New EU antitrust law burdens licensing

The European Commission (EC; Brussels) has implemented new Technology Transfer Block Exemption Regulations (TTBER) to define rules with which companies need to comply to be exempt from proving that a licensing agreement does not hinder competition. But the haphazard 'one-size-fits-all' rules are a poor fit for biotech companies, which are dependent on licensing for income and to access technologies.

Since May 1, companies striking a deal with an EU partner systematically have had to prove to the EC that the deal does not break antitrust laws, but rather works in favor of competition. The EC has established a set of criteria that will exempt companies that meet them from the trouble of actively demonstrating they are in line with antitrust laws. If firms meet this so-called 'block exemption,' their licensing agreement is considered safe. If companies are legally challenged and don't meet the exemption criteria, they will need to convince the EC that their deal does not hinder competition—a costly and time-consuming proposition.

Most biotech companies consider the guidelines complicated and disagree with some of the criteria necessary for exemption. For example, a licensing agreement will not be eligible for 'block exemption' if the overall market share of both parties exceeds 20% if they are competitors or 30% if they are noncompetitors. This approach is an attempt to harmonize licensing regulations with other deals such as distribution agreements, which commonly use market share as a method of distinguishing competitors from each other.

The stance of the European biotech industry association, Europabio (Brussels), is that using a market share threshold to determine whether block exemption is applicable is not compatible with the needs of a sector that heavily relies on licensing, like biotech. For example, a biotech company that brings an innovative product to the market for an unmet medical need would automatically command a 100% market share and would therefore not benefit from the exemption. "[The new TTBER] are not good for [promoting technological] breakthroughs," says Valentine Korah, professor of competition law at University College London. She believes there is a risk that "parties will chose to do their R&D in the United States, Canada or Australia" because antitrust laws in those countries are not as restrictive.

In order to meet the 'block exemption' criteria, companies will be burdened with additional legal costs that could otherwise have been spent on R&D. "[TTBER] add cost and complexity to licensing," says John Murphy, legal director at PharmaGene (Royston, UK). Agreements, past and future, will have to be drafted in a way that does not include restrictions that are black listed in the TTBER (see **Box 1**). For example, the agreement should neither restrict parties from developing competing technology, nor set a threshold below which the product cannot be sold, according to Matthew Warren, partner at law firm Bristows (London). "It is going to be very difficult for small companies because [TTBER] require a lot of legal advice," warns Ian Harvey, CEO of BTG (London).

On May 1, national courts in Europe replaced the European Commission to deal with antitrust challenges on licensing agreements.

TTBER could also prevent companies from entering an exclusive deal unless they word the agreement in a particular way. To strike an exclusive agreement, a company must prove that that it has improved the technology and that there is no method other than exclusivity to bring the product to market in a timely manner, according to Korah.

Another issue is that TTBER are retroactive, which adds a level of uncertainty to the long-term validity of licensing agreements. "It is a time bomb," explains Peter Cozens, chair of the intellectual property working group of the BioIndustry Association (London). "The commission could examine licensing deals retrospectively, once a product is successful." This means that companies have to think about their future market. If their market share nudges above the exemption threshold after the agreement has been signed, the parties could have to renegotiate the agreement, creating more costs and headaches. Companies would then have to define through self-assessment whether they are breaking EC anti-trust laws, which forbid collusion practices such as price fixing, production control and market sharing. Only a company challenged in court would need to prove its case.

Given the time and cost involved in the self-assessment exercise, companies may just ignore the law and try to stay below the EC's radar screen. If a deal is challenged, the case will be dealt with by national courts, which replaced the EC on May 1 in deciding whether an agreement is anticompetitive. Clearly, companies could also use the law to disrupt the work of competitors. "Competition law could be more like a sword than a shield," warns John Wilkinson, partner at law firm Bird and Bird (London). He recognizes, though, that smaller biotech companies are unlikely to spend their limited resource on court cases.

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Box 1 Examples of restrictions forbidden in licensing agreements seeking block exemption

- Restriction of a party's ability to determine prices when selling products to third parties
- Limitation of output or sales, except for nonreciprocal agreements
- Allocation of markets or customers (for example, through geographical parting)
- Restriction of the licensee's ability to exploit its own technology
- Restrictions of the parties' ability to carry out R&D, unless such restrictions are indispensable to prevent disclosure of know-how to third parties

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