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MÜNCHEN LONDON

LICENSING IN THE EUROPEAN UNION

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I. Introduction

1. Licensing opportunities in the EU

More than three years have passed since, on May 1, 2004, ten new member countries joined the European Union. This created a common market of 450 million people (compared, for example, to 285 million in the US). It is a market in which goods, services and capital shall freely circulate. The now 25 member states of the European Union have shared high hopes that their economies will receive a new impetus and that production and trade will profit from this historic development. In fact, the East European countries have already notably gained affluence in the meantime.

As has been generally accepted since Schumpeter and Solow, technological progress is the foremost factor for productivity and competitiveness, for wealth creation and economic growth. Technological progress articulates itself in innovation, and innovation is protected by intellectual property rights. The creation and exploitation of intellectual property is thus a decisive element of innovation, technical progress and economic welfare in the enlarged European Union.

The exclusive right of the owner of intellectual property to use his protected intellectual creation and to prohibit others from using it constitutes the core of intellectual property protection under the national IP legal systems. However, the right to commercially exploit intellectual property is not limited to manufacturing, distributing and selling the protected innovative product. Many owners of intellectual property do not have the resources to engage in such activities, especially in foreign countries. Thus, intellectual property rights can also be exploited by authorizing third parties to use the intellectual property, in other words, by granting licenses.

The wheel had to be invented only once, but imagine how many times you could have licensed it. Many intellectual property owners therefore license their rights to other parties in order to realize a maximum of the financial potential of their intellectual property. This involves negotiating and entering into agreements which reflect the licensor’s and licensee’s commercial concerns.

These are promising prospects for globally active companies who as licensors or licensees wish to exploit business opportunities in the enlarged European market.

2. Licensing Agreements: The applicable law

License agreements are civil law contracts. A license agreement usually comprises a number of standard provisions, regardless of the applicable law which is also stipulated therein. Such clauses relate to the nature of the license, exclusive or non-exclusive, the license territory, royalties, warranties etc. Which law shall be applicable usually depends on the nationality of the contract parties, their agreement, or in the absence thereof, on statutory conflict of law rules.

Furthermore, in addition to the applicable civil law, competition law impacts even standard provisions of license agreements. It is practically impossible to draw up a valid agreement without giving careful attention to the regulatory systems which have as their object the protection of free competition in the market.

Generally, licensing is considered to be pro-competitive. It encourages the exploitation of intellectual property and has the effect that there is more than one potential supplier of the protected products. However, licensing can also be anti-competitive. For example, cross-licensing arrangements between competitors in state of the art technology may reduce competitiveness between such parties, weakening their incentive to gain the technological lead.

If a license agreement may affect trade in a specific market, the competition law applicable in that market will have to be heeded.

In Europe, there exist both national and supra-national competition laws. Basically both are applicable if the license has an effect in the respective territories. An example of national competition law is the German Act against Restraints of Competition (*GWB*). The applicable supra-national competition law is provided in the legal system of the European Union.

While *both* the pertinent national and the supra-national regulatory schemes have to be considered when licensing IP in European countries, we will focus on the competition law of the European Union. It is applicable to all license agreements which may affect trade between the member states of the EU.

What may be the consequence if your license agreement does not conform to EU competition law?

The risk is that the whole agreement or part of the agreement shall be null and void. In addition, fines may be imposed on the parties to the agreement by the European competition authorities belonging to the so-called ECN, the "European Competition Network". Such fines can amount to 10% of the worldwide turnover of your company.

Needless to say, if you are a professional advisor to the company and the violation of competition law rules in the license agreement was due to your negligence, you will also be liable for damages.

Third parties, for example competitors or shunned potential contract partners, may attack the agreement by filing complaints to invoke infringement of EU competition law before the Commission, a national competition authority or a national court if they consider themselves to be harmed by the agreement.

There are further risks when the license agreement is terminated because of a dispute between the parties. If you have claims against the other party which you must enforce in court, your former licensing partner may raise the so-called "Euro defense", asserting that the whole agreement was unenforceable due to the infringement of competition law, so that there is no legal basis for your claims.[1]

Competition law is complex. But the consequences of infringement of competition law rules in license agreements are so severe that licensors and licensees cannot

[1] Pursuant to Article 2 of Council Regulation 1/2003 on the implementation of the rules on competition laid down in Articles 81 and 82 of the Treaty, the party alleging infringement or claiming the benefit of Article 81 EC bears the burden of proof for its assertions.

ignore it. For all companies confronted with technology licenses and their advisors it is crucial to be familiar with the working of the competition law rules.

The purpose of this paper is to present an outline of the EU competition law that must not only be observed when negotiating and entering into a patent and know how licensing deal effective in the European common market, but throughout the lifetime of the agreement.

II. The Legal System of the European Union

Before discussing the specific effect of European competition law on licensing, let us take a short look at the history of what is called the European Union today and the legal system governing it and relevant to intellectual property.

1. History

1.1 The three Communities

A recurrent dream of unification is part of the European cultural heritage. The Second World War finally demonstrated the futility of conquests and the vulnerability of the sovereign state concept. Interdependence of states rather than independence became the key to post-war international relations in Europe. This was also reflected in the trends of global international law, such as the concept and structure of the United Nations.

An admirable example of cooperation and practical application of the call for peace was the first instrument of European integration, the European Coal and Steel Community (ECSC) of 1951. It was built on the premise that, if the basic raw materials for war at that time, coal and steel, were removed from national control, war between the traditional enemies, France and Germany, would become impossible since they would be prevented from developing a war industry.

Some years later, in April 1957 in Rome, a treaty was signed to establish the European Economic Community (EEC), a common market in the six member states Belgium, France, Germany, Italy, Luxemburg and the Netherlands.

At the same time, a second Treaty of Rome which set up the European Community of Atomic Energy (EURATOM) was signed. Its purpose was the coordination of action of the member states in developing and marketing their nuclear resources.

These two Treaties of Rome added two new Communities to the Coal and Steel Community. However, the objectives of the European Economic Community were wider than the objectives of the other two Communities, because the EEC was not a mere specialist organization but an instrument of progressive economic integration with the corresponding political potential. Over the years an outward expansion of the Communities was accompanied by inner growth and consolidation.

1.2 The Treaty on European Union

In February 1992, the Treaty on European Union (TEU) was signed at Maastricht. The extent of this treaty was far wider than the Treaty of Rome. Firstly, it made substantial amendments to the EEC Treaty by widening its scope and effect beyond its original economic field. In doing so, it renamed the EEC Treaty as the European Community (EC) Treaty. It introduced the concept of Citizenship of the Union and set a goal for the creation of a single currency, which was introduced in 2002.

Secondly, the TEU established the European Union, which stands as a separate Treaty. This treaty is political in nature; it seeks to establish cooperation between the member states in fields such as foreign policy, security policy and defense.

