

Pharma and biotech in-licensing and collaboration agreements: a deal lawyer's guide to EU anti-trust pitfalls



David W Hull and Michael J Clancy, Covington & Burling LLP

www.practicallaw.com/1-205-6037

Pharmaceutical and biotech companies are turning with increasing frequency to in-licensing and collaboration agreements - pharmaceutical companies to put new products in their pipelines and biotech companies to access the resources needed for final-stage development, clinical trials, manufacturing, and distribution. One result of the increasing importance of these agreements is the greater prominence of anti-trust issues. There are at least two reasons for this:

- In-licensing and collaboration agreements frequently involve competitors, or at least potential competitors, which means that there is often a threshold issue of whether the agreement is permissible at all under the anti-trust laws.
- These agreements have become so central to the business of many companies both in strategic and financial terms, that it is essential to ensure their provisions are enforceable. Often, the clauses that deal with the most business-critical issues, such as exclusivity, non-compete obligations, field-of-use restrictions, territorial and customer restrictions, and the ownership of intellectual property (IP) rights, are precisely the ones that will be the most suspect under the anti-trust rules and therefore potentially the most vulnerable to challenge. The invalidity of a specific clause (or the entire agreement if the clause is central to the agreement) may not only undermine a key business goal, but it may result in the emergence of an unrestrained competitor instead of a contractually-controlled ally.

This chapter aims to help deal lawyers avoid the main EU anti-trust pitfalls likely to arise in in-licensing and collaboration agreements. Against this background, the chapter:

- Provides an overview of the relevant EU anti-trust rules.
- Discusses a practical approach to resolving anti-trust concerns by assessing whether parties are competitors, and avoiding hardcore restrictions.

The chapter focuses on an abridged approach. This is not a substitute for a thorough analysis by anti-trust counsel, but some deals may not be large enough to justify a full legal review. In these cases, a risk that certain clauses may not be enforceable may be acceptable. Even where anti-trust counsel are involved, the following "quick-look" approach should help identify issues early and facilitate a productive dialogue with counsel.

While in-licensing and collaboration agreements can cover a wide variety of agreements, this chapter analyses the two basic structures that seem to be used most often in practice:

- One party carries out research and development (R&D) and then licenses the results of this R&D to the other, which is responsible for production and marketing.
- One party simply licenses its IP rights to the other, which is responsible for the final-stage development and clinical approvals as well as production and marketing.

Arrangements that do not involve an element of collaboration with respect to R&D or production are not discussed (that is where one party simply supplies the finished product to the other for distribution in a given territory). These relatively straightforward distribution arrangements are covered by the rules on vertical restraints.

OVERVIEW OF RELEVANT ANTI-TRUST RULES

Broad prohibition

Article 81(1) of the Treaty Establishing the European Community (EC Treaty) prohibits agreements "which have as their object or effect the prevention, restriction, or distortion of competition within the common market". Article 81(2) provides that any agreement prohibited pursuant to Article 81(1) "shall be automatically void". Often, Article 81(2) is raised as a defence to an action to enforce an agreement. Therefore, if an agreement contains restrictive clauses that are caught by Article 81(1)'s broad prohibition and is not eligible for the *de minimis* exception or an individual or block exemption pursuant to Article 81(3) (see below, *De minimis exception* and *Article 81(3) exemption*), it is unenforceable.

In addition to being unenforceable, an agreement that is restrictive within the meaning of Article 81(1) and that is not eligible for exemption, can result in fines and follow-on actions for damages. As a practical matter, however, in-licensing and collaboration agreements are unlikely to result in fines or damages unless they involve a sham that is nothing more than a disguised market-sharing arrangement. Therefore, the main concern with these agreements is their enforceability.

De minimis exception

A potentially significant exception to the competition rules is the so-called *de minimis* exception. A threshold requirement for the

application of Article 81 is that the agreement has an "appreciable" effect on competition. If an agreement does not have an appreciable effect on competition, the Article 81(1) prohibition does not apply.

