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New EU Tech Regulations Will Impact Life Sciences

Law360, New York (April 09, 2014, 6:21 PM ET) -- The European Commission has just published the definitive text of the new rules on the interface between intellectual property and antitrust law. This article looks at the main changes made by the new law which are likely to have a particular impact on the life sciences industry.

On March 28, 2014, following a public consultation process initiated in February 2013, the European Commission published a revised Commission Regulation (EU) No. 316/2014 on the application of Article 101(3) of the Treaty on the Functioning of the European Union to categories of technology transfer agreements, the so-called Technology Transfer Block Exemption Regulation ("TTBER"). The European Commission also published accompanying guidelines: the Guidelines on the application of Article 101 of the Treaty on the Functioning of the European Union to technology transfer agreements. The new rules will enter into force on May 1, 2014, and replace the previous regulation (EC 772/2004) and accompanying guidelines, which will expire on April 30, 2014.

The new TTBER will apply not only to new technology transfer agreements entered into from May 1, 2014, onwards, but also, as of April 30, 2015, to agreements concluded under the old regime. This means that agreements which entered into force prior to April 30, 2014, need to be checked for compliance with the new TTBER and, if not yet compliant, need to be brought in conformity by April 30, 2015, at the latest.

The TTBER provides a safe harbor under Article 101(3) of the European Union Treaty, which prevents license and other technology transfer agreements being challenged as anti-competitive under Article 101(1) of the treaty (the prohibition of anti-competitive agreements). The new TTBER, like the old one, stipulates under which prerequisites agreements are exempt from anti-competition challenges. It further contains a list of provisions which are not exempted, and thus subject to competition law scrutiny, under the so-called "Excluded Restrictions" in Article 5 of the TTBER, as well as a list of provisions which, if included in an agreement, would put the whole agreement and not just the concerned provision outside the scope of the safe harbor (i.e., the so-called "Hardcore Restrictions" under Article 4 of TTBER).

While the differentiation between excluded restrictions and hardcore restrictions, as well as other main principles underlying the new TTBER, remain the same as under the old law, certain changes are worth to mention, some of which specifically target, or have particular relevance for, the life sciences industry.

Changes Relevant to the Life Sciences Industry

Extension of the Exemption

The exemption applies from now on even to technology licenses containing other elements, such as obligations to buy equipment from the rights owner, as long as these are directly related to the products which the licensee makes with the licensed technology. This is the case even if those other elements are more valuable than the licensed technology. This will extend the scope of the safe harbor. However, most of the other changes restrict that scope and so expose agreements to a greater risk of being found anti-competitive.

Market Share

Under both the new and the old TTBER, an agreement only benefits from the safe harbor where the parties' combined market shares are below 20 percent if they are competitors, and 30 percent if they are not.

Under the new TTBER, the basis for calculating the licensor's market share has been clarified. The market share will now be calculated on the sales data for the products produced by the licensor and all its licensees in the relevant geographic area.

This change is likely to particularly affect the life sciences sector, where it is often difficult to calculate market share. A single product may constitute a single market, and so mean that the license does not benefit from the exemption. Calculating market shares on the basis of sales data is also problematic in the biotechnology industry, because innovations often originate in small- and medium-sized enterprises, which do not have the resources or expertise to develop compounds into pharmaceutical products.

The licensee — often a large and established company — is responsible for the further development, marketing and exploiting of finished products. Applying the new rule, the licensor and innovator will have no sales whereas the licensee may have 100 percent of sales and, thus, of market share. Such agreements would therefore often fall outside the safe harbor established by the new TTBER.

No-Challenge Clauses

An outright prohibition on the licensee to challenge the licensed intellectual property right (e.g., applying to invalidate the licensed patent) remains inadmissible under the new TTBER. Under the old law, however, parties were allowed to give the licensor the right to terminate, if the licensee brought a challenge. Such termination-on-challenge clauses can be found in many license and other technology transfer agreements.

The draft of the new TTBER suggested excluding termination-on-challenge clauses from the safe harbor altogether. During the consultation phase, this proposed tightening up of the rules was criticized by industry. While the suggestion might be important for the protection of licensees in industries in which they are economically weaker than the licensor, this is rarely the case in the life sciences sector.

As indicated above, the licensor is often the smaller and weaker party to the agreement. Allowing the licensee to bring challenge claims against the licensor without allowing the latter to terminate the agreement may put the licensor in an even more vulnerable situation, since termination would often have been its only weapon against the licensee.