The Treaty of Amsterdam of 1997 amended the Maastricht version of the EC treaty and incorporated the Schengen Treaties which abolished border controls for travel between all member states (except Denmark, Ireland and the UK).

The Treaty of Nice of 2001 introduced further amendments to prepare the EU for its enlargement in May 2004.

1.3 The Treaty establishing a Constitution of Europe

On June 19, 2004, a Treaty establishing a Constitution of Europe was signed by the now 25 member states which proclaims in its preamble that

> *while remaining proud of their national identities and history, the peoples of Europe are determined to transcend their ancient divisions and, united ever more closely, to forge a common destiny.*

In historical dimensions this development of European union in a time-span of little more than fifty years is truly incredible.

A few weeks ago the adoption of the Constitution was rejected in referendums held in France and The Netherlands, and the political plans of further fast expansion and even the inclusion of Turkey in the European Union have suffered a setback. It may take a miracle to enact a European Constitution after all, and only the future will tell, but as Walter Hallstein, the first president of the EEC Commission once remarked, "If you don't believe in miracles in European affairs, you are not a realist".

2. Community law

2.1 The three pillars of the EU

As a political entity, the European Union today rests on three pillars.

The main pillar is the EC Treaty, at present as amended by the treaty of Nice. It establishes the European Community as a subject of international law and provides the primary Community law.

The second pillar consists of political provisions to establish a common foreign and security policy of the EU member states (Title V, Arts J et seq. TEU).

The third pillar consists of political provisions on cooperation between the member states in the fields of justice and home affairs (Title VI, Arts K et seq. TEU).

The political provisions of the second and third pillar are not legally binding. This is because the member states were hesitant to transfer their core competencies of traditional sovereignty, e.g. defense, police and justice, to the European Community. These political provisions are practically waiting to be transformed into Community law. And this process of integration is presently taking place. But as far as Community law is concerned, the EC Treaty alone is relevant.

2.2 Primary and secondary Community law

The EC Treaty embodies what is called the "primary Community law". It contains the legal provisions on the principles of the Community, the citizenship of the Union, the Community policies and the institutions of the Community.

The EC Treaty also provides the legal basis for the so-called "secondary Community law", which are Regulations, Directives and Decisions.

Pursuant to Art. 249 (2) EC, a *Regulation* has general application. It is binding in its entirety and directly applicable in all member states. In the field of intellectual property law, this legal instrument has been employed to establish uniform rights, e.g. by the Community Trademark Regulation (40/94), the Community Design Regulation (6/2002) and the Regulation concerning Supplementary Protection Certificates (SPCs) for Medicines (1768/92).

Pursuant to Art. 249 (3) EC, a *Directive* is binding on each member state to which it is addressed as to the result to be achieved, but it leaves the choice of form and methods to the national authorities. Directives have been used to harmonize the IP laws in the member states as well as to provide the framework for IP rights yet to be created. Examples are the Council Directives on the legal protection of computer programs (91/250/EC), topographies of semiconductor products, and databases (96/9/EC)

Finally, an important source of law are Decisions (Art. 249 (4) EC Treaty), which are binding in their entirety on those to whom they are addressed.

Moreover, the case law of the European Court of Justice is important as legal precedents since it has the purpose to ensure that in the interpretation and application of the EC Treaty, the law is observed.

III. The 4 Freedoms and Intellectual Property in the EU

1. Free movement of goods, persons, services and capital

The EC Treaty provides for "4 Freedoms" in the common market of the European Union, the free movement of goods, persons, services and capital (Art. 14 (2) EC).

The free movement of goods is realized by a customs union covering all trade in goods and the prohibition of customs duties on imports and exports between the member states and of all charges having equivalent effect as well as the adoption of a common customs tariff in the relation with third countries (Art. 23 (1) EC). Furthermore, quantitative restrictions on imports and all measures having equivalent effect are prohibited between member states (Art. 28 EC).

The freedom of movement of persons in the Community is provided for workers (Art. 39 EC) and also comprises the freedom of establishment of self-employed persons (Art. 43 EC). The freedom to provide services cross-border within the Community may also not be restricted in principle (Art. 49 EC), and all restrictions on the movement of capital between member states and between member states and third countries are prohibited (Art. 56 EC).

2. Intellectual Property in the EU

If you consider the nature of intellectual property rights in the member states of the European Union, a conflict between such rights and the basic principle of free movement of goods in a common market becomes apparent.

Intellectual property rights which are established by the national law of a member state are confined to the territory where they are granted. They are subject to the so-called "principle of territoriality". As long as a Community patent which affords uniform protection in the whole territory of the European Union does not exist, a Europe-wide protection for an invention can only be acquired by obtaining parallel national patents in all member states of the EU.

Each of these patents affords its owner the right to prohibit any third party from making, offering, putting on the market or using a product which is the subject matter of the patent, or stocking or importing the product for these purposes into the territory, i.e. the country, for which the patent has been granted. It is obvious that this national limitation is difficult to reconcile with the concept of a common market.

The basic freedom of movement of goods in the common market proclaimed and guaranteed by the EC Treaty, which is realized by abolishing government restrictions such as customs duties and import and export quotas between member states, would be deficient if patent owners could impose zero quotas by enforcing their national patent right when a patented product is imported from one member country to the member country for which the patent has been granted. This raises the question of the relationship between the rules for the free movement of goods and intellectual property.

It would also be of little use to abolish the government restrictions on the free movement of goods if they could be replaced by agreements between undertakings to keep out of each other's home market. This raises the question of the relationship between rules for free competition in the EC Treaty and intellectual property.

In order to uphold the basic four freedoms and the principle of freedom of competition in the common market, national intellectual property rights are subject to the provisions of the EC Treaty as well, and this has a special impact on licensing in the European Union.

IV. The Exercise of Intellectual Property Rights under the EC Treaty

1. Art. 28 EC: Quantitative restrictions and measures of equivalent effect

The free movement of goods is a fundamental principle of the EC Treaty because it is the essence of a common market. This is reflected in Art. 3 (1) (a) EC, where in a long enumeration of activities of the Community,

> *the prohibition, as between Member States, of customs duties and quantitative restrictions on the imports and exports of goods, and of all other measures having equivalent effect*

is mentioned in first place.

The basic provision regarding the prohibition of quantitative restrictions between member states is Art. 28 EC.

Art. 28 EC reads:

> *Quantitative restrictions on imports and all measures having equivalent effect shall be prohibited between Member States.*

"Quantitative restrictions" is a term referring to customs quotas: only so many products A shall be imported from state B each year. An extreme quantitative restriction is a zero quota: no products A at all shall be imported. The right of the owner of intellectual property in one member state to prevent imports of the protected product into the territory where his IP right exists is a measure of equivalent effect to a zero quota: no IPR-protected products shall be imported without his consent. Art. 29 EC provides correspondingly for exports.

