Resolving Life Science Collaboration Disputes

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Life science companies frequently collaborate to develop drugs or devices. Some collaboration agreements refer disputes to arbitration. Others are silent so any disputes go to court.

On the whole, arbitration works better to resolve disputes that occur during the collaboration, while court litigation works at least as well and maybe better to resolve disputes that occur after the collaboration ceases.

As a result, collaborators should consider agreeing that disputes be submitted to arbitration if the arbitration request is filed before the collaboration terminates or to resolve a dispute about whether the collaboration has been terminated, but that any later disputes proceed to court.

The commonly sought advantages of arbitration include speed, confidentiality, the ability to choose the decision-maker and finality given the very limited right to judicial review. By contrast, court proceedings have the advantages of liberal discovery rights before trial, jury trial rights and the ability to obtain review and correction of errors of law on appeal.

But every collaboration agreement this author can recall is "all or nothing;" that is, it either has an arbitration clause covering all disputes relating in some defined way to the collaboration or it has no arbitration clause at all.

Although logic suggests that the advantages of arbitration fit better with the circumstances of collaborators during the arbitration, this author cannot recall seeing a clause that limited the arbitration remedy to that time.

Arbitrations seem to work well to resolve disputes over rights of control during the collaboration. One example was the reported arbitration between Biogen Idec Inc. and Genentech Inc. regarding their collaboration on Rituxan and follow-on products.

Biogen Idec commenced an arbitration to establish the need for both companies, not merely Genentech, to approve certain development plans. Genentech counterclaimed in the arbitration to establish its superior rights based on the theory that when its collaboration partner, Idec Pharmaceuticals, had merged with Biogen Inc., to form Biogen Idec, there had been a "change of control" under the collaboration agreement, thus enlarging Genentech's rights.

The arbitration panel determined that both parties, through their joint development committee, needed to approve a development plan for specific diseases before the plan

could go forward, and rejected the claim that there had been a change of control, allowing the collaboration to get back to work.

Similarly, in a case relating to a collaboration regarding the Salk Institute for Biological Studies AIDS immunotherapeutic, progress in the collaboration ground to a halt due to a dispute about which party controlled the regulatory filings.

The arbitration was resolved within 60 days from filing, including discovery, two weeks of hearings and a decision reaffirming one party's right of control and allowing the development program to move ahead. [The author represented the prevailing party.]

In a more recent example, a dispute arose between Merck & Co. Inc., and a Johnson & Johnson (J&J) affiliate regarding their collaboration on Remicade.

When J&J's original counterparty in the collaboration, Schering-Plough Corp., acquired Merck & Co. Inc., and Schering-Plough then changed its name to Merck & Co. Inc., J&J filed an arbitration in May 2009 claiming this was a "change in control" that would enhance its rights in the collaboration.

The parties announced a resolution of this dispute by agreement in 2011—perhaps more quickly and likely with less public disclosure than a court action might have required.

Collaborations often involve subjective levels of effort that the parties must make regarding development, regulatory approval, marketing and the like, such as "best efforts" or, more frequently these days, alternative requirements such as "commercially reasonable efforts" or "diligent efforts."

Arbitration seems to work for disputes between ongoing collaborators regarding whether one party is fulfilling its duties, such as when Glenmark Pharmaceuticals Inc. obtained an interim arbitration order to prevent a termination of a development agreement by Napo Pharmaceuticals Inc. for the gastro-intestinal compound crofelemer—where Napo purported to terminate for the alleged failure of efforts by Glenmark.

Another example is the arbitration recently filed by Sucampo Pharmaceuticals Inc. against Takeda Pharmaceuticals USA Inc. for allegedly inadequate efforts to promote and sell Amitza.

Arbitration even seems suited to the determination whether a collaboration is terminated. So, when Warner Chilcott Ltd. filed an arbitration to determine whether it had the right to terminate its collaboration with Sanofi-Aventis U.S. LLC regarding Actonel, the arbitration resolved that it did not have that right and the collaboration continued.

The importance of having a prompt and definitive resolution of disagreements during a collaboration is underscored by the fact that many collaboration arbitration clauses provide for very limited discovery, presumably on the theory that collaborators will already have good information during the collaboration.

But this is often much less true after the collaboration has ended. And some collaborations put such a high value on prompt and definitive resolution of disputes that the parties have even agreed to give one of the parties the tie-breaking vote.

Such unilateral tie-breaker rights have been reported publicly for collaborations between Roche USA and Memory Pharmaceuticals Corp., Pfizer Inc. and Elan Pharmaceuticals Inc., and Verus Pharmaceuticals Inc. and AstraZeneca plc.

But it's not so clear that arbitration is the best option after the collaboration has ended.

To be sure, there are examples where significant damage recoveries have been achieved, such as the International Chamber of Commerce arbitration award of $91 million to Asahi Kasei Pharma Corp. against CoTherix Inc. where the latter was acquired by Actelion Pharmaceuticals Ltd. and ceased work on the collaboration to develop fasudil.

Another example is Elan Pharmaceuticals' arbitration recovery of $49.8 million in milestones and expenses from King Pharmaceuticals Inc. for termination of their development agreement for its Sonata MR insomnia product.

But the efficiency of arbitration proceedings is less demonstrated once the collaboration has ended and the mutual interest in a prompt decision may have vanished. A recent illustration is the arbitration between two public pharmaceutical companies regarding ownership of certain patents following the termination of their collaboration.

The dispute was ordered to arbitration in 2006, not decided by the arbitration panel until 2010 and finally resolved in the courts in late

2011. And even then the parties had no right of judicial review for errors of law.

Once the collaboration is concluded and the parties have gone their separate ways, court litigation may be more appropriate than arbitration.

For one thing, after the collaboration has ended, the parties may need court discovery to find out the relevant facts. Several years ago, Eli Lilly and Co. claimed that its long-terminated collaboration with Elan Pharmaceuticals gave Lilly joint rights in a promising Alzheimer's vaccine announced by Elan. Elan sued to clear its title.

Unlike an arbitration, discovery was freely available in court. And when Lilly refused to answer whether it had any ongoing programs that, by its legal arguments, would also be joint property, the court was quick to order it to answer, and the parties soon resolved the matter by a court-guided settlement within 14 months after initiation of the action. [The author represented Elan.]

Courts can also deal efficiently with accusations of inadequate efforts by a party to a terminated collaboration. For example, when AstraZeneca ended its collaboration with Verus Pharmaceuticals regarding a delivery system to treat pediatric asthma and went forward instead with a competing technology, Verus sued. It alleged the failure of AstraZeneca to use the requisite "diligent efforts."

The court dismissed the case because Verus did not contest the validity of AstraZeneca's safety concerns as to the proposed treatment.

So, once the collaboration has ended and the parties are merely contesting rights remaining from the old collaboration—such as their respective rights to use technology from the collaboration—their rights of discovery and the importance of having appellate review on issues of law may be more important than the efficiency of arbitration, because the collaboration is no longer subject to being delayed by the dispute.

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