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Comments on the draft Technology Transfer Regulation and Guidelines on the application of Article 81 to technology transfer agreements

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1. **Introduction**

Our experience of acting for innovators, licensors and licensees in industries characterised by extensive investment in research and development prompts us to request the Commission to pay the highest regard to creating a climate in Europe which is favourable to innovators and to the dissemination of innovations protected by intellectual property rights ("IPR's") through licensing. We urge the Commission to promulgate a legal safe harbour which promotes the exploitation for reward of the fruits of innovative effort through licensing under rules which maximise legal certainty for undertakings.

The Commission's 2001 Evaluation Report concluded that the reform of the existing Technology Transfer Block Exemption Regulation ("TTBE") is required because it is excessively formalistic, complex and narrow in scope, and "by imposing on companies an unnecessary compliance burden and forcing industry into a legal straitjacket, [the Regulation] may skew enforcement towards over-deterrence, which may have a negative impact on dynamic efficiency".

We are concerned that the proposed draft fails this test, as it would increase uncertainty for parties in many licensing situations, and will for that reason tend to reduce incentives to disseminate technology through licensing. Through erecting obstacles to exploitation of IPR's through licensing, incentives both to innovate in the first place, and to license, will be reduced, leading to a less efficient allocation of resources and a less innovative and efficient economy in Europe.

2. **General Comments**

The Commission should, we think, be particularly aware of the practical consequences for companies in industries characterised by dynamic competition of the combined impact on the same date of radical change to the technology licensing block exemption and implementation of the Commission's modernisation package.

Of particular importance is the fact that the Commission will no longer make exemption decisions, whilst for the first time the National Competition Authorities and the Member State Courts will apply the exemption provision in Article 81(3). In particular, it can be foreseen that proceedings before national courts where Article 81(3) is in issue, in the context of technology licensing agreements, will be complex, expensive and uncertain in their outcome. In view of the fact that the party claiming exemption bears the burden of proof, there will be an ever present risk that Member State courts unable to deal with the complexity of these issues will fail to uphold the enforceability of licensing agreements which they should. It is essential in such circumstances that the TTBE has as broad a coverage as possible, and in this context we believe the key concern is that it should not have restrictive market share limitations, as is proposed.

We are concerned more generally that the draft TTBE may reflect an unduly negative attitude to IPR's and their exploitation, because of suspicion by competition enforcement officials of the protection granted under IPR's. This, together with apparent ready adoption of aspects of the approach to vertical distribution agreements, is not, we believe, appropriate. This block exemption will be particularly important to industries characterised by dynamic competition through ongoing innovation (e.g. pharmaceuticals, semi-conductors, software etc), and the

importation of concepts from, for example, the rules relating to distribution of goods is not appropriate, since the framework there emphasises the importance of static competition.

More specifically, the market share thresholds proposed for non-competitors appear to be adapted from the verticals BER, and the position on certain territorial restrictions appears to have been conformed in many respects. The subject matter here – licensing of IPR's – justifies substantial difference in treatment from simple distribution of goods. The Commission recognised this in proposing the current TTBE. To take one example, the Commission permitted a five year (from first Community marketing) ban on passive sales. This would not be acceptable in the context of distribution of goods, but should be in the context of IPR licensing. The Commission recognised this expressly in Recital 10 and Articles 1.1(b) and 1.3 of the current TTBE, reflecting the Court of Justice's holding in Nungesser, that a grant of time-limited territorial protection may be necessary to provide the licensee with the necessary incentives to gear up to produce and sell the products manufactured by the licensed technology. Nungesser remains good law. If there is any objective to conform this TTBE to the regime for vertical distribution and supply agreements, this objective is misguided and based on a false premise.

When the first round of consultation on a review of the block exemption took place, the majority of commentators agreed that the Commission should move closer to the approach of the newer block exemptions. In our view this comment was commonly meant to suggest a move away from the current form-based, legalistic approach, depending on a large number of complex formal requirements to be found in "white", "grey" and "black" lists. It was not – and is not – the prevailing view that market share tests are appropriate.

