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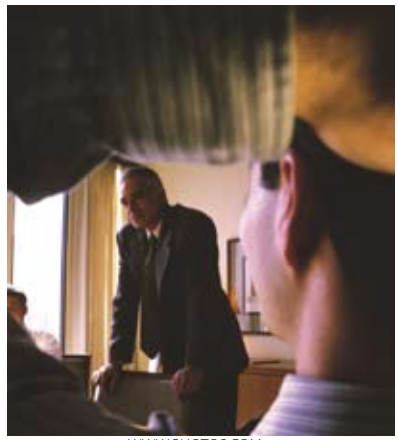
# Doing the Deal

## Avoiding Problems When Blending Small Biotech Companies with Industry Giants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**by Serle Ian Mosoff**

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Many advances in biotechnology — human, animal, and plant — come from academic laboratories and other nonprofit entities and from small entrepreneurial companies instead of from large pharmaceutical multinationals. Big pharma has taken note and discovered that entering into joint arrangements with more entrepreneurial entities is a lower cost, lower risk way to get insights into new technologies and products than trying to develop those insights in-house. For its part, "small bio" has discovered that big pharma offers not only cash resources, but also expertise that can't be provided by a pure equity funder. In addition, funding from big pharma tends to be more stable: Equity funding from other sources tends to vary with short-term investor perceptions.

So the impetus has been for big pharma and small bio to come together with visions of a synergistic future in an arrangement that allows each to do what it does best. The small bio brings its product to market and provides a new solution to a problem (and its owners become millionaires along the way), and big pharma fills its product pipeline cost effectively.

But the needs and desires of the two partners are inherently different. Small bio is tightly focused on its single product or technology whereas big pharma's focus is diffused among multiple product opportunities. Small bio is concerned about ceding control to big pharma, and big pharma is concerned about small bio meddling in further development and marketing activities.

Big pharma–small bio marriages require skills analogous to those required in making a fine vinaigrette: The oil and water blend can remain stable only under controlled conditions of preparation and proper maintenance. Otherwise, the two ingredients settle out with unhappy results for the salad or the business arrangement. This article discusses the main sources of dissatisfaction that emerge for both parties in small bio–big pharma blendings and ways to mitigate against the breakdown of the relationship.

### Dissatisfaction Will Happen

There will be dissatisfaction. Absent a crystal ball, the most informed negotiators and best lawyers will not be able to foresee every eventuality during negotiations. And even if they did, the original agreement may not adequately represent the parties' later needs. Negotiators must acknowledge the high likelihood that dissatisfaction will occur and provide institutionalized methods for dealing with it as it happens.

**Outlets for Dissatisfaction:** Some people find this concept objