Bloomberg Law

INSIGHT: How Biotech, Pharma Team Up to Promote Their Products

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Biotechnology companies are increasingly seeking to team up with drugmakers to promote products under a single brand name—a strategy that allows them to build up their sales force with the help of an established drug company. Ropes & Gray attorneys explore how negotiators tailor these collaboration agreements to win deals and provide data on market trends.

The life sciences industry is witnessing an explosion in biotechnology companies joining teams with pharmaceutical companies to promote products under a single brand name.

The trend, called co-commercialization, co-promotion, or co-detailing, appears to be driven, at least in part, by skyrocketing biotechnology valuations and increased competition among pharmaceutical companies to partner with biotechnology companies to license key technology. In this environment, biotechnology companies are increasingly gaining the leverage to demand co-commercialization arrangements.

Co-commercialization arrangements are valuable tools that allow life science companies to share in the financial risks and rewards associated with the development and commercialization of a drug product.

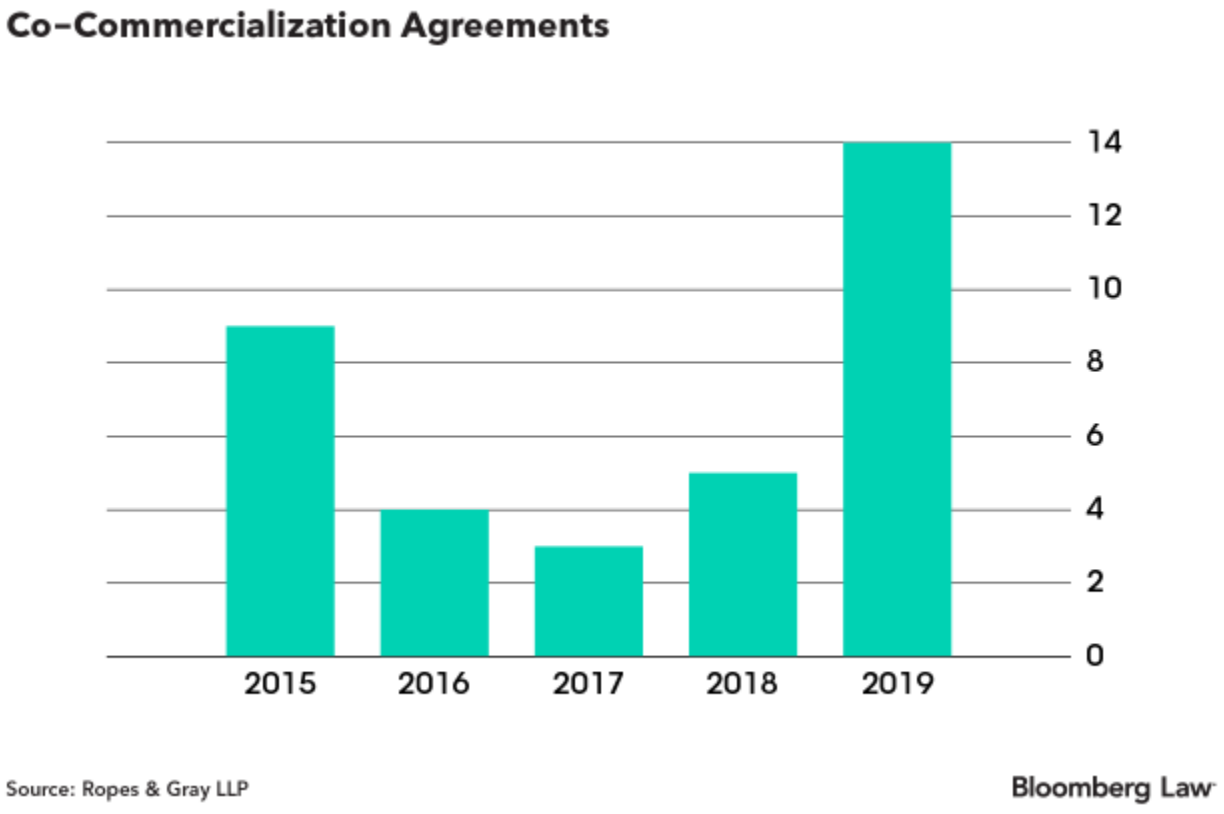
Ropes & Gray conducted a sample survey of life science collaboration agreements and observed over a four-fold increase in the use of co-commercialization arrangements from 2017 to 2019.