Furthermore, the current draft places too much emphasis on *ex post* analysis. The impact of a licensing agreement on competition should clearly be analysed at the time the licensing agreement is struck. There should in our view be no question of analysing the impact on competition between the parties on an *ex post* basis – the Commission has shown in the past a willingness to treat a licensee under a non-reciprocal licence as a competitor of the licensor even during the period of the licensing agreement, but this approach should be ended categorically as fundamentally reducing the incentives to license. Any later exceptional adverse effects on third parties may be adequately dealt with by a withdrawal mechanism.

The pharmaceutical industry is a leading example of one where only the most successful companies can afford the huge amount of investment in R&D required to innovate, but where if the approach in the draft is followed, the market share caps will discourage the licensing of new applications or new delivery methods for existing products. A good deal of R&D is directed at improving or extending existing products, finding novel products to replace established market products, or novel applications of those products or processes for manufacturing them more cheaply and efficiently. Where the results of such R&D are licensed, however, the danger is that the technology licence will be held to fall within the same market as the established products and processes, and that the parties' existing market shares will therefore automatically preclude reliance on the TTBE. This is not a satisfactory state of affairs for the very companies that need to be encouraged to innovate and to develop existing technologies, and not simply to rely on previous inventions.

Regarding the scope of the TTBE, in our view the extension of the definition of "technology transfer agreement" to include "software copyright licensing agreements" is a positive change, as the characteristics of software copyright licensing are sufficiently similar to be treated as equivalent for the purposes of the TTBE.

We would however make a more general comment in respect of the scope of the block exemption. As we suggest above and explain further below, the draft TTBE does not currently recognise the peculiarities of licensing of technology protected by patent or software copyright, or otherwise consisting of secret and substantial know-how. In particular, the need for an *ex ante* approach in order to encourage liberation of the protected/secret technology through licensing is

not reflected in the block exemption. Rather, in our view the current draft addresses such licensing arrangements in a manner that is somewhat similar to vertical distribution arrangements. Unless the unique characteristics of technology licensing are properly reflected in the block exemption, there is simply no logic to limiting the block exemption to technology licensing (for example, with very limited technical amendments, the new draft of the block exemption might extend to all licensing of IPRs¹). In this context, it should be recalled that the aims of the existing TTBE (as described in paragraph 10 of the Commission's evaluation report) were:

"first [....] to "encourage the dissemination of technical knowledge in the Community and to promote the manufacture of technically more sophisticated products" (Recital 3). The second objective was to guarantee effective competition in technologically new or improved products. The third aim was to create a favourable legal environment for companies investing in the EU, by providing them with legal certainty [...]"

It is submitted that sight has been lost of these aims, the first two of which are distinct to the licensing of technology, and all of which remain valid.

3. Legal Certainty – Withdrawal the Appropriate Mechanism

3.1 Market Share Thresholds

We suggest that adoption of market share thresholds as an entry requirement is the single greatest problem with the current draft, and that this should be replaced with a withdrawal mechanism modelled on Article 7 of the current TTBE.

The Commission does not appear to have experienced a worryingly large number of cases where the current TTBE is inappropriate in this regard, leading it to withdraw exemption. We do not therefore believe this aspect of the current regime needs to be changed, and nor do we believe change is desirable.

Further, outside the application of the TTBE itself, the Commission refers to royalties and poles of research as potentially appropriate in analysing an agreement. In fact, private parties self-assessing their own market shares will not - and should not as a matter of principle - know about the royalties generated by their competitors in licensing technology. These will be paid under confidential contracts whose terms will constitute business secrets. Equally, they may not be aware of other poles of research in many cases.

Market Definition

In particular, defining markets and the calculation of market shares is difficult in relation to both technology and to innovative products, where new markets may be created. In any event, historic market shares have little relevance in markets where competition is based on innovation, and where products, services, software etc are rapidly superseded by new products.

A number of aspects of the approach suggested in the Guidelines to this issue appear more geared to the merger control context, where the Commission will routinely ask questions of competitors as to licensing activity, royalties generated from licensing, the nature of technology licensed and the existence of poles of research.

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In our submission this should not be the approach adopted – licensing of technology does require a more liberal approach, and the draft TTBE should address this rather than playing to the lowest denominator.