The European Commission (Commission) has tried to quantify what is meant by an appreciable effect on competition in the Notice on agreements of minor importance (*OJ 2001 C368/07*) (De Minimis Notice). The De Minimis Notice explains that there is no appreciable effect on competition in the case of:

- Agreements between competitors or potential competitors with a combined market share threshold of less than 10%.
- Agreements between non-competitors with individual market shares of less than 15%, unless:
 - there are a large number of similar agreements in the market that have a cumulative anti-competitive effect; or
 - the agreement contains certain "hardcore" restrictions that would result in price-fixing, market-sharing, or territorial restrictions.

In the case of in-licensing and collaboration agreements, the exception afforded by the De Minimis Notice is not particularly significant. Even if the parties fall below the thresholds and do not have any of the hardcore restrictions described in the De Minimis Notice, the block exemptions on joint R&D agreements and licences, which set out additional hardcore restrictions, still need to be considered (*see below, Avoiding hardcore restrictions*).

Article 81(3) exemption

Despite the language of Article 81(2), an agreement that restricts competition within the meaning of Article 81(1) is not necessarily void. Article 81(3) provides that agreements are exempt from the Article 81(1) prohibition if they have certain pro-competitive effects. Specifically, Article 81(3) exempts agreements from the prohibition of Article 81(1) where they lead to an improvement in the production or distribution of goods or promote technical or economic progress, while allowing consumers a fair share of the resulting benefit, provided that the restrictions are essential to obtaining the benefits and that the agreement does not eliminate a substantial amount of competition. In essence, the availability of an exemption under Article 81(3) depends on an analysis that is similar in many respects to the "rule of reason" analysis applied under US anti-trust law, where the restrictive effects of an agreement are weighed against the pro-competitive effects.

The Commission has published various notices and guidelines to provide guidance on the evaluation of agreements under Article 81, particularly on the assessment under Article 81(3). Two of these notices are particularly relevant to in-licensing and collaboration agreements: the Technology Transfer Guidelines governing licences (*2004 OJ C101/2*) and the Horizontal Guidelines governing agreements between competitors (*2001 OJ C3/2*).

Category-specific block exemptions

The Commission has issued a series of "block exemptions", which grant an automatic exemption under Article 81(3) to certain categories of agreements, including vertical agreements, licences, joint R&D agreements and specialisation agreements.

In essence, a block exemption operates as a safe harbour for agreements involving parties whose market shares for the products covered by the agreement are below the thresholds specified in the block exemption and that do not contain certain hardcore restrictions.

If an agreement falls outside the scope of a block exemption because, for example, the market shares of the parties exceed the relevant threshold, this does not mean that the agreement is unenforceable or even that it raises greater anti-trust concerns. It simply means that the agreement does not benefit from the safe harbour and it may be necessary to conduct a more in-depth analysis to determine whether it gives rise to any particular concerns. As it may not be necessary or feasible to conduct such a detailed analysis in every case, a "quick-look" approach is offered in this chapter (*see below, A practical approach to the application of the rules*).

If an agreement falls outside the scope of the block exemption because it contains a hardcore restriction, it is unlikely that the agreement will be eligible for an individual exemption under Article 81(3). In fact, the inclusion of a hardcore restriction means that the entire agreement will be struck down as unenforceable, not just the offending provision.

Two block exemptions are particularly relevant to in-licensing and collaboration agreements:

- Regulation (EC) No. 2659/2000 on research and development agreements, which provides for a market share threshold of 25% in the case of agreements involving competitors.
- Regulation (EC) No. 772/2004 on the application of Article 81(3) of the EC Treaty to categories of technology transfer agreements (Technology Transfer Block Exemption Regulation), which provides for a market share threshold of 20% in the case of agreements involving competitors and 30% for those involving companies that are not competitors.

Article 82

While Article 81 deals with restrictive agreements, Article 82 of the EC Treaty deals with the abuse of a dominant position. Specifically, it prohibits a dominant firm from engaging in abusive conduct. Abuses of a dominant position are not dealt with in this chapter, but it should be noted that an in-licensing or collaboration agreement that does not raise anti-trust concerns when it is between companies that are not dominant may raise concerns if a dominant firm is involved.