Although our sample size was limited, our survey echoes observations shared to us by industry insiders—co-commercialization arrangements are hot.

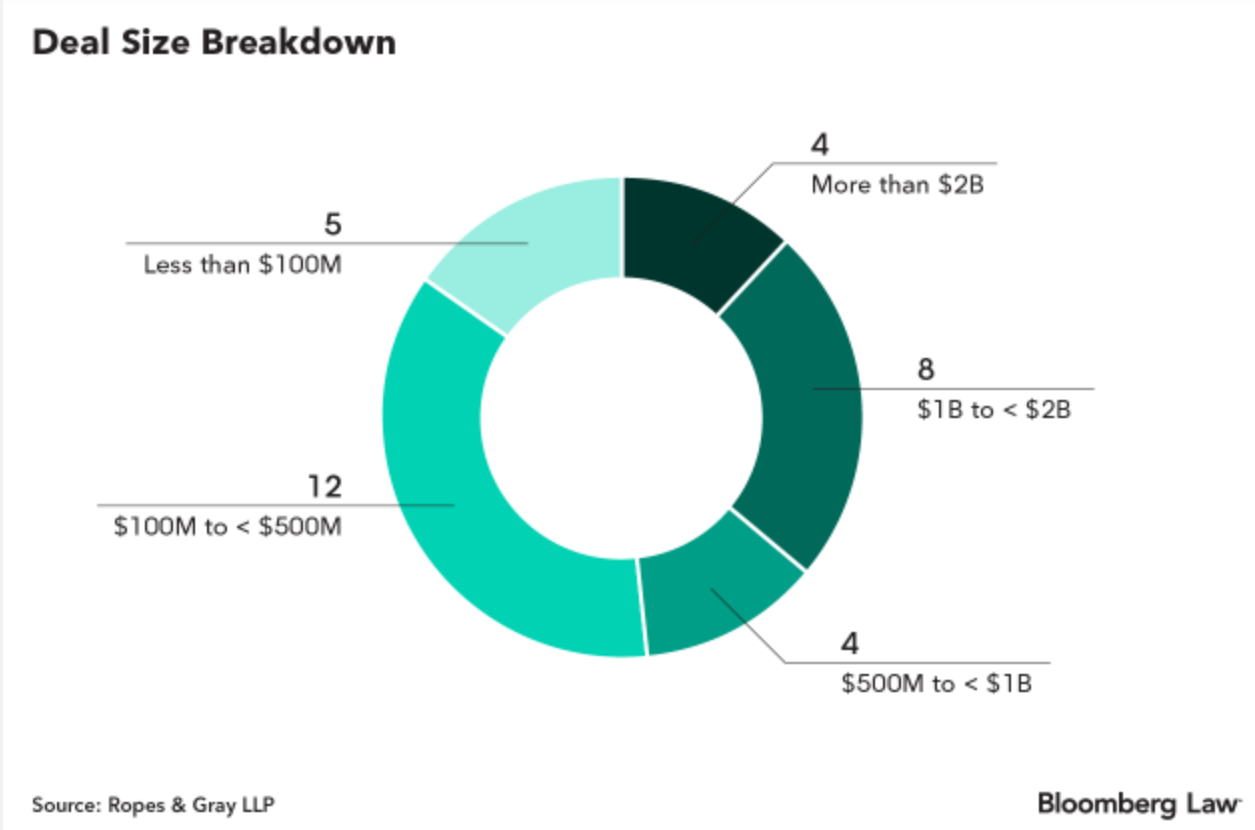
This Insight highlights some of the creative ways negotiators tailor collaboration agreements to win deals and provides data on market trends for co-commercialization terms. While our survey showed some common trends, we found that there is an abundance of diverse approaches, with no "one size fits all" approach.

Recent Trends

We reviewed all agreements dating from Jan. 1, 2015, until Dec. 1, 2019, that were publicly available in redacted form via filings with the Securities and Exchange Commission or otherwise confidentially available to our firm. We identified 35 agreements containing co-commercialization arrangements. Figure 1 illustrates the sharp growth in the use of co-commercialization arrangements over that period.



