to an R&D contract policy under which free access to the R&D results is granted to a partner that participates to and sponsors the R&D program for the full contract term, LESI also considers that an early withdrawal of the industrial party from the R&D agreement through an anticipated termination thereof may be sanctioned through a forfeiture of its rights to exploit the results of the program for free. The withdrawing party may therefore continue to have access to the results for the purposes of further research, but not (at least not for free) for the purposes of exploitation.

4.4 *Article 3.3*

Article 3.3 stipulates that "where the research and development agreement provides only for joint research and development, each party must be free independently to exploit the results of the joint research and development and any pre-existing know-how necessary for the purposes of such exploitation". LESI submits that inclusion of the word "free" could be misleading. Although it is acceptable that an access right exists for each participating party to use the results and the pre-existing know-how to

the extent that they are "necessary for the purposes of such exploitation", such access rights may be subject to royalty payments in favour of the party that grants such access rights. LESI submits that a necessary amendment to Article 3.3. is the addition of the standard language used by the European Commission in its FP7 Grant Agreement General Conditions, i.e. access rights to Foreground Technology and Background Technology shall be granted either under fair and reasonable conditions or on a royalty-free basis.

Another useful addition would be the inclusion of wording that the access rights for all parties to the pre-existing know-how of another party are subject to possible overriding third party rights existing at the date of signature of the R&D agreement, e.g. exclusivity commitments, rights of first refusal, confidentiality obligations, that limit if not overall prevent a party from granting such rights to exploit its pre-existing know-how. If necessary, a requirement could be included that each party formally attests the existence and scope of such possible overriding third party rights, to the extent that the necessity of access by the other parties for the purposes of future exploitation was reasonably established at the date of signature of the agreement.

4.5 *Article 4.1: Extension of the seven year Period*

LESI proposes an extension of the seven year period, as contained in Article 4.1. The period in question should be extended to the life of the patent in question where this is greater than the seven year period under Article 4.1, in order to ensure that the undertakings concerned can recoup the investment both in terms of risk and financial resources associated with the R&D project in question, and in order to incentivise future investment. Whilst the rationale is explicitly recognised under the Horizontal Guidelines at paragraph 73, LESI believes that the seven year period does not, in many instances go far enough to ensure that those companies engaged in R&D and subsequent commercialisation have sufficient incentives to continue such investments in future agreements.

The references in Paragraph 73 of the Horizontal Guidelines to the individual assessment under Article 81(3) where an agreement in question allows for a greater period of seven years, should be specifically adopted into any future RDBE. In that regard paragraph 73 states that "this does not exclude the possibility of more than seven years also meets the criteria of Article 81(3), if it can be shown to be the minimum period of time necessary to guarantee an adequate return on the investment involved". Any future RDBE must take due account of the requirement for a robust patent system across Member States, with the result that it should specifically recognise the necessity for an extended period of the life following the R&D; for any patent taken on foot of the R&D subject to the agreement. As such, LESI submits that for R&D agreements between non-competitors and competitors (where economic efficiencies outweigh restrictions), the joint exploitation should be authorised for the full duration of the IP rights (including confidentiality of know-how) taking into account the pro-competitive impact of the R&D initiative taken by the partners.

4.6 *Article 4.3*

The exemption shall continue to apply as long as the combined market share of the participating undertakings does not exceed 25% of the relevant market for the contract products. It follows that, whenever the combined market share of the undertakings exceeds 25% of the relevant market, Article 81(1) of the Treaty applies and, if the agreement is found to have restrictive effects, article 81(2) of the Treaty shall apply, resulting in the annulment of the agreement.

This automatic sequence may have unexpected and undesirable results. In cases where certain restrictive clauses cannot be severed from the agreement, or the agreement itself is held to be void for the purposes of Article 81(2) the annulment of the agreement will imply that the parties' relationship is no longer embedded by a contractual framework, implying that the respective license grants no longer apply. The annulment of the agreement could therefore lead to the annulment of the contractual arrangement and in particular, the annulment of the respective cross-licenses.

Consequently, if the contractual organisation of the R&D program was based on an attribution of IP rights to the inventor combined with mutual cross-licenses in order to allow each party to exploit the results, the exploitation of the products may have to cease when the parties enter into a "patent war" as a result of the disappearance of the respective cross-licenses. Each party will fall back on its respective patents and may consequently decide to extract, as the case may be, a royalty payment from the other parties. Such additional royalty payments may lead either to an unexpected setback under the business plans initially prepared by those parties in order to justify the manufacturing and marketing investment, or a need to raise the sales price of the product in order to recoup the royalty payments from the end-user.

This automatic consequence of annulment is even harder to swallow where it is extremely difficult for a party to determine the combined market share on the market - e.g. for lack of pertinent data to determine the respective market shares or to define the perimeter of the relevant market.