A PRACTICAL APPROACH TO THE APPLICATION OF THE RULES

This section provides a practical, "quick-look" approach to the evaluation of an in-licensing or collaboration agreement under the EU anti-trust rules to identify potential anti-trust concerns and to avoid major pitfalls.

This truncated analysis focuses on two key questions:

- Whether the parties are competitors in the market. To make this determination, the relevant market must be defined (*see below, Are the parties competitors?*). If the parties are competitors and have high combined market shares, anti-trust counsel should review the agreement to see whether it is permissible and, if it is, whether there is a material risk that certain provisions may not be enforceable. While there is no set threshold above which a transaction poses unacceptable anti-trust risks (as this ultimately depends on the overall structure of the relevant market), concerns of dominance typically begin to arise when combined market shares exceed 40%. At this point, anti-trust counsel should always be consulted.
- If there are no anti-trust concerns arising from the market power of the parties, it must then be determined whether the agreement contains any impermissible hardcore restrictions. If the agreement contains such a restriction, it is not only the provision in question that could be struck down as unenforceable, but the entire agreement (*see below, Avoiding hardcore restrictions*).

Apart from the issue of whether the agreement contains hardcore restrictions, this chapter does not consider issues that would be considered under a more traditional approach to the assessment of these agreements, such as whether the agreement would qualify for the safe harbour offered by the applicable block exemption. This is because, as a practical matter, whether an agreement qualifies for a safe harbour is unlikely, in cases where the parties are not competitors with high combined market shares, to affect the actual text of the agreement. In other words, whether the agreement falls within the safe harbour or is outside of the safe harbour, it will look basically the same. In either case, it cannot contain hardcore restrictions.

ARE THE PARTIES COMPETITORS?

Whether the parties are competitors is a fundamental question that should be answered as soon as possible, that is, as soon as the parties and the scope of the licence or collaboration are known. If there is too much overlap between the parties in the market covered by the in-licensing or collaboration agreement and their position in this market is too strong, the deal may not be possible because of anti-trust concerns. Apart from this threshold concern, whether the parties are competitors and the degree of their combined market power can affect the scope and duration of certain key provisions in the agreement. For example, under the rules on licensing set out in the Technology Transfer Block Exemption Regulation, the licensor may place greater restrictions on the ability of its licensee to sell outside of its territory if the parties are not competitors.

Whether the parties are competitors depends on the definition of the relevant market, that is, the market covered by the agreement. Therefore, the fact that the parties are in the same industry (for example, pharmaceuticals) or even the same general product area (for example, cancer treatments) does not necessarily mean that they are competitors for anti-trust purposes. In the case of pharmaceutical products, the definition of the relevant product market can involve complex inquiries into

the therapeutic properties of a product to determine to what extent various products are substitutable for one another.

In most cases, however, a preliminary idea of the appropriate market definition and the size of the parties' market shares can be ascertained by looking at the products grouped together in Level 3 of the World Health Organisation's Anatomical Therapeutic Classification (ATC) scheme. The Commission generally uses this ATC Level 3 category as the starting point for its analysis of the relevant market. In many cases, this category will be the relevant product market, although the Commission sometimes concludes that the market should be narrower. IMS sales data is frequently grouped according to the ATC categories, so market share data can generally be found quickly. Preliminary conclusions can also be cross-checked with the parties' marketing departments as their view of which products are competitive frequently matches the relevant product market definition used for anti-trust purposes.

In addition to defining the relevant product market, the relevant geographic market for measuring the parties' market power must be considered as well as determining whether there is any competitive overlap. As a general rule, the relevant geographic market for pharmaceutical products is considered to be national due to regulatory differences among countries. Consequently, market share figures should be looked at on a country-by-country basis.

Whether the parties are competitors is not just a question of whether they currently sell products in competition with each other, but also whether they are competitors with respect to the technology covered by the agreement. For example if the parties are the only two companies carrying out R&D with respect to products to treat a specific disease, a collaboration agreement could raise significant anti-trust concerns, even if there are currently no products on the market to treat that disease.