2. Art. 30 EC: Protection of industrial and commercial property

Exceptions to Articles 28 and 29 are provided in Art. 30 for measures justified on various grounds, including the protection of industrial property.

Art. 30 reads:

> *The prohibitions of Articles 28 and 29 shall not preclude prohibitions or restrictions on imports, exports or goods in transit justified on grounds of public morality, public policy or public security; the protection of health and life of humans, animals or plants; the protection of national treasures possessing artistic, historic or archaeological value; or* ***the protection of industrial and commercial property****. Such prohibitions or restrictions shall not, however, constitute a means of arbitrary discrimination or a disguised restriction on trade between Member States.*

The mention of "the protection of industrial and commercial property" in Art. 30 confirms that the authors of the EC Treaty thought that industrial property could be of equivalent effect to quantitative restrictions.

Since the IP rights granted by the member states pertain to intellectual property protected under the national laws of the respective state, the relation between the national laws on property ownership and the provisions of the EC Treaty is also relevant. In this regard, Art. 295 EC provides:

> *The Treaty shall in no way prejudice the rules in Member States governing the system of property ownership.*

On this background, the question important for licensing in the European Union is:
To what extent are intellectual property rights which are granted pursuant to the national laws of the member states and may be licensed for use in the EU protected in view of Articles 28 and 30 EC Treaty?

3. Case law

3.1. ECJ, 31 October 1974 (Case 16/74) - *Centrafarm v Sterling Drug*

The leading case on the effect of Art. 30 EC Treaty and the principle of free movement of goods on intellectual property in the EU is the European Court of Justice decision of 31 October 1974 in the case of *Centrafarm v Sterling Drug*.

Sterling Drug held parallel national patents in several countries, including the Netherlands and the Great Britain on a drug for the treatment of urinary tract infections which was sold under the trademark “Negram”. Centrafarm bought the drug in Great Britain where it had been put on the market by a Sterling Drug subsidiary and imported it into the Netherlands to sell it there and profit from a considerable price difference, as the product was sold cheaper in Britain than in the Netherlands.

Sterling Drug and its Dutch licensee brought actions before a Dutch court requesting injunctions based on infringement of its Dutch patent and the “Negram” trademark.

The Dutch Supreme Court stayed proceedings in both cases and referred the following question to the ECJ:

> *Do the rules in the EEC Treaty concerning the free movement of goods prevent the IP right holder from exercising the right conferred to him by legislation of the member state to prevent the protected products from being marketed by others, even where these products were previously lawfully marketed in another country by the IP right holder or his licensee?*

Pursuant to Art. 234 EC a national court can ask the ECJ to give a ruling concerning the interpretation of the EC Treaty if it considers a decision on its question necessary to enable it to give a judgment in the case before it.

The ECJ held (summarized):

(1) The effect of the provisions of the Treaty on the free movement of goods, particularly Art. 28, is to prohibit between member states measures restricting imports and all measures of equal effect.

(2) Pursuant to Art. 30, Art. 28 does not however prevent restrictions on imports justified on grounds of protection of industrial and commercial property.

(3) But it appears from the same Art. as well as from the context that while the Treaty does not affect the ***existence*** *of the rights in industrial and commercial property recognized by the law of a member state, the* ***exercise*** *of such rights may nonetheless affected by the prohibitions in the Treaty.*

(4) In so far as it makes an exception to one of the fundamental principles of the Common Market, Art. 30 allows derogations to the free movement of goods only to the extent that such derogations are justified for the protection of the ***specific object*** *of such industrial or commercial property.*

The Court continued:

(5) As regards patents, the ***specific object*** *is to ensure to the holder, so as to recompense the creative effort of the inventor, the exclusive right to manufacture and first put into circulation the industrial products, either directly or by grant of licenses to third parties, as well as the right to oppose any infringement.*

(6) The existence of provisions in national laws on industrial property of provisions that the right of a patentee is not exhausted by the marketing of the patented product in another member state, so that the patentee may oppose the import into his own state of the product marketed in another state, may constitute an obstacle to the free movement of goods.

(7) Such an obstacle to the free movement of goods is not justified when the product has been lawfully put on the market by the patentee himself or with his

consent in the member state from which it has been imported, in particular in the case of a holder of parallel patents.

(8) It a patentee could forbid the import of protected products which had been marketed in another member state by him or with his consent he would be able to partition the national markets and thus maintain a restriction on trade between the member states without such a restriction being necessary for him to enjoy the substance of the exclusive rights deriving from the parallel patents.

(9) Thus the exercise by a patentee of the right given him by the laws of a member state to prohibit the marketing in that state of a product protected by the patent and put on the market in another member state by such patentee or with his consent would be incompatible with the rules of the EEC Treaty relating to the free movement of goods in the Common Market.

This line of argumentation has become the standard reasoning of the ECJ for its *doctrine of exhaustion of national intellectual property rights in the European Union*: If a product protected by intellectual property is put on the market in one member state by the owner of the IP right or with his consent, the IP right is exhausted and cannot be invoked when the product is imported into another member state.

3.2. ECJ, 14 July 1981 (Case 187/80) - *Merck v Stephar*

In *Merck v Stephar*, the ECJ held that while it is the specific object of a patent to accord the inventor an exclusive right of first putting the patented product into circulation to obtain the reward for his creative effort, this reward is not guaranteed under all circumstances. It is up to the patentee to decide in the light of all circumstances under what conditions he will sell his product. If he decides to market it in a member state where the law does not provide patent protection for the product in question, he must accept the consequences of his choice as regards the free movement of the product within the common market. National patent rights in the EU are exhausted when the product has been placed on the market by the patentee or with his consent in any member state regardless of whether patent protections exists in the state where the product was marketed. Thus Merck who had sold its drug in Italy at the time when drugs and their manufacturing processes were not patentable in that country was not able to prohibit, based on its Dutch patent, the import of the drug from Italy into the Netherlands by Stephar.

3.3. ECJ, 09 July 1985 (Case 19/84) - *Pharmon v Hoechst*

In *Pharmon v Hoechst*, however, the ECJ held that the doctrine of exhaustion of IP rights in the Common market does not apply when the product has been manufactured by the holder of a compulsory license. While Articles 28 and 30 of the EC Treaty preclude the application of national provisions which enable the patent owner to prevent importation and sales of a product which has been lawfully marketed in another member state by the patent owner himself or with his consent, these provisions do not preclude the application of legal provisions of a member state which give the patent owner the right to prevent the marketing in that state of a product which has been manufactured in another member state by the holder of a compulsory license, regardless whether the compulsory license fixes royalties payable to the patent owner. This is because where a compulsory license is granted to a third party, the patent owner is deprived of his right to determine freely the conditions under which he markets his product, which is the specific object or substance of the intellectual property right.