The automatic annulment provided for in the block exemption whenever the combined market share of the parties exceeds 25% of the relevant market therefore seems to be an excessive measure. LESI submits that a more appropriate measure would be to list certain restrictive clauses as "excluded" restrictions rather than "hardcore" restrictions, or the application of the withdrawal procedure under Article 7 of the RDBE rather than the automatic annulment of the agreement.

4.7 *Article 5*

The list of prohibited clauses under Article 5 should be reduced. For example, a joint exploitation of the results will necessarily lead to the fixing of prices (when the joint exploitation is "carried out by a joint team, organisation or undertaking" under article 2.11 (a)) or to a restriction of customers (when the joint exploitation is "allocated between the parties by means of specialisation" under Article 2.11 c), to name some of the incompatibilities between Article 5 and Article 1 in conjunction with Article 2.11.

Joint exploitation of R&D results can be considered to be the logical progression of a collaboration where each party has invested considerable time and financial resources to the R&D program - and where the risk of failure is high owing to the uncertainty of any R&D process and the unpredictability of the commercial value of R&D results when they are extrapolated to an industrial and commercial scale. A joint exploitation regime of the fruits of the R&D is, therefore, a legitimate concern of the parties, and certain restrictive clauses may be justified insofar as they are necessary to incentivise a partner to invest personally and/or financially in the R&D program. In particular, the allocation of production and distribution rights amongst the parties through a specialisation mechanism will inevitably require the incorporation of some of the prohibited clauses under Article 5, which should actually be considered "ancillary restrictions" directly related to, and necessary for, the joint exploitation. Such ancillary restraints should be assessed together with the joint R&D program itself- and the ancillary restrictions should be authorized when the latter are necessary in order to reach the legitimate business objectives pursued under a joint exploitation of the R&D results, without which the parties would not have engaged in the R&D program, for lack of business incentive. It would be useful if a future RDBE contained guidance, such as in the VRBE, as to which ancillary restraints/non-competes would be considered compatible, in the context of R&D agreements and exploitations.

5. Special Recognition for SMEs in future RDBE

Future amendments to the RDBE should also consider the unique position of SMEs, and their contribution to the European economy. The Horizontal Guidelines specifically acknowledge the utility of pooling resources in the context of R&D. Paragraph 56 states that "if the parties are not able to carry out the necessary R&D independently, there is no competition to be restricted". This can apply, for example, to firms bringing together complimentary skills, technologies and other resources. The issue of potential competition has to be assessed in a realistic basis. For instance, parties can not be defined as potential competitors simply because the cooperation enables them to carry

out the R&D activities. The decisive question is whether each party independently has the necessary means as to assets, know-how and other resources.

Clearly the special position of SMEs and their contribution to the European economy deserves reference within any future RDBE. Similarly the market failures present in many industries where SMEs compete are recognised explicitly by the recently enacted State Aid GBER, whereby SMEs receive a special uplift and treatment in order to incentivise them to compete within markets. Given the size and financial resources of SMEs, it is precisely these firms that are most likely to require the putting together of complimentary skills and technologies, in order to bring new products and services to the market. This is particularly so, when an SME competes in a dynamic market against a stronger well-resourced player. The GBER increases the aid intensity available to SMEs active, for example, in the life sciences sector, intending to focus existing aid budgets on better targeted aid and trebles the number of aid measures which are exempt from the usual State aid notification requirement to the European Commission. In particular, the new thresholds for SME investment aid, R&D project aid for SMEs, intellectual property rights costs for SMEs, and the risk capital aid exemption for SMEs, should not be undermined by an unduly restrictive RDBE as applied to SMEs. Rather, it should complement the existing aid incentivisation measures, though favourable treatment for SMEs, in order to stimulate competitiveness.

6. Conclusion

LESI therefore recommends the following key amendments to any future RDBE:

- Clarification and inclusion of "Ancillary Restraints", averred to in Article 1.2, directly necessary to implementation of an R&D and exploitation agreement;

- Reduction of the number of "Hardcore" restrictions for the purposes of Article 5 of RDBE, and inclusion of new list of "Excluded" clauses, similar to that of the TTBER;

- Clarification of definition of "Joint" exploitation of results under Article 2.11(c) and current tension between Article 1 and certain prohibited Clauses in Article 5;

- Extension of the 7 year comfort period under Article 4, to encompass lifetime of patents filed on foot of results of R&D project, in appropriate circumstances;

- Special recognition for SMEs owing to unique contribution to the European economy.

Contact Details

The LESI European Committee would welcome the opportunity to expand upon any of the points raised in these comments. The Committee can be reached through its chairman, Jean-Christophe Troussel at the following address:

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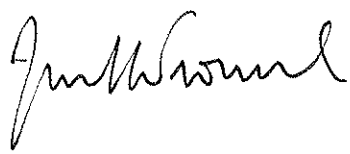

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Brussels, 30 January 2009