With regard to the products covered by the in-licensing or collaboration agreement, even if the parties are not actual competitors on the market, the agreement may raise competition concerns if they are potential competitors. The Technology Transfer Block Exemption Regulation treats the parties as potential competitors if they would enter the market over a period of one or two years in response to a small, but permanent price increase. In the case of pharmaceutical products, it is necessary to consider products in the pipeline in addressing the issue of potential competition. As a general rule, a party will only be considered as a potential competitor if the product is in Phase III of the development process.

AVOIDING HARDCORE RESTRICTIONS

If the proposed transaction is not prohibited because of the high combined market power of the parties, the second issue to be addressed is whether any of the agreement's provisions raise anti-trust concerns. The following discussion of hardcore restrictions considers the most common concerns, yet does not cover every restrictive provision. As discussed above, this approach takes certain shortcuts, which involve legal risks.

The first step in examining whether the agreement contains hardcore restrictions is to determine which of the various block

exemptions, notices, and guidelines apply to the agreement, because the list of hardcore restrictions can vary according to which set of rules apply. This exercise is not always easy in the case of in-licensing and collaboration agreements because of the hybrid nature of these agreements. Often, they involve all phases of a product's life cycle: R&D, production, and distribution. For example:

- Where the collaboration involves a heavy element of joint R&D, the R&D Block Exemption is likely to apply.
- Where the collaboration involves the licensing of the IP rights to a product to one of the parties who will then carry out final-stage development work and clinical trials, produce the product, and distribute it, the Technology Transfer Block Exemption Regulation and the accompanying guidelines are likely to apply.
- Where collaboration between competitors is involved, the Horizontal Guidelines may also apply.

The relevant rules from these guidelines and block exemptions are discussed below.

Determination of the retail price

In cases where one of the parties is charged with the marketing and distribution of a jointly-developed product on behalf of both parties, as might be the case where the collaboration involves a joint R&D effort, both parties can normally determine the pricing policy for the product. In contrast, where the product is not jointly-developed, such as where one party licenses the IP rights to the product to the other, who is responsible for production and distribution, restrictions placed on the prices charged by the distributing party could give rise to anti-trust concerns. More specifically, any attempt to fix the price or set a minimum price will constitute resale price maintenance, which is treated as a hardcore restriction under the rules on licensing set out in the Technology Transfer Block Exemption Regulation. However, it is permissible to agree on recommended prices or maximum prices.

Restrictions on output

In some cases, the party licensing the technology under the in-licensing or collaboration agreement may place restrictions on the quantity of products that can be produced by the other party. While such output restrictions are treated as hardcore restrictions when imposed on a reciprocal basis in licences between competitors, they are generally permissible when they are imposed on a non-reciprocal basis. The Commission recognises that output limitations can have pro-competitive effects because the ability to impose such restrictions can provide an incentive to licensors who are also manufacturers of the licensed product to disseminate their technology. Concerns may arise, however, if the parties have significant market power or if the output restriction is part of a broader arrangement to partition markets.

Restrictions on R&D

In-licensing and collaboration agreements often contain provisions that restrict the ability of the parties to engage in R&D outside of the collaboration to prevent them from competing with

the joint R&D effort or free-riding off the results of that effort. Such restrictions can be pro-competitive to the extent that they provide an incentive for the parties to work together to create new products and technology. If they are overly broad in scope or duration, however, they can restrict competition by stifling innovation that would otherwise occur.

Restrictions on the freedom of the parties to carry out R&D independently or in co-operation with third parties are impermissible hardcore restrictions to the extent they cover technical fields unconnected with the collaboration. Likewise, in the context of a licensing arrangement that does not involve R&D, restrictions on R&D (whether in or outside the field of the collaboration) that extend beyond the term of the R&D phase of the collaboration are treated as hardcore. The only exception to this rule is if such a restriction is necessary to prevent the disclosure to third parties of know-how related to the collaboration.