3.4. ECJ, 31 October 1974 (Case 16/74)) - *Centrafarm v Winthrop*

In *Centrafarm v Winthrop*, the ECJ applied its doctrine of exhaustion of IP rights in the Common Market to trade marks as well, holding that the specific object of this right is the guarantee that the owner of the trade mark has the exclusive right to use that trade mark for the purpose of putting products protected by the trade mark into circulation for the first time, and to protect him against competitors wishing to take advantage of the status and reputation of the trademark by selling products illegally bearing that trade mark.

3.5. ECJ, 20 January 1981 (Cases 55/80 and 57/80) - *Musik-Vertrieb and K-Tel v GEMA*

In *Musik-Vertrieb and K-Tel v Gema*, the ECJ held that the expression "protection of industrial and commercial property" in Art. 30 EC includes the protection conferred by copyright, especially when exploited commercially in the form of licenses for the distribution of goods incorporating the protected work in the member states. Accordingly, neither the copyright owner or his licensee can enforce his exclusive exploitation right conferred by copyright to prevent the importation in that case of sound recordings which had been lawfully marketed in another member state by the owner or with his consent.

3.6. ECJ, 14 September 1982 (Case 144/81) - *Keurkoop v Nancy Kean Gifts*

Likewise, in *Keurkoop v Nancy Kean Gifts*, the ECJ held that the protection of designs comes under the protection of industrial and commercial property within the meaning of Art. 30 EC as well, so that the doctrine of exhaustion of IP rights in the EU can be said to apply to all such rights that may be the subject matter of license agreements.

From the above case law the doctrine of exhaustion of national IP rights in the European Union can be stated as follows:

Exhaustion of parallel IP rights in the member states occurs if the protected product has been put into circulation in one member state by the IP owner or by a third party with his consent.

Parallel imports of such products from one member state into another member state can thus not be prevented by the IP owner or his licensee under the above circumstances.

V. The EU Competition Law Rules

1. Article 81 EC: The basic regulatory provisions

The EU competition rules relating to agreements between undertakings are set out in Article 81 EC. While the text of this article of the EC Treaty has remained unchanged over the years, its implementation has changed dramatically. If trade between the member states might be affected, then the competition rules of the EU must be observed, even if the agreement, for example a license agreement, relates only to one member state.

Article 81(1) prohibits anti-competitive agreements, i.e. agreements which may affect trade between member states and have as their object or effect the prevention, restriction or distortion of competition within the common market.

Article 81(2) provides that agreements prohibited under Article 81 (1) are automatically void, at least in respect of the prohibited clauses. Consequently, national courts will not be able to order a party to fulfill its contractual obligation if the provision in question violates Article 81(1). This is the basis of the "Euro-defense" that may be raised when you try to enforce a license agreement.

Last but not least, Article 81(3) embodies a "rule of reason". It provides that any agreement may be exempted individually, or any category of agreements may be exempted *en bloc* from the prohibition of Article 81(1), if certain conditions are met. The agreement must *cumulatively*

- contribute to improving the production or distribution of goods or promote technical or economic progress,
- allow consumers a fair share of the resulting benefit,
- not impose restrictions which are not indispensable to the attainment of these objectives, and
- not afford the undertakings the possibility of eliminating competition in respect of a substantial part of the products in question.

Article 81(1) only prohibits anti-competitive agreements "which may affect trade between member states". According to the so-called "NAAT Rule" established by the EC Commission, if the parties to the license agreement do not have a market share of more than 5% in relevant market and the annual turnover of the licensee and the licensor with the licensed product is less than 40 million euros, there is no *appreciable affect on trade* between the member states. Such agreements are not caught by Article 81(1).

There is also a so-called "*de minimis* Rule" which provides that agreements which do affect trade between member states do not *appreciably restrict competition* if the combined market share on any relevant market does not exceed 10% in case of an agreement between competitors and 15% each in case of an agreement between non-competitors.[2]

2. History of EU competition rules and licensing

A license merely permits the licensee to do something that would otherwise be unlawful. Thus granting a license clearly does not infringe Article 81(1) unless it is coupled with other clauses that have the object or the effect of restricting competition in some way.

Actually, most systems of anti-trust law have had difficulty in distinguishing permissible license clauses from those that constitute undue restrictions on competition.

The European Commission formerly took the view that *any* license other than a *non-exclusive* license for the whole common market was caught by the prohibition of Article 81(1). The Commission was therefore prepared to carry out, upon notification, an analysis of each and every license agreement based on Article 81(3), to decide whether an individual exemption was possible. The Commission had exclusive competence to apply Article 81(3) and to grant exemptions from the prohibition of agreements under Article 81(1). If an agreement was notified and individually

[2] Commission notice on agreements of minor importance which do not appreciably restrict competition under Article 81(1) of the Treaty establishing the European Community (*de minimis*) (2001/C 368/07)

exempted by the Commission, it was immune from administrative fines in the future. However, individual exemptions required a cumbersome and time-consuming proceeding which imposed heavy burdens on the limited personnel of the Commission.

Thus, in 1984 a block exemption for patent license agreements based on Article 85(3) was adopted (Regulation 2349/84).[3] The basic scheme of this Regulation was to provide a "white list" of clauses that normally did not infringe Article 81(1) and were exempted, and a "black list" which specified clauses that prevented exemption. If a license agreement contained only white list clauses, Article 81(1) was not applicable, and so a notification for individual exemption was not required.

In 1989, the Commission issued a block exemption for know-how licenses (Regulation 556/89). It was very similar to the block exemption relating to patent licenses, but the white and black lists permitted more provisions to be included in an agreement which qualified for the exemption.

In 1996, the two block exemptions were combined into a single regulation covering technology transfer agreements (Regulation 240/96). In the meantime the Commission had come to realize the importance of intellectual property for innovation. As a result, this Technology Transfer Block Exemption Regulation, or in short "TTBER", reflected an even more liberal attitude toward patent and know-how license agreements.

3. Modernization Package

Then, after the turn of the century, work began to redesign completely the competition rules of the EU

> *to meet the challenges of an integrated market and a future enlargement of the Community.*

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[3] Over the years, similar BERs were adopted concerning vertical agreements (e.g. distribution agreements), horizontal agreements (e.g. co-operation between competitors) etc.

This objective was proclaimed in the new Council Regulation 1/2003 on the implementation of the rules on competition laid down in Articles 81 and 82 of the Treaty.[4] Based on this so-called "Anti-trust Enforcement Regulation", which entered into force on May 1, 2004, the day when ten countries joined the European Union, increasing the number of member states from 15 to 25. Also on May 1, 2004, the Commission put into effect, also on May 1, 2004 its so-called "Modernization Package".

