How Pharma Cos. Can Evaluate Alliance Agreements' Validity

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In 2013, the U.S. Supreme Court issued a landmark decision regarding antitrust reverse payments in Federal Trade Commission v. Actavis.[1] The court's decision was followed by a surge of more than 25 antitrust cases that were filed or revived, such as the Loestrin 24 Fe antitrust litigation and the Opana ER antitrust litigation.[2]

A central issue in these cases is whether certain alliance agreements are legitimate, i.e., are they sham agreements? Alliance agreements can take many forms, including intellectual property license, research and development, collaboration, marketing, distribution, and promotion agreements.[3]

The alliance agreements being asserted as sham typically were entered into by and between a brand pharmaceutical company and a generic pharmaceutical company contemporaneously with agreements to resolve patent infringement disputes.

Companies in many industries regularly enter into alliance agreements in order to enhance their business development activities and pursue mutual benefits and/or complementary interests. Such alliance agreements may help to mitigate scientific and business risks associated with the assets and opportunities underlying these activities, and allow the co-parties to take advantage of their respective capabilities and strengths.[4]

Alliance agreements in the pharmaceutical industry are particularly pervasive. Based on publicly available information, pharmaceutical companies[5] entered into more than 3,000 alliance agreements involving assets in development (discovery stage through Phase III clinical trial) between 2011 and 2019.[6]

More than half of these agreements involved early stage assets (i.e., discovery or preclinical). Senior management representing the co-parties in such alliances recognize that only a small percentage of the products associated with these early-stage development alliance agreements will receive regulatory approval and ultimately be commercialized.[7]

Yet, despite the low probability of regulatory clearance and successful commercialization, as well as the significant costs incurred to discover, develop and bring a new drug to market, the potential upside can be substantial, as witnessed by the number of blockbuster drugs commercialized over the past decade.

As industry activity accelerates in a rush to develop, manufacture and distribute an effective COVID-19 vaccine, questions are likely to arise about the nature of these agreements, many of which are being made in haste under pressure to solve the crushing health and economic impact of the pandemic.

During times of economic uncertainty, pharmaceutical companies may feel pressure from shareholders to close more deals in a shorter time, resulting in such alliance agreements not being fully vetted. Understanding and evaluating the validity of such alliance agreements requires extensive real-world experience in structuring, valuing, negotiating and drafting these agreements.

Prior to determining whether an alliance agreement is worth pursuing from a strategic and financial perspective, parties need to consider due diligence activities in a variety of pharmaceutical-related contexts. The extent of due diligence performed by a co-party can vary and may depend on different factors such as information asymmetry, familiarity with the therapeutic area and target information, availability of germane information on the product, and projected revenue and profit.

There is no typical approach to due diligence as pharmaceutical companies may face different circumstances. In our experience, examples of common practices in due diligence include the valuation of the potential alliance agreement by a third party (e.g., external consultants) to forecast sales and revenue growth, to determine whether the proposed deal exceeds a co-party's internal hurdle rates (e.g., target rate of return), and to provide critical knowledge for negotiation purposes.

The co-parties' achievement in clearly defining roles and responsibilities, risks and rewards provides foundational elements for success of the potential alliance agreement.

A reality of such alliances, however, is that a portion results in disputes between the co-parties. Such disputes can arise when one co-party believes the other has violated the agreement in part or in full. In other instances, a third party, such as the government or a class of individuals/businesses, may dispute the legitimacy of the alliance itself, as in FTC v. Actavis.

Dispute resolution may then be pursued through the courts or through arbitration. While many disputes settle, important themes have emerged in decisions in such matters, including a determination of what constitutes a material breach.[8]

Real-world experience in structuring, valuing, negotiating and drafting alliance agreements may be helpful to the co-parties, third parties and the courts in demystifying the evolution and negotiation of the terms of the agreement. Real-world experience can be especially useful in explaining such key features as the valuation of the underlying business opportunities and the due diligence efforts of the co-parties, and can provide context for understanding the circumstances surrounding the negotiation of the agreement and highlight its key provisions.

An experienced expert can assist the court in determining whether the business development processes leading up to the agreement and whether the provisions of the agreements are consistent with industry custom and practice.