In the context of a broad collaboration agreement that includes joint R&D as well as production and distribution, it is clear that restrictions on R&D are permissible during the R&D phase of the project. Whether such a restriction may be imposed for the term of the entire agreement is less clear. On this point, the R&D Block Exemption Regulation is ambiguous because, while it prohibits post-term restrictions on R&D, it is unclear whether it is referring to the term of the entire agreement (which could include manufacturing and distribution) or whether it only applies to the term of the R&D portion of the project. As a practical matter, it may not make much difference because, even if one of the parties is allowed to carry out R&D with a third party, it can be prevented from exploiting that R&D to make and sell competing products.

Exclusivity and non-compete obligations

In addition to restrictions on the ability of the parties to engage in competing R&D, in-licensing and collaboration agreements often restrict the ability of the parties to compete with the collaborative venture at the production and distribution stages. Indeed, such restrictions are often among the most important provisions in the entire agreement because, in many cases, the very purpose of the agreement is to give one or both parties a competitive edge over others active in the same field. Therefore, the partners must be committed to the joint effort on an exclusive basis.

In the context of a licence of IP rights from one party to the other, the licensor may be restricted from using the licensed technology in the licensee's territory as well as from licensing the technology to third parties in the territory (the Technology Transfer Guidelines refer to this as "exclusivity"). Such restrictions can be pro-competitive to the extent that they give the licensee the protection it needs to induce it to invest in the technology. Such restrictions can give rise to anti-trust concerns, however, if they are reciprocal and involve competitors or if the licensor has a dominant position.

In return for the exclusivity granted by the licensor, the licensee may be restricted from using the technology of third parties in the territory (the Technology Transfer Guidelines refer to this as a "non-compete" provision). Such a restriction can be pro-competitive to the extent that it can lower the risk of misappropriation of technology (particularly know-how) by the other party and

therefore promote the development and dissemination of technology through pooled know-how, shared risks and reduced cost. Further, non-compete obligations ensure that the licensee concentrates its efforts on the collaborative venture. Such a restriction is only likely to give rise to anti-trust concerns if this arrangement has the effect of excluding competitors from the market. For example, if the licensee is one of the few companies with a strong distribution network for a given product market, the non-compete obligation could raise anti-trust concerns if it prevents competitors from getting their products to market.

Customer or territorial restrictions on sales

Closely related to exclusivity and non-compete provisions are provisions that restrict the ability of one or both parties to sell to a particular customer group or into a certain territory. Customer or geographic restrictions can foster the dissemination of products or technology by protecting a licensor from competition with its licensees. Further, these restrictions can foster investments by licensees or distributors by protecting their efforts from freeriding by wholesalers, other licensees, or even the licensor.

Where the parties to the agreement are not dominant, the benefits of these restrictions are passed onto the consumer and satisfy the requirements of Article 81(3). However, should either of the parties hold a substantial market share, the risk of foreclosure of competition grows. Such foreclosure must be outweighed by real efficiencies created for the specific product to allay competition concerns. As a practical matter, one way to address this issue is to limit the duration of the restriction.

As a general rule, if a territorial restriction is aimed at giving one of the parties protection with respect to the entire European Economic Area (EEA), it is unlikely to raise anti-trust concerns unless it is part of a global market-sharing arrangement. For example, if a Japanese pharmaceutical company licenses its IP rights to a US pharmaceutical company for the production and sale of the product in the US, a restriction imposed on the ability of the US licensee to sell in the EEA is unlikely to raise concerns under the EU competition rules, because the Japanese company could always rely on its IP rights in the EEA to prevent such sales. Such a contractual restriction would therefore simply reinforce its already-existing rights under the relevant IP laws. In contrast, if the Japanese company entered into a reciprocal exclusive licence with a European competitor under which it granted the European competitor exclusive rights in the EEA and agreed not to sell in the EEA, and the European company granted reciprocal rights for Japan, such a licence would likely raise competition concerns.