Part of this new legal framework of competition policy in the European Union is a novel "Block Exemption Regulation 772/2004 on the application of Article 81(3) of the Treaty to categories of technology transfer agreements". It follows the style introduced already earlier by the Vertical Agreements BER[5] and the R&D[6] and Specialisation Agreements[7] Block Exemption Regulations.

The new TTBER, which itself is quite short, is accompanied by detailed Commission Guidelines on the application of Article 81 of the EC Treaty to technology transfer agreements. The Guidelines are invaluable as the first source of reference for companies undertaking a legal review of their proposed and existing license agreements.

Taken together, this development constitutes a fundamental change in the application of Article 81 EC to technology transfer agreements.

The Commission now finds that "the vast majority of license agreements are pro-competitive"[8] and that exclusive licensing – at least between non-competitors –, if it is caught at all by Article 81(1) EC, is likely to be exempted under Article 81(3) since

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4 Council Regulation 1/2003 on the implementation of the rules on competition laid down in Articles 81 and 82 of the Treaty [2003] O.J. L1/1.

5 Commission Regulation 2790/1999 on the application of Article 81(3) EC Treaty to categories of vertical agreements and concerted practices [1999] O.J. L336/21; Commission Guidelines on Vertical Restraints [2000] O.J. C291/1.

6 Commission Regulation 2659/2000 on the application of Article 81(3) EC Treaty to categories of research and development agreements [2000] O.J. L304/7.

7 Commission Regulation 2658/2000 on the application of Article 81(3) EC Treaty to categories of specialisation agreements [2000] O.J. C291/1; Commission Guidelines on the applicability of Article 81 of the EC Treaty to horizontal co-operation agreements [2000] O.J. C291/1.

8 TTBER Guidelines, para. 17.

it is generally necessary in order to induce the licensee to invest in the licensed territory and to bring the products to market in a timely manner.[9]

According to former competition commissioner Mario Monti, the new TTBER "will lead to a happy marriage in Europe of innovation and competition policy".

The Modernization Package has brought about the biggest change in 40 years of EU competition law enforcement. These changes include:

- the abolishment of the *ex ante* notification system for agreements where the parties seek clearance or an individual exemption under Article 81(3) EC, in favour of self-assessment by the parties. The parties and their advisors are now entirely responsible themselves for the compliance of their agreements with competition law or whether they can benefit from an exemption under Article 81(3);
- all national competition authorities (NCAs) and the courts of the member states must now apply EC competition rules directly in their entirety ("decentralization of competition law enforcement"), but only *ex post*,
- the Commission is endowed with new decision making powers (e.g., structural remedies, interim measures, binding commitments without finding on legality); and
- the Commission's investigative powers are reinforced (possibility of searching the private premises of senior company employees on pre-emptive order from national court).

On the basis of Council Regulation 1/2003, the Modernization Package itself consists of a Commission Regulation and six Notices:

- Commission Regulation 773/2004 relating to the conduct of proceedings by the Commission pursuant to Articles 81 and 82 of the EC Treaty,
- Commission Guidelines on the application of Article 81(3) of the Treaty,
- Commission Notice on the handling of complaints by the Commission,

9 TTBER Guidelines, para. 165.

- Commission Notice on informal guidance to business (guidance letters),
- Commission Notice on cooperation within the Network of Competition Authorities,
- Commission Notice on the cooperation between the Commission and the courts of the EU Member States in the application of Articles 81 and 82 EC, and
- Commission Guidelines on the "effect on trade" concept contained in Articles 81 and 82 of the Treaty.

In face of all these changes, which all entered into force on May 1, 2004, competition lawyers in the EU only half-jokingly speak of "May Day Mayhem".

4. The TTBER 772/04

4.1. Scope of application

The new TTBER is applicable to technology transfer agreements in a broad sense. They concern the licensing of technology and comprise patent licensing agreements, know-how licensing agreements, software copyright licensing agreements and mixed agreements covering all or some of these intellectual property rights.[10] The scope of application is broader than the old regime because the licensing of software copyright is included.

The term patent is to be understood broadly as well.[11] Patents as subject matter of licensing with regard to the TTBER means

- patents,
- patent applications,
- utility models,
- utility model applications,
- designs,
- topographies for semiconductor products,

[10] Article 1(b).
[11] Article 1(1)(h).

- supplementary protection certificates, and
- plant breeder certificates.

Know-how is defined as a package of non-patented practical information, which is secret, substantial and identified.[12]

Mixed agreements to which the TTBER is applicable may also include provisions relating to other intellectual property rights, such as trademarks and copyrights, if these are not the primary object of the license agreement. The TTBER defines intellectual property rights as including industrial property rights, know-how, copyright and neighbouring rights.[13]

The TTBER also covers non-assertion and settlement agreements whereby the licensor permits the licensee to produce within the scope of the patent.[14]

The TTBER provides block exemption for as long as the licensed IP right remains valid or the know-how remains secret. In contrast, under the previous TTBER, know-how licences were only exempted for a maximum of 10 years.

4.2. Purpose

The purpose of the TTBER is to provide “safe harbour” for companies licensing in Europe with regard to Article 81(1) and (2) EC: i.e. “if you comply, your ok”.

It marks the end of a development in which the European Commission has gradually rid itself of the burden to supervise whether license agreements fall under the prohibition of Article 81(1) EC and are exempted under Article 81(3).

In the beginning, the Commission had thought that it would assess each and every license agreement concluded. Next it introduced block exemption regulations with lists of acceptable and unacceptable license clauses to reduce the number of cases that

[12] Article 1(1)(i).
[13] Article 1(1)(g).
[14] TTGuidelines, para. 43.

would require individual assessment. Then it revised the block exemptions to increase the number of white clauses and further reduce the number of cases that would require its involvement.

And now, with the new TTBER, the Commission has completely relieved itself of the burden to assess license agreements under Article 81 EC. The responsibility has been shifted to the parties themselves, the national competition authorities (NCAs) and courts of the member states. It is no longer possible to notify the Commission of a license agreement to obtain an individual exemption.

Only in exceptional cases of Community interest, parties may be able to request that the Commission consider issuing a finding of inapplicability of Article 81(1) to the agreement pursuant to Article 10 of Regulation 1/2003 in order to obtain legal certainty and avoid future enforcement actions or lawsuits.

The Commission will continue to be the guardian of the Treaty and will publish guidance for the alignment and consistency of the activities of the members of the newly established European Competition Network. It considers itself to be first among equals in the enforcement of EU competition law and reserves the right to pursue the most serious cases of infringement. But its future focus is expected to be on cartels, for which there is zero tolerance, and the abuse of dominant positions, prohibited under Article 82 EC. Generally speaking, license agreements do not attract its attention anymore. But the risks of infringement of Article 81(1) remain.