Ex Post Analysis

The ongoing nature of application of the proposed market share tests also has the negative effect that where, say, the licensee is highly successful in exploiting the licensed technology, so as to achieve a substantial share of all sales in the relevant market, the chances of the licensing agreement falling out of the scope of automatic exemption are increased. It surely cannot be intended that there is in practice an ongoing monitoring obligation, such that the parties must continuously check matters outside their control such as the impact on market shares of a merger between third parties, or a competitor business being closed through insolvency.

All of these difficulties can be avoided by replacing the market share entry requirement with a withdrawal mechanism.

3.2 The Actual and Potential Competitors Tests

The application of the concept of two companies being potential competitors is of great difficulty in technology and product markets characterised by frequent replacement of existing products by new products. There is limited Commission case precedent here and the Guidelines do not provide sufficiently clear practical tests precedent to provide parties with satisfactory levels of legal certainty.

Whilst there may be logical arguments in favour of distinguishing between competitors and non-competitors in order to specify the different hard core restriction lists, the necessity to perform this exercise is likely to give rise to considerable uncertainty in practice.

Take, for example, collaboration between pharmaceutical and biotech companies. Each may be pursuing fundamentally different approaches in terms of technology employed to obtain a product to treat a given disease or other therapeutic need. The chances of any one strand of research leading to a commercially viable product will likely be very low. Can the parties be confident that if the biotech company licenses technology to the pharmaceutical company, which is at the time not confident of bringing any product to market at all, or in a relevant time frame, they will be classed as non-competitors?

If they are classed as competitors, the draft TTBE proposes that an exclusive licence cannot be granted from one to the other, and this major change from the scope of the current TTBE appears wholly unjustified in the case of this example (and indeed generally). We comment on this below.

3.3 Withdrawal the Appropriate Mechanism

In view of the conceptual and practical objections to the market share entry thresholds, we propose that the Commission retain the withdrawal mechanism as the appropriate way to deal with those exceptional cases in which it is felt that technology transfer agreements should not benefit from automatic exemption.

3.4 An alternative structure

If the Commission takes the view that a distinction between competitors and non-competitors must be retained, we would propose the following structure be adopted in place of the existing draft:

1. Different hard-core lists be retained for competitors and non-competitors;

- 2. No market share thresholds in either case², but rather an extensive hard-core list/list of conditions for actual or potential competitors (possibly including *addition* of non-compete clauses to the current draft list) and a less restrictive list for non-competitors:
- 3. A definition of "competing undertakings" which incorporates the following elements:
 - (a) The assessment as to whether the parties are actual or potential competitors is to be made *ex ante*, at the time just before the agreement is entered into. This approach allows for a one-off assessment that gives legal certainty for the life of the agreement (limited to the life of the patent/secrecy of the know-how).
 - (b) The current definition of actual or potential competitors on the product market (Article 1 (h), second indent) could remain.
 - (c) The current definition of "actual competitors on the technology market" (Article 1 (h), first indent) could be amended so as to include parties which <u>own</u> competing technologies (ie. whether or not currently licensed).
 - (d) It must also be made clear that the question of whether undertakings compete or not is to be answered by reference to the relevant market in its product and geographic dimensions. While it may be implicit in Article 3.3 that a share of the technology market shall be calculated on the basis of sales on both relevant product and geographic market, this should be made explicit. For example, in the Vertical Agreements Block Exemption, the reference is simply to "relevant market" (Article 3 and paragraph 90 of the Guidelines) which incorporates a product and geographic dimension.

In our view this approach provides the necessary legal certainty and is preferable to the existing structure. The draft Article 6 should remain in order to address the (likely very few) issues that arise in individual cases (including, if necessary, cases where the position of the parties alters very significantly over time.

