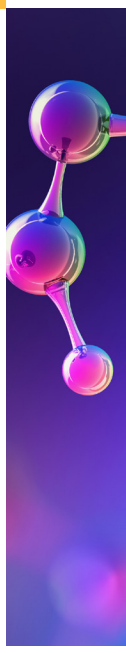
Licensing: Developing combination therapies grows in popularity but creates unique hurdles for partnering agreements

LICENSING TRENDS:

The accelerating pace of the development of combination therapies will increasingly complicate the structuring of licensing agreements.

New regulations around pricing and market access will continue to make partnering increasingly complex.



Combination therapies — therapeutic and diagnostic products that combine different drugs and/or biological products — are on the rise. For example, with the success of new classes of checkpoint inhibitors (a type of immunotherapy used in cancer treatment), research into the health benefits of combining active therapeutics and immune response modulators has accelerated at an astonishing pace and will continue in 2022 and beyond. But just as these therapies are more complicated, so are the partnerships that bring them to market.

A combination therapy creates new pathways to market and potential new uses for a particular compound or biologic. It also introduces new variables that must be considered when structuring the licensing and partnering arrangements. We therefore expect both the pace of partnering and the factual complexity involved in partnerships to increase in line with the accelerating pace of research and development for combination therapies.

Combination therapies pose unique challenges for developers. For instance, the licensing of combination therapies is a very different arrangement from traditional licenses of a single compound for use in a monotherapy. They bring different questions to mind when structuring and create the potential for misalignment of interests between licensor and licensee. For example, because the combination often is targeted to specific disease states and patient populations, the likelihood of indication-splitting increases, meaning the licensee gains rights to the combination for particular disease states rather than for the mitigation or treatment of all diseases. Also, fixed-dose combinations need to be considered carefully for their potential impact on pricing and the allocation of value to the components in the combination. In the year to come, it will be crucial for licensees to be mindful of such concerns when structuring their partnerships.

In 2022, regulators are expected to increase their focus on reducing healthcare costs. This is likely to continue to exert downward pricing

pressure and create increased tension over the allocation of value in a shrinking pool of revenue for a particular therapeutic treatment. As discussed in the Global Drug Pricing section of this report, recently introduced regulations around pricing and market access will also continue to make partnering increasingly complex.

LICENSING TIPS:

- Life sciences companies should consider whether a combination therapy can or will be priced as a single combination therapy, or whether there will be separate pricing for each compound.

- If a generic or biosimilar is introduced as competition to one compound in the combination, the company should consider whether and how this will affect the value of the combination therapy, and by extension, the other compound in such combination.

- If the compound retains significant value and opportunity beyond the initial partnership, companies should think carefully about who controls pricing and market access for the compound. They should also consider the impact of generic or biosimilar competition on each party's right to use data and IP relating to the combination.

- Companies need to remember that the licensee is selling the combination therapy, but may share revenue with the licensor on only one component.

- Life sciences companies need to consider responsibility for market access, pricing, and patient support activities for each compound used in the combination.

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