The *old* regime of Block Exemption Regulation 240/96 distinguished between a white list of clearly exempt provisions of license agreements, a black list of prohibited provisions and a grey list of potentially exempted provisions. It practically told you, “You can do this and you can’t do that”. Economic criteria such as the market shares of the respective companies, and whether they were competitors or non-competitors, were completely irrelevant. The old TTBER was straightforward in listing exempted clauses and this resulted in companies merely copying them into their license agreements. The Regulation was therefore criticized as being formalistic, prescriptive, and having a straitjacket effect.

The *new* regime of TTBER 772/04 states the need to simplify the regulatory framework and its application. It announces an economics-based flexible approach to assess the impact of licensing agreements on the relevant market (so-called "effects-based approach")[15]. The new TTBER exempts clauses in license agreements of companies not exceeding a certain level of market power, distinguishes between agreements between competitors and agreements between non-competitors, and specifies some severely anti-competitive restraints called "hardcore restrictions" as well as some "excluded restrictions", which basically shall not be contained in such agreements. All other contract clauses are exempted. License agreements that fulfill the conditions laid down in the TTBER are automatically legally valid and enforceable.

The new TTBER asserts that "the great majority of license agreements are compatible with Article 81", and that it creates safe harbour for most agreements. But the assessment of exemption of license clauses has become more difficult. Although the new TTBER may be more liberal than the old one, it has resulted in less legal certainty. It may be better founded in economic theory than the old regime, but probably few licensors and licensees will find solace in that observation.

In order to provide guidance on the application of the TTBER as well as on the application of Article 81 of the Treaty to technology transfer agreements that fall outside the scope of the TTBER, the Commission has issued Guidelines that are six times as long as the TTBER itself. These Guidelines are indispensable for assessing whether a license agreement is caught by the prohibition of Article 81(1) or not.

5. Key provisions

Pursuant to Article 2 TTBER and subject to the provisions of the Regulation, Article 81(1) shall not apply to technology transfer agreements entered into between two undertakings and permitting the production of contract products. Contract products means products produced with the licensed technology.[16] Product means a good or a

[15] This is also the basis of the Horizontal (*see*, para. 7) and Vertical Guidelines (*see*, para. 19).
[16] Article 1(1)(f).

service and includes both intermediary goods and services and final goods and services.[17]

The TTBER applies to supply contracts under which the licensor grants the licensee a technology license with the sole purpose of producing the products and delivering them to the licensor.

The TTBER does not apply to agreements between more than two parties or to technology pools.[18] This has been criticized by the chemical industry where license agreements are concluded between more that two parties, for example when different parts of a technology are developed by different companies. Such arrangements will have to be assessed individually on the basis of the Guidelines.

The TTBER also applies to agreements where the licensee must carry out further development work before obtaining a product or process ready for commercial production, provided that the contract product has been identified. Such license agreements are common for biotech companies which do not have the resources for late stage clinical trials and thus rely on out-licensing to big pharma partners to see their products through to market.

For the TTBER to apply, production has to be a primary element of the agreement. Agreements whereby a technology is licensed for the mere purpose of further research and development are not covered.[19] R&D agreements are covered by the Horizontal Agreements BER.

The further basic provisions of the TTBER are Articles 3, 4 and 5.

5.1. Market share thresholds

Article 3 defines the market share thresholds which determine whether the exemptions of the Regulation are applicable or not. If the undertakings are

[17] Article 1(1)(e).
[18] TTGuidelines, para. 41.
[19] TTGuidelines, para. 45.

competitors, their *combined* market share may not exceed 20% on the relevant technology and product market, otherwise the automatic exemption is lost.

If the undertakings are *not competitors*, the market share of *each* may reach 30% and their license agreement will be exempted. This differentiation reflects the thinking of the Commission that the effect of agreements between competitors can be presumed to be more restrictive of competition than agreements between non-competitors.[20]

The parties will be competitors on the relevant *technology market* only if they are actual competitors and license technologies that are substitutes for each other. If the royalty charged were to increase by 5%, would the licensee switch to an alternative licensor? This is said to be a test to determine substitutable technologies.

The parties will be competitors on the relevant *product market* if they are actual or potential suppliers of competing products. The relevant product market comprises products that are regarded as substitutable by buyers. Again, the test of substitutability roughly is, if the price of the product were to increase by 5%, would that encourage the buyer to switch the supplier?

Whether the licensor and the licensee are competitors is in principle established before the license is concluded. A licensee does not become a competitor of the licensor merely by producing under the license. Thus the rules for non-competitors remain applicable unless the license agreement is subsequently amended in a material aspect.

The introduction of market share thresholds constitutes the most controversial aspect of the new TTBER regime. In some industries it may be difficult to delineate the market. The problem becomes worse by the necessity to distinguish between competitors and non-competitors. In many cases it may also be difficult to establish what a competing technology is.

[20] This thinking is also found in the Vertical and Horizontal Guidelines.

Market shares are calculated on the basis of market sales value data, where such data are available (Article 8). Where value based data are not available, estimates based on other reliable market information may be used, including market sales and volume data. For the purpose of this calculation, the licensor's market share includes the market shares of his existing licensees.

Market share thresholds may be difficult to apply, particularly in innovation markets. As long as a new technology is not distributed, the relevant market share remains at 0%. At the start of distribution the market share will increase and in the case of a great innovation the relevant thresholds will soon be exceeded, and in some cases even a market share of 100% is conceivable. As a result, all license agreements of such a licensor would no longer be within the safe harbour of the TBER. The exact determination of market shares at any given point in time is one of the most difficult tasks facing business under the new TTBER.

5.2. Hardcore restrictions

Regardless of market shares, the entire agreement will lose the benefit of block exemption pursuant to Article 4, if the license agreement contains "hardcore restrictions" of competition. The list of hardcore restrictions is short, and a distinction is made between license agreements concluded between competitors and license agreements concluded between non-competitors.

Hardcore restrictions in license agreements between *competitors* that bar exemption are:

(1) price fixing, i.e., limiting the ability of the party to set its prices,
(2) output restrictions, i.e. limiting output,
(3) allocations of markets or customers,
(4) restrictions on the licensee's research and development or use of his own technology.

However, as regards output restrictions, allocations of markets and customers, and restrictions on the licensee's RD or use of his own technology, exceptions are stipulated which, if given, exempt the restriction.

Hardcore restrictions in license agreements between *non-competitors* that bar exemption are

(1) price fixing,
(2) passive sales restrictions, and
(3) sales restrictions for the selective distribution system licensee.

In all these cases exceptions are again stipulated which, if given, exempt the restriction.

5.3. Excluded restrictions

Article 5 finally stipulates restrictions which are generally excluded from exemption, namely

(1) the licensee must exclusively license or assign severable improvements or new applications of the licensed technology (grant-back obligation),
(2) no challenge clause, and
(3) if the parties are not competitors, restrictions on licensee's RD or use of own technology.

But here as well exceptions are stipulated for the no challenge clause and the restrictions on licensee's RD or use of own technology.