Evaluation of the Validity of an Alliance Agreement

FTC v. Actavis provides an illustrative context for understanding how to appropriately evaluate the legitimacy of an alliance agreement.[9] Pharmaceutical companies may agree to settle a patent infringement dispute or threatened litigation in which the defendant, the generic pharmaceutical company, agrees to cease its alleged infringing activity on the plaintiff, a brand pharmaceutical company, or not pursue at-risk launch and sale of the alleged infringing product.

While settling the litigation, the two pharmaceutical companies may also enter into one or more contemporaneous business transactions, i.e. alliance agreements. The legitimacy of such contemporaneous business transactions may be challenged by third parties with claims that they are a form of a reverse payment made by the plaintiff to the defendant as part of the overall settlement.

A third party may claim that such contemporaneous business transactions were not borne out of legitimate business necessity and/or that the value ascribed by the plaintiff to the defendant is inconsistent with the underlying value of the business development opportunity.

In its 2013 decision, the Supreme Court held that reverse payments, while not presumptively unlawful, may be anti-competitive when they involve payments that are large and unjustified, and require some rule of reason to evaluate claims to the contrary.[10] The court's decision was categorical only in its rejection of the more presumptive rules that had been proposed previously, and took the middling position that such settlements sometimes violate antitrust laws, leaving it to the lower courts to apply the rule of reason.

Since then, different district courts have come to conflicting decisions regarding reverse payment agreements, leaving the issue far from settled.[11]

When evaluating the legitimacy of an alliance agreement, an expert may be asked to opine on the validity of any disputed alliance agreement. He or she may be able to opine on whether the circumstances and provisions of the alliance agreement are consistent with those of comparable and/or similar alliance agreements that are regularly entered into by pharmaceutical companies. The expert may assess:

- Whether the premise of the alliance agreement was aligned with the strategic business interests of co-parties, based on information available to the parties' decision makers at the time (ex ante);
- Whether the alliance agreement's structure and key provision and clauses (e.g., due diligence) were consistent with those of other alliance agreements; and/or
- Whether the financial terms of the alliance agreement were consistent with the parties' valuations of the business opportunity, with industry custom and practice, and/or within the range of financial terms found in comparable or similar alliance agreements.

In doing so, the expert can help to evaluate the validity of the alliance agreement in dispute based on his or her professional experience and supported and corroborated by available evidence, including information produced by the co-parties, testimony, research and analysis of publicly available comparable and/or similar agreements from third-party databases, and academic and industry literature.

Types of Evidence Relied Upon in Evaluating Legitimacy of an Alliance Agreement

- Professional experience negotiating alliance agreements;
- Documents relied upon by co-parties during agreement negotiation;
- Testimony (e.g., deposition, declaration);
- Publicly available comparable/similar agreements; and
- Academic and industry literature.

Expert opinions on the characteristics of alliance agreements may also be relevant to other types of legal matters, such as transfer-pricing disputes, allegations of material breach, or patent infringement disputes. As with reverse payment cases, expert opinions can be useful in explaining the evolution of the agreement and the rationale underlying the key provisions and clauses.

Regardless of the nature of the dispute, the prevalence of alliance agreements in the pharmaceutical industry, and the resulting litigation that may arise, will likely result in the need for expert opinions based on real-world experience to help evaluate such agreements and resolve disputes.

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Endnotes

1 FTC v. Actavis, Inc., 133 S. Ct. 2223 - Supreme Court 2013.
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4 Id.
5 Pharmaceutical companies include those developing large molecule biologic drugs and small molecule drugs.
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7 DiMasi J.A., Innovation in the Pharmaceutical Industry: New Estimates of R&D Costs, Tufts Center for the Study of Drug Development. (https://static1.squarespace.com/static/5a9eb0c8e2ccd1158288d8dc/t/5ac66afc-6d2a732e83aae6bf/1522952963800/Tufts_CSDD_briefing_on_RD_cost_study_-_Nov_18, 2014.pdf).
8 MDS v. RadSource, 720 F.3d 833 (11th Cir. 2013) (finding a breach of contract due to failure to pay maintenance fees for the patent, but finding that the breach was not material).
9 FTC v. Actavis, Inc., 133 S. Ct. 2223 - Supreme Court 2013.
10 Id.
11 Gallagher, Michael, et al., "United States: Pharmaceutical Antitrust," Global Competition Review, September 20, 2019.

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