If the agreement contains provisions that allocate customers or territories within the EEA, however, these provisions must be in line with the relevant set of rules. The R&D Block Exemption and the Technology Transfer Block Exemption Regulation each contain slightly different rules on territorial and customer restrictions, so it will be important to determine which set of rules applies.

One common feature of all of these rules is the distinction between so-called "active" and "passive" sales. Active sales are those made through active solicitation by the seller while passive sales are made in response to unsolicited orders. As a general rule, restrictions on passive sales are treated more harshly than

those on active sales because they can result in absolute territorial protection. This undermines one of the fundamental goals of EU competition law of creating a single market. In the case of technology licences, however, the Commission is more willing to allow some restrictions on passive sales, presumably on the grounds that the licensee will be making significant investments in the new technology and deserves more protection than a company that simply distributes products.

In cases where the primary purpose of the agreement is to facilitate joint R&D, the R&D Block Exemption would apply and an absolute ban on sales to certain customers can be imposed for a period of seven years from the time that the product is first put on the market. A ban on active sales in territories reserved for the other party can be imposed for the same seven-year period (passive sales must be allowed).

In cases where the IP rights to a product are licensed to a party for final-stage development in connection with subsequent production and sale, the Technology Transfer Block Exemption Regulation would apply and the rules on territorial and customer restrictions become more complicated, as they differ depending on whether or not the parties are competitors.

In the case of non-reciprocal licences between competitors, each party can be prevented from making active or passive sales in the territories reserved for the other party on an exclusive basis. In addition, the licensee can be prevented from making active sales in territories reserved for other licensees on an exclusive basis provided that the other licensee was not a competitor of the licensor at the time of the conclusion of the agreement.

In the case of agreements between companies that are not competitors, the licensor can be prevented from making active or passive sales in the licensee's territory. Likewise, the licensee can be prevented from making active or passive sales in the territory of the licensor and can be prevented from making active sales in the territories of other licensees. In all of these cases, and in contrast to the case of licences involving competitors, it does not matter whether the territory being protected is exclusive. The licensee can also be prevented from making passive sales in the exclusive territory of other licensees for an initial period of two years from the date that the protected licensee first markets the product in its territory.

Royalties

A royalty clause is the common way in which the licensee pays the licensor for the use of IP under the licence agreement and, as such, does not fall under Article 81(1). Royalties calculated on the price of the final product, where the licensed technology is an input into the final product, are generally not restrictive of competition. Likewise, a minimum royalty clause that requires the licensee to pay the licensor a minimum level of income as a condition for being granted the licence, generally does not fall under Article 81(1).

Historically, the Commission has viewed a clause requiring the licensee to pay royalties after the expiration of the IP rights (or the entering of the licensed know-how into the public domain) as restrictive of competition within the meaning of Article 81(1) because it is more difficult for the licensee to compete with

others who are under no obligation to pay royalties. In recent years, however, the Commission has adopted a much more tolerant approach towards such a clause, recognising that it is a matter of negotiation between the parties. Under the Technology Transfer Guidelines, an obligation placed on the licensee to pay royalties after the expiry of the licensed patent, or after the know-how is publicly known, generally is not restrictive of competition.

The Commission's approach towards an obligation to pay royalties on products not protected by the licensed IP right has also softened considerably. Under previous regulations concerning patent and know-how licence agreements, such an obligation was prohibited, while it is not even mentioned in the current Technology Transfer Block Exemption Regulation. The case law suggests that an obligation to pay royalties on unprotected products is permissible if it is simply a matter of the method of calculating royalties and is not meant to prevent the licensee from selling the protected and unprotected products separately.

Field-of-use restrictions

In-licensing and collaboration agreements often contain field-of-use restrictions as the licensor wants to reserve the possibility of exploiting the technology in other fields, either alone or with third parties. Field-of-use restrictions in licences between non-competitors generally fall outside of the Article 81(1) prohibition either because they do not restrict competition or because they are justified by their pro-competitive effects. If the licensor could not reserve certain fields, this could undermine his incentive to grant a licence at all.