The difference between hardcore restrictions and excluded restrictions is that in case of a hardcore restriction the whole license agreement is not exempted. In case of an excluded restriction, only the restrictive clause itself is not exempted while the remainder of the agreement will continue to benefit from the TTBER.

5.4. Common clauses of license agreements

While the TTBER and the Guidelines cannot be examined here in all detail, we have prepared a list of common clauses of license agreements with references to the provisions of the TTBER and the paragraphs of the Guidelines where these clauses are discussed. The list may serve as a tool to check the clauses of a license agreement having effect in the European Union or to draft such a license agreement. The numbers in the list refer to paragraphs of the Guidelines; articles refer to provisions of the TTBER.

- **Exclusive and sole licenses**

  Terminology 162: A license is *exclusive* if the licensee is the only one permitted to produce in the territory. A license is a *sole* license where the licensor undertakes only not to license third parties to produce in the territory.

  Between non-competitors 165: Exclusive licensing between non-competitors is likely to fulfill the conditions of Article 81(3). It is generally necessary to induce the licensee to invest in the licensed technology.

  Dominant licensee 166: Where a dominant licensee obtains an exclusive license to one or more competing technologies, the agreements are likely to be caught by Article 81(1) and unlikely to fulfill the conditions of Article 81(3).

  Cross license creating a de facto industry standard 167: It will normally be required that the technologies which support such a standard be licensed to third parties on fair, reasonable and non-discriminatory terms.

  Reciprocal exclusive licensing between competitors 163:
  Reciprocal exclusive licensing between competitors amounts to an allocation of markets which is a hardcore restriction pursuant to **Article 4(1)(c)**.
  Reciprocal sole licensing is block exempted up to the market threshold of 20%.

Non-reciprocal exclusive licensing between competitors 164: is block exempted up to the market threshold of 20%.

- **Sales restrictions**

Between non-competitors 172: block exempted up to the market threshold of 30%. Sales to the territory reserved to the licensor may fall outside Article 81(1) even above the market share threshold because a technology owner cannot be expected to create direct competition with himself on the basis of his own technology.

Restrictions on active selling between territories 174:
Active sales into territory allocated to another licensee 171
Passive sales into territory allocated to another licensee: hardcore 4(1)(c) 171
Reciprocal agreement between competitors: hardcore 4(1)(c) 169
Non-reciprocal agreement between competitors 4(1)(c)(iv),
on licensor 173

- **Output restrictions**

Between non-competitors ≦30% 176, 178
Non-reciprocal restriction on licensee between competitors ≦20% 175
Reciprocal between competitors: hardcore 4(1)(b) 175
Combined with exclusive territories or customer groups 177

- **Field of use restrictions** (technical fields of application or product markets)

Normally block exempted 180, 182
On licensees in agreements between actual or potential competitors ≦20% 183
On licensee and licensor between non-competitors ≦30% 184, 185

Symmetrical and asymmetrical 183
Combined with exclusive and sole licences treated in same way 181

If market sharing arrangement: hardcore 4(1)(c)

- **Captive use restrictions**

  Block exempted ≦20%/≦30% 186
  Above threshold: Competitor prevented from supplying components to third parties 187
  Above threshold: Licensee restricted in serving after-market for own products 189

- **Tying and bundling**

  Block exempted ≤20%/≤30% 192
  Above threshold: 193, 194

- **Non-compete obligation**

  Block exempted ≤20%/≤30% 197
  Above threshold: 198, 199, 200, 201, 202, 203

- **Obligation on licensee not to sublicense** 155b

- **Royalty obligation**

  Normally 156
  Beyond the period of validity of the licensed intellectual property right 159
  Products produced solely with licensee's technology 4(1)(d)
  Products produced with licensed technology and also royalty on products produced with third party technology 160
  Price fixing between competitors 4(1)(a) 157
  Disproportionate 158

- **Obligation to pay minimum royalty or to produce a minimum quantity of products incorporating licensed technology** 155e

- **Obligation to assist licensor in enforcing licensed intellectual property rights** 155d

- **Obligation to us licensor's trade mark or indicate name of licensor on product** 155f

- **Obligation not to use licensed technology after expiry of agreement, provided that licensed technology remains valid and in force** 155c

- **Confidentiality obligation** 155a

- **Settlement and non-assertion agreements**

  Block exempted if no hardcore restrictions set out in 4 205
  Cross license 207, 208
  Non-challenge clause 209

- **Technology pools**

  Not covered by TTBER, addressed in Guidelines 212 et seq.

6. Self-assessment

Contrary to the old competition law regime, if the license agreement is no exempted under the TTBER, there is no presumption that it is consequently caught by the prohibition of Article 81(1).[21]

For example, a license agreement between undertakings that exceed the market share thresholds cannot benefit from the TTBER. If the parties' market shares exceed the thresholds at any time during its lifetime, the agreement will fall outside the TTBER

[21] TTBER, Recital (12), Guidelines, para. 37.

after a grace period of 2 years, following the year in which the threshold was first exceeded.[22]

Such license agreements are not per se deemed to be prohibited and can still qualify for exemption under Article 81(3). However, since individual exemptions by the Commission are not available anymore, it is now up to the licensing partners themselves to determine by self assessment whether their agreement is individually exempted under Article 81(3) EC.

The Guidelines set out the principles of assessment that apply to cases falling outside the safe harbour principle.[23] Furthermore, if the TTBER is not 100% applicable, it may be applied by analogy.

Self-assessment consists of two parts:

(1) The first step is to assess whether the license agreement has an anti-competitive object or actual or potential anti-competitive effects.

(2) If the agreement is found to restrict competition, it must be determined in a second step whether the pro-competitive benefits produced by that agreement outweigh the anti-competitive effects. This balancing of anti-competitive and pro-competitive effects is conducted in the framework of the criteria laid down in Article 81(3).

Your self-assessment must thus convincingly demonstrate that your license agreement, while containing anti-competitive elements,

- results in efficiency gains,
- brings a fair share for consumers,
- contains only indispensable restrictions of competition, and
- does not eliminate competition in respect of the products concerned.

[22] Article 8(2) TTBER.
[23] For details, *see* Guidelines, para. 130 et seq. and Commission Notice "Guidelines on the application of Article 81(3) of the Treaty (2004/C 101/08).

The self-assessment should be preserved in writing so that it can be presented to the competition authorities or in court if the validity of the license agreement under Article 81(1) is challenged. The parties will have to make sure that they have good arguments at their disposal to defend their license agreement on the basis of Article 81(3).

While the Guidelines set out the Commission's current views on what may be exempted by self assessment, the boundaries of what is lawful are likely to be worked out in future cases as the assessments carried out by licensing parties are tested in enforcement actions or in court.