We also reviewed related press releases for these deals. We calculated that the average deal value size, where such information was available, was approximately $840 million, taking into account upfront payments, milestone payments and other equity investments. Figure 2 breaks down the deal value sizes of the surveyed agreements.



More than three-quarters of surveyed agreements involved pre-clinical stage assets, with the remainder covering clinical-stage assets. Nearly half of agreements were for cancer therapies.

Timing for opt-in varied widely. Popular opt-in times focused on the filing of an investigational new drug application, completion of Phase I clinical trials and the filing of regulatory or marketing approval of a product.

Only two agreements hard-wired the biotechnology company's co-commercialization rights from the outset, as opposed to giving the biotechnology company the right to opt-in.

The vast majority of the surveyed agreements limited co-commercialization rights to the U.S. A handful of agreements further allowed the biotechnology company to co-commercialize in one other territory.

Negotiation Considerations

We found that companies take a variety of approaches with co-commercialization, with no one-size-fits-all solution. We highlight below some drafting considerations that negotiators can consider with these arrangements.

Basic Co-Commercialization Terms. Parties can consider tailoring the fundamental terms of a co-commercialization arrangement, including geography, products, and duration. For example, the geographic territory can be narrow (e.g., U.S.) rather than broad (e.g., worldwide). An agreement could also be limited to a set number of products or the opt-in period could be narrow.

Criteria for Opt-In. One approach to limit co-detailing options is a requirement that biotechnology companies meet certain threshold criteria before they can opt into co-detailing activities.

These criteria can be specific and objective (e.g., having a sales force of a certain size in place by a certain date) or more general and subjective (e.g., having sufficient capability, in the pharma company's reasonable discretion, to be an effective co-detailing partner). We have also seen agreements that only permit the biotechnology company to opt-in if net sales of a product are below a certain dollar threshold by the end of the year.

Profit/Loss Share. Traditional co-commercialization schemes have the parties equally splitting profits and losses of the co-commercialized product. However, we have seen ratios such as 80-20, with the pharmaceutical company receiving the higher share. We have also seen cases where profits were equally split, but commercialization costs were not.

Negotiators could consider approaches other than strict profit sharing. We have seen deals where the biotechnology company received a set amount of compensation per detail rather than a share of profits. Another approach may include a royalty "buy up" scheme, where the biotechnology company could instead receive higher royalty payments upon opt-in.

Development Costs. While parties typically split development costs 50-50, it is not unusual to see pharma companies bearing a higher share. Negotiators should contemplate whether the biotechnology company will reimburse the pharmaceutical company for any past development costs incurred prior to opt-in. Our survey showed that in most cases, past development costs were not reimbursed.

Governance. Parties need to determine which issues joint committees will oversee. For example, does the pharmaceutical company create the joint commercialization plan or does the joint committee?

In addition, parties must determine how committee disputes are resolved. From our survey, the majority of agreements gave final decision-making authority to the pharmaceutical company. However, some agreements provided that disputes escalate to arbitration.

Commercialization Activities. Coordination of specific co-commercialization activities is another area for parties to address. Even if co-detailing is in a shared territory, should the parties have the right to designate some geographies or types of medical practices to be the sole domain of one party? These types of questions can significantly affect deal finances.

Opt-Out Rights. A slight majority of the surveyed agreements gave biotechnology companies the right to opt-out of co-commercialization. Parties can consider whether to limit opt-out rights to a specific period, or let the biotechnology company opt-out at any time.

Our survey showed that most agreements did not time bar opt-out rights. While opt-out often triggers reversion to the economics in place prior to opt-in (e.g., milestones and royalties), we have seen other unusual approaches, such as penalty fees for opt-out.

Change of Control. Change of control clauses are an underutilized tool in co-commercialization agreements. A pharmaceutical company could include a change of control trigger, allowing it to terminate the biotechnology company's co-commercialization activities, disband joint commercialization committees, cease co-detailing activities and limit information sharing to just high-level financial information.

In summary, co-commercialization arrangements are valuable tools that allow life sciences companies to share in the financial risks and rewards associated with the development and commercialization of a product. It is increasingly important that life sciences companies familiarize themselves with different approaches to negotiating co-commercialization terms to effectively close favorable deals.

For a deeper analysis on this topic by Ropes & Gray, see their Bloomberg Law Practical Guidance.

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