In contrast, field-of-use restrictions in licences between competitors generally fall under the Article 81(1) prohibition. If a field-of-use restriction is combined with an exclusivity provision in a reciprocal licence between actual or potential competitors, this is treated as an impermissible hardcore restriction because the exclusivity restriction prevents anyone other than the licensee from exploiting the field of use. In other words, the competitors are agreeing not to exploit the technology in the field licensed to the other, which amounts to a market-sharing agreement. However, symmetrical field-of-use restrictions in a cross-licensing collaboration (where the parties are licensed to use each other's technologies within the same fields of use) allow competitors to combine their respective technologies for the benefit of both. Such restrictions are not likely to restrict competition and are therefore unlikely to fall under the Article 81(1) prohibition.

Field-of-use restrictions in non-reciprocal licences between competitors are less likely to raise competition concerns. They can have pro-competitive effects to the extent that they encourage the licensor to licence the technology in fields outside of the licensor's primary field. Such restrictions can give rise to concerns, however, if the licensee is particularly well-placed to compete in the areas outside of the licensed field.

AVOIDING SOFTCORE RESTRICTIONS

The Technology Transfer Block Exemption Regulation places exclusive grant-backs and no-challenge clauses in the category of "excluded" restrictions. This means they are not hardcore restrictions, but are not exempted either. Therefore, there is a risk that an exclusive grant-back or no-challenge clause will be unenforce-

able, but compared with a hardcore restriction, there is very little risk that the entire agreement will be struck down.

Grant-back obligations

Under a grant-back obligation, the licensee agrees to grant a licence to the licensor for any improvements that the licensee has made to the licensed technology. A grant-back obligation can be pro-competitive in that it encourages the licensor to grant a licence in the first place because the licensor knows that he can maintain some control over his technology. However, grant-back clauses can have anti-competitive effects if they are exclusive because they can dampen the incentive to make improvements. If a licensee knows that he will not be able to grant licences to third parties for improvements, he may have no incentive to try to make improvements.

The treatment of grant-back obligations depends on whether or not the improvement is severable. An improvement is severable if it can be exploited without infringing on the licensed technology. Grant-back obligations related to non-severable improvements do not fall within the Article 81(1) prohibition because the licensee would infringe the licensor's IP rights if it attempted to use the improvement without the licensor's permission.

The treatment of grant-back obligations for severable improvements differs according to whether or not they are exclusive. Non-exclusive grant-back obligations are treated more leniently because they allow the licensee to keep the benefit of his improvements, therefore preserving the incentive to make improvements. For that reason, non-exclusive grant-backs are unlikely to raise competition concerns and are exempted under the Technology Transfer Block Exemption Regulation.

In contrast, exclusive grant-back obligations to severable improvements may raise competition concerns because they can remove the incentive for a licensee to make improvements. In order to qualify for an exemption, separate and adequate consideration must be provided for the obligation to a degree that offsets the restriction on competition. Further, should the licensor have a significant amount of market power, such obligations are more likely to raise competition concerns and will need to be analysed closely.

No-challenge clauses

A no-challenge clause imposes an obligation on the licensee not to contest the validity or the ownership of IP rights covered by a licence or resulting from the R&D collaboration. This restriction may distort competition because it can result in the preservation of invalid IP rights. As invalid IP rights stifle innovation, such clauses generally fall under the Article 81(1) prohibition. However, a no-challenge clause relating to know-how is less likely to give rise to anti-trust concerns because, once know-how is disclosed, it may be impossible to recover it. Providing a licensor with the protection of a no-challenge clause results in broader dissemination of its technology, especially in the case of weaker licensors.

The Technology Transfer Block Exemption Regulation specifically allows the licensor to terminate the agreement in the event of a challenge. For many licensors, a provision to this effect is sufficient protection against challenges by the licensee.



COVINGTON & BURLING LLP
Life Sciences Industry Group

Integration

Corporate
Collaboration
Regulatory
Intellectual Property
Commercial
Competition
Litigation

Worldwide

BRUSSELS LONDON NEW YORK SAN FRANCISCO WASHINGTON

WWW.COV.COM