4. Some Specific Issues

4.1 Know-how

We see no justification for any change in or restriction of the definition of know-how from that in the current TTBE. There is no reason we are aware of for narrowing the scope of automatic exemption to know-how which is "useful", as set out in Article 10(3) of the existing TTBE, to that which is "indispensable" (Article 1.1(g) and Guidelines para. 44). First, this new definition would exclude certain know-how that should benefit from the block exemption, such as a secret process which significantly reduces the cost of production as against other possible processes. Such know-how, while clearly extremely useful, would not fall within the natural meaning of the word "indispensable". Second, the requirement of "indispensability" would apply assymetrically as between patents and know-how for no good reason³ – there is no equivalent requirement that a

It must be borne in mind that once a position of dominance is attained, behaviour is severely constrained. In our view this will in many cases be the appropriate threshold in the context of technology licensing.

Indeed, in a many cases a company will have the option to keep technology secret (as secret knowhow) or to put it into the public domain but protect it under a registered patent – the distinction thus becomes purely formal and should not affect the application of the block exemption.

patent be "indispensable", indeed it is often the case that a patent is "useful" (for example, in increasing efficiency through a new process⁴) rather than "indispensable", and there can be little doubt that the TTBE should apply to such patents.

We also see no justification for the differing definitions of "secret" and "identified" as compared with Article 10 of the current TTBE, and suggest that these definitions be retained.

4.2 Exclusive Licences between Competitors

The draft proposes to remove from automatic exemption, through express black-listing, the grant of exclusive licences as between "competitors" (i.e. the licensor is not permitted to grant the licensee a territory or customer group with a promise that he will neither license another, nor compete there himself). The position is similar in the case of field of use restrictions.

This is an important and, we believe, regrettable narrowing of the scope of automatic exemption, in comparison with the current TTBE. As numerous Commission decisions and block exemption Regulations have made clear, the grant of an exclusive right to IPR's may be essential to creating the incentives for the licensee to take a risk in signing the contract, gearing up to produce and supply, and devoting his scarce resources and efforts to developing a market and maximising output and sales of the end product.

Furthermore, we are not aware from the Evaluation Report or the Commission's Annual Competition Policy Reports of any substantial number of cases causing difficulties under the current TTBE.

This is an important issue of principle. It is magnified in practice by the substantial uncertainty relating to whether the parties will be classified as competitors (actual or potential), which is of particular concern in certain pharmaceutical industry contexts as exemplified above.

Further, it appears that it will not be possible to settle patent litigation which in most cases would be between at least potential competitors, with exclusive territorial, customer group or field-of-use licences and remain within the scope of the block exemption. This appears unnecessarily restrictive (see below).

4.3 **Technology Research Tools**

An extremely important form of collaboration in the pharmaceutical, biotech and pharmaceutical/biotech collaboration fields involves the use of technological research tools. We see no reason in principle for excluding these from the scope of any European safe harbour and would urge the Commission to include them within the scope of the TTBE.

4.4 **Sub-Contracting**

We are concerned by the proposed withdrawal of the Subcontracting Notice, which we consider to be of general application and appropriately drafted in terms of issues of principle.

The Guidelines state at para 49 that sub-contracting of specific research and development functions is not covered by the proposed TTBE. We believe this should be reconsidered. This is a very important and standard part of licensing in for example the pharmaceutical field, and it is crucially important that the parties have legal certainty as to the enforceability of their agreements. We see no reason to distinguish between the sub-contracting of specific R&D tasks and the supply of a service based on licensed technology. If this restriction in the scope of the

Which, it will be noted, may equally be achieved through the licensing of secret know-how.

TTBE stops companies going to third parties for contracted research and development activity, this would be a most unfortunate consequence.

4.5 Non-Assertion Agreements and Settlement Agreements

The draft TTBE is not to cover non-assertion or settlement of agreements. According to the Guidelines (para 35), this is because such agreements are not entered into for the manufacture or provision of contract products and must for that reason be excluded.

We do not think this is a correct reason to exclude these agreements. In fact such agreements are very often entered into because one party wishes to commence (or continue) manufacturing particular products and is concerned that the IPR's of another prevent it from doing so. In order to end expensive and time-consuming litigation, a non-assertion or settlement agreement may be entered into which will allow one or both parties the ability to make and sell onto the market-place, sometimes subject to agreed exclusions. As the purpose of these agreements is to permit the manufacture of goods or the provision of services, at the time blocked by time consuming litigation, it would seem desirable, instead, to include such agreements within the scope of the block exemption.