The solution adopted by the European Commission is a compromise. Under the new TTBER, termination-on-challenge clauses will only be covered by the safe harbor, if the license is exclusive.

Termination clauses in nonexclusive licenses are excluded from the exemption, which means that they can be scrutinized and potentially declared anti-competitive by antitrust authorities. In the European Commission's view, this will in particular support SME innovators, which now have an incentive to license out their technology on an exclusive basis, without creating a situation of dependence towards their exclusive licensees.

Improvements and New Applications

Under the old law, a licensor could not insist on owning improvements to its IP, which the licensee made, but it could insist on these being exclusively licensed back to it, so as to achieve a similar effect, where those improvements were "nonseverable," meaning that the improvements could not be used without infringing the underlying patent.

This carve-out from the antitrust rules has disappeared from the safe harbor under the new TTBER. All exclusive grant-backs of improvements as well as new applications of the licensed technology developed by the licensee are now excluded from the safe harbor, regardless of whether the improvements are severable or not. Under the new TTBER, a licensor can require only a nonexclusive license of improvements and new applications, leaving the licensee free to exploit them.

Pay-For-Delay and No-Challenge Clauses in Settlement Agreements

Neither the old regulation nor the accompanying guidelines contained provisions concerning reverse payments — paid by the innovator to generic competitors — in order to delay or restrict the entry of the generic into the market. Following a number of inquiries and investigations by the European Commission in the pharmaceutical sector since 2009, reverse payments have been targeted by the commission as possibly being anti-competitive.

The increased scrutiny of pay-for-delay deals in Europe does not come as a big surprise following similar developments in the U.S. However, in contrast to the U.S., reverse payment arrangements and their compliance with competition rules have not yet been the subject of high court judgments in Europe; but administrative proceedings have been initiated by the European Commission against several players in the market, for instance against Servier SAS, Johnson & Johnson and Lundbeck A/S, amongst others. In the latter case, the innovator Lundbeck was condemned to pay a fine of €93.8 million and the four generic competitors €52.2 million each.

The new guidelines address pay-for-delay clauses to clarify that they are not covered by the safe harbor and may, thus, be held anti-competitive. If the parties to such a settlement agreement are actual or potential competitors and there is a significant value transfer from the licensor to the licensee, the European Commission will be "particularly attentive to the risk of market allocation/market sharing," which could take the whole of the settlement agreement outside the safe harbor, since market allocation and market sharing are hardcore restrictions.

No-challenge clauses included in settlement agreements are also subject to a new regime. While no-challenge clauses in license and other technology transfer agreements are not exempted, the new guidelines provide that no-challenge clauses in the context of settlement agreements are "generally" admissible. However, these clauses may in certain cases still restrict competition, for instance where an IP right was granted following the provision of incorrect or misleading information to the relevant patent office. The European Commission seems to have been particularly concerned that businesses are trying to protect patents despite substantial concerns about their validity.

These changes increase the possibility for antitrust authorities in the European Union to scrutinize settlement agreements with pay-for-delay or no-challenge clauses and initiate investigations and administrative proceedings against the parties, which can lead to substantial fines. Parties involved in settlement agreements falling under the competence of the European Union's antitrust authorities — whether or not they are based in the European Union — should therefore be particularly attentive to the newly adopted rules.

Technology Pools

Similar to settlement agreements, technology pools can be pro- or anti-competitive. For a pool to be treated as pro-competitive, the technology in it must be essential. The guidelines clarify the meaning of "essential": There must be no viable substitutes, both from a commercial and technical point of view, and the technology must be necessary either to produce the product(s) or carry out the processes to which the pool relates, or to comply with the standard supported by the pool. The new guidelines also set out the conditions under which both the creation of a pool and licensing of technology by the pool to third parties generally benefit from the exemption, in particular imposing the obligation to license the pooled technology on fair, reasonable and nondiscriminatory terms.

Effective Date

Pursuant to Article 10 of the new TTBER, it applies not only to agreements concluded after its entry into force on May 1, 2014, but also to agreements already in force on April 30, 2014. If existing agreements satisfy the conditions for exemption of the old law but not the conditions of the new TTBER, a transitional period is granted until April 30, 2015, during which the prohibition of Article 101(1) of the European Union Treaty shall not apply.

In other words, parties to license and other technology transfer agreements in force on April 30, 2014, have one year in which to make sure their agreements conform to the new rules, or they risk having them declared anti-competitive by the competent authorities as of April 30, 2015.

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