In principle, *any* restriction of competition, even explicit hardcore restrictions such as price fixing, may be exempted under Article 81(3). But such exemptions will of course be exceptional and will require a very strong justification. Normally, agreements containing a hardcore restriction will be prohibited under Article 81(1).

As a specific exception, the Commission takes the view that as long as there are no hardcore restrictions in the agreement, Article 81 is unlikely to be infringed if there exist four or more independently controlled technologies that are substitutable for the licensed technology at a comparable cost to the user.[24]

7. Caveats

On the basis of the new regime, the first step for parties to a technology transfer agreement will be to identify whether or not they are competitors.

As a next step, the parties will need to identify their respective market shares.

According to whether or not the parties are competitors and what share of the relevant markets the parties have, they will thereafter need to identify whether or not the proposed agreement contains any hardcore or excluded restriction.

[24] Guidelines, para. 131.

If the relevant market thresholds are not exceeded, and the agreement contains no hardcore restrictions, the proposed agreement will be exempted under the TTBER.

If the market share thresholds are exceeded or the proposed agreement does contain a hardcore restriction, the agreement will need to be individually assessed to establish whether it falls under Article 81(1) EC and thereafter, whether or not it will be exempt under Article 81(3) EC

There are three main caveats to be aware of relating to the new competition law rules if you are involved in licensing in the EU.

7.1. Adaptation of prior license agreements

The TTBER 772/2004 and the regulations and notices of the Modernization Package are applicable to technology transfer agreements concluded on or after May 1, 2004.

All prior agreements existing in force after April 30, 2004 even if exempted under the old regime must comply with the new rules at latest by March 31, 2006. This is the date until which the former TTBER 240/96 of 1996 was due to remain in application.

Existing agreements should therefore have been re-examined to see whether they will continue to be exempted by the new TTBER, or require adaptation. Most likely quite a number of license agreements will have been adapted and possibly even renegotiated to align them to the new rules. This can lead to difficulties, particularly when bargaining positions have changed and one party is unwilling to agree to the necessary modifications. But failing to bring existing agreements in line with the new requirements may lead to nullity of contract, fines and claims for damages.

7.2. Constant review

Since the TTBER grants exemption only in the boundaries of specific market shares and becomes inapplicable if these market shares are exceeded, the parties are required to assess on an ongoing basis throughout the lifetime of their agreement, whether or not they are competitors, and the size of their respective and combined market shares.

Businesses themselves have now become responsible for ensuring full compliance with the EU competition rules at the risk of nullity of contract, being faced with fines, or damages claims before the courts. No doubt the assessment of market shares throughout the life of the agreement decreases legal certainty and may be costly if the relevant markets are in a state of flux.

Self assessment needs to be dynamic and to change with market circumstances. For example, the risk profile of an agreement may become lower with the entry into the market of a new substitutable technology, and this may in turn allow the licensor to impose more onerous restrictions on the licensees.

The parties will often be unable to predict at the outset whether their market shares are likely to remain below the safe harbour thresholds. As a result, many agreements cannot safely be deemed to be in safe harbour for their entire duration. An agreement which at the time of its execution was between parties whose market shares did not exceed the threshold, can become unenforceable if, at a later stage, the market shares increase to exceed the relevant threshold.

A periodic and dynamic risk assessment of the license agreement in its market context will thus be required to prevent that the parties will be penalized for their success. Under the TTBER, agreements can continue to benefit from the exemption for a grace period of 2 consecutive years following the year in which the relevant threshold was first exceeded. In case thresholds are surpassed, the parties may even need to renegotiate their agreement.

It may be prudent to provide for such renegotiation of the agreement at the outset. Ask yourself: “Where will we be in five years?”. Alternatives to essential clauses could be included in the agreement from the start. If a clause can become hardcore, it could be designated as severable (based on national law) when the agreement is entered into.

Because of the abolition of the notification system and the decentralized application of competition law under the new EU system, companies will have to rely increasingly on sophisticated legal analysis and self-review. For this purpose outside legal and economic advice may have to be sought.

7.3. Significance of self-assessment

If the TTBER is not applicable or becomes inapplicable while the license agreement is in force, for example because the parties have outgrown the agreement, they must conduct and properly document their self-assessment under Article 81(3) EC.

Self assessment has become the rule and may be quite complicated, involving a mix of legal and economic arguments, particularly in respect of definition of markets, calculation of fluctuating market shares, determination whether technologies are essential, substitutable etc. This can be particularly difficult in technologically complex and innovative sectors.

Essentially there are 5 key questions to be answered when carrying out self assessment:[25]

(1) What is the agreement and does it have an anti-competitive object or effect?
(2) Does the agreement affect trade between member states?
(3) Does the agreement have an appreciable affect on competition?
(4) Is safe harbour of block exemption available?
(5) Does the exemption pursuant to Article 81(3) apply on an individual basis?

If the cumulative conditions of Article 81(3) are not fulfilled, the parties may even have to renegotiate their agreement in the midst of their contractual relationship to prevent it from becoming null and void.

In practice, self-assessment may now become more important than the exemption under the TTBER. Its scope of application and the market share thresholds might

[25] *See* also Guidelines, para. 132 et seq.

result in that many technology transfer agreements are not exempted. A proper self assessment is therefore essential to prevent that agreements are declared null and void and that parties expose themselves to fines or claims for damages.

The Commission's view is that the new competition law regime aligns the EU rules to those of the U.S.[26] It is a positive aspect that this may facilitate the negotiation of global license agreements.

According to a former director of the Bureau of Competition of the Federal Trade Commission of the U.S., the basic question you will have to ask yourself with respect to each clause of your license agreement is, "Why are we doing it?": If the answer is not anti-competitive, there is no violation of competition law.

This is certainly a good starting point. But the concrete answer may not be that simple.

VII. Summary

The regulatory system that governs licensing in the European Union is, as we have seen, the result of a constant balancing of interests. On the one side there is the protection of intellectual property and the economic freedom of the IPR owner, which are acknowledged by the EC Treaty, on the other side there are the principles of free movement of goods and services and the freedom of competition, which are fundamental to the common market in the EU.

This balancing of interests is reflected in three groups of provisions of the EC Treaty:

Articles 28 and 30 EC are the basis of Community exhaustion of intellectual property rights in the EU.

[26] Cf., the 1995 U.S. Antitrust Guidelines for the Licensing of Intellectual Property (www.usdoj.gov/atr/public/guidelines/ipguide.htm).

Article 81 paragraphs 1 and 3 EC together with the Block Exemption Regulation 772/04 for technology transfer agreements are applicable to restraints of competition in license agreements and provide individual and block exemptions for such restraints.

Article 82 EC applies in exceptional circumstances where the refusal of an IPR owner occupying a de facto dominant position in the market to grant a license constitutes an abusive conduct.

If you intend to enter into an intellectual property license agreement in Europe, these, in summary, are the aspects you must take into consideration.