Para 197 of the Guidelines says that, in the context of settlement of litigation, restrictions on the use by the parties of their respective technologies is likely to be caught by Article 81 and unlikely to be exemptible. It is stated that cross-licensing without restriction is sufficient to bring an end to the litigation, presumably because it allows the parties to produce and market themselves.

In our view, this approach is overly simplistic and formalistic and accords no weight to the public policy objective of encouraging settlement of otherwise expensive and lengthy litigation, uncertain in its outcome, which is likely to prevent, during its pendancy, either party devoting its full resources to exploiting its own technology until the litigation is finally ended. We believe it is far better that the parties settle and resolve the scope inter se of future exploitation of IPR's within the scope of the litigation. A withdrawal mechanism would deal adequately with any exceptional cases perceived to have anti-competitive outcome.

Parties will certainly wish to continue to settle litigation with agreements providing for exclusivity as to territories, customer groups and fields-of-use. If such settlement agreements fall outside the scope of the new TTBE, they will in the absence of the possibility of notification for exemption, following modernisation, constitute a rather unusual beast – a settlement agreement which is open at any time to be challenged before national courts by either party. This would, we consider, be a regrettable situation.

We would also urge the Commission to review the general, though qualified, hostility to reciprocal royalty payments in the context of cross-licences, expressed at paras. 77 and 199 of the Guidelines. In many contexts, royalties will be a relatively small proportion of total costs for suppliers and we do not see that there is likely to be a real concern as to coordination of downstream price in many cases, so we do not share the view that reciprocal royalties amount presumptively to price-fixing (unless the rather convoluted requirements set out in para 77 are met).

4.6 Agreements between Non-Competitors - Passive Sales Ban

Whilst the current TTBE exempts passive sales bans for 5 years, the draft contains no such provision and indeed the Guidelines, which are not of legislative effect, merely indicate that a 2 year passive sales ban will "normally" be acceptable (Guidelines para 84). We do not see there is a need to alter the approach of the current TTBE on this issue, and in any event urge that whatever period is ultimately accepted be incorporated in the Regulation itself, not placed in Guidelines which are not binding on courts or National Competition Authorities.

4.7 The Conditions (Article 5)

We welcome the clarification of the position in relation to no-challenge clauses and, in particular, the clear acknowledgement that exemption may well be available when no-challenge clauses are imposed in the context of a settlement of litigation. We suggest that the Commission should go further to apply the same treatment to no-challenge clauses in the context of know-how licences. Once know-how has been transmitted to the recipient, the only means of control available to a licensor are the rights created by contract and the law on confidentiality. There are therefore good reasons why the owner of know-how might not license another person to have access to and use know-how without the licensee agreeing not to challenge the secrecy of the know-how package. We believe this point should be addressed in the Guidelines.

4.8 Transitional Period

We think it is wrong for the Commission to seek to withdraw block exemption on only 18 months' notice, in circumstances where the Regulation adopted in 1996 with a 31 March 2006 expiry date is withdrawn, and a substantially narrower block exemption Regulation replaces it.

In contrast to vertical agreements covered by the vertical agreements block exemption, it is desirable that technology transfer agreements can have long duration – including for the period of time that know-how remains secret and useful, and for the life of patent protection (which can give rise to agreements of well over 20 years duration, given that patent applications can be licensed, and the patent period can be extended by a supplementary protection certificate in the case of pharmaceutical patents). Contracting parties will have entered into contracts negotiated at one time in the past and it may not be possible to renegotiate them. Changes in the legal framework may simply give rise to windfall gains to one party or the other, or insert substantial uncertainty where previously there was certainty.

This becomes in effect a retrospective change in the legal treatment of agreements. We would propose that any agreement complying with the current TTBE which entered into force before the publication of the draft of the TTBE and Guidelines should remain exempt until the earlier of the date the agreement expires. This exceptional step would recognise the unique character of technology licensing, which in many cases requires significant investment and a long term agreement. As an alternative, the transitional period should at the very least extend to the 31 March 2006 (or expiry of the agreement if earlier).

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