A Practical Solution To Life Sciences Joint Venture Disputes

By **Scott Bass**

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The burgeoning world of medical technology and innovative pharmaceuticals is woven with thousands of intricate joint ventures and acquisitions among huge established innovators and nimble emerging stars.

With the advent of recent severe pricing and comparative effectiveness limitations imposed by the Inflation Reduction Act, the new European Drug legislation and an unstable investment climate, potentially explosive disagreements threaten to disrupt many promising development and commercialization ventures.

What we address here is how to keep the delicate dance of business marriage from tripping into sadly predictable implosions — most often created by discordant compliance cultures and conflicting visions.

Sound, systematic input from a neutral board provides a steam valve to lower the temperature before these issues escalate and become financial disasters or costly legal battles. These boards may, in fact, alter the intercompany deal landscape by creating a presumption of successful interface that leaps over common cultural clashes and avoids lawsuits.

Proof that deals need help can be found in the record of recent life sciences arbitration awards: In the first half of 2023 alone, there have been four public licensing and misappropriation awards,[1] involving claims ranging from hundreds of millions to billions of dollars. The number of arbitration filings is much higher, since most proceedings remain confidential.

As litigation costs rise and the approval stakes get trickier, given more excruciating government approval scrutiny, disagreements have grown quickly into war.

Scenarios to Watch For

Consider the following hypothetical scenarios that could cause early friction between companies.

Research Joint Venture and Unreported Pharmacovigilance Signal

An emerging company CEO decides not to report a signal in a Phase III clinical study, relying upon her medical director. The larger company quality person in charge of pharmacovigilance is furious. The contract provides escalation, but there's no real path past the CEOs. A clash of viewpoints and cultures looms as the fate of the drug lies on the table.

Joint Commercialization Agreement With Out-of-Territory Promotion

Both companies receive good training on off-label and preapproval promotion, but Partner A decides to use social media to sell over the border of its defined territory — and violates the law in that country. Company B is furious but seemingly without practical recourse. Company B considers blowing up the whole deal.

Joint R&D Agreement With Defective Market Authorization Holder Filing

An emerging company CEO takes the lead on the final approval documents since it is their baby. Advice from the larger partner is politely ignored, and a faulty application is filed in both Europe and the U.S.

The application includes a request for a weak second indication that is barely supported by clinical data but pushed by an investor. The U.S. Food and Drug Administration Prescription Drug User Fee Act filing date is missed, and hence investment milestones are also missed.

Reimbursement Triggers Missed and Drug Loses Price Base

Especially with the new U.S. and European legislation noted above, there are many signals — legislative, administrative and other — that require immediate actions to stem best price, comparative effectiveness or reference price disasters. The viability of a drug is often on the line.

Toll Manufacturing Contract and Systems Failure

A market approval holder subcontracts to a toll manufacturer that refuses detailed inspections by the holder.

A subsequent good manufacturing practice failure causes a recall. Recourse for these situations is rarely adequately fleshed out in quality agreements. They need objective direction going forward, as there is usually no alternate manufacturing site and millions in sales at risk.

Advisory Boards

All the above scenarios are sadly common, often with personal visions being the deciding factor. The good news is that a recently developed oversight mechanism provides a solution for these potential time bombs.

Life sciences dispute advisory boards, also known as review boards, provide an economical way to make deals work and keep the ground cool. This is not mediation or litigation — that is where conflicts create opposing trenches and require lawyering up and taking sides. Dispute advisory boards, agreed upon as part of the initial deal agreements, remove future cultural clashes and resolve common joint venture hiccups.

Composition

Boards are made up of three people who have deep industry expertise and who keep abreast of the operation so that if an issue simmers, they immediately can weigh in with a practical, risk-based and smart advisory decision. The three board members are:

- A seasoned industry executive;
- A medical or regulatory industry veteran; and
- A lawyer with extensive practical industry knowledge.

All should ideally have deep industry experience, including in Europe and Asia, because: (1) many trials and marketing agreements span multiple continents, and (2) catching cultural

warning signs is often half the battle. Also, all should be accustomed to making risk-based decisions, not just reciting the law.

Meeting Frequency

Boards should meet at least two times a year. The board will get updates on key fronts from a few designated company leads and thus be ready as any issues simmer to the surface.

How Issues Are Raised

If a dispute seems not immediately resolvable, the designated company lead person will contact the dispute advisory board members. The two disagreeing teams will send a written statement of the issue along with any relevant documents. Then a meeting will take place with the key players and the advisory board. No lawyers need to be hired.

What Happens Next

The advisory board meets and will ask for a second meeting to explore the facts or will go right to a meeting to discuss the joint advisory committee recommendation.

In most cases, this settles the issue. If a strong disagreement remains, the joint venture or acquisition agreement will provide for escalation, which would be a formal dispute resolved through mediation, arbitration or court filing.

Dispute advisory boards are about making deals work. In the examples above, a dispute advisory board would have been able to provide closure without an expensive contentious proceeding — and would have done so quickly — and without pitting the parties against each other.

This is about making deals last by reconsidering the day-to-day functioning of any joint pharmaceutical or medical tech arrangement.

The stakes are now so huge and rife with risk that building up a steam valve is much safer than permitting explosions based upon inadequate experience, conflicting cultures or overly conservative approaches.

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[1] Tanabe Pharma Corporation/Novartis (Global Arbitration Review February 2023), GenMab/Janssen (Global Arbitration Review April 2023), I-Mab Biopharm/ Tracon (Global Arbitration Review April 2023) and Janssen/Alkermes (Global Arbitration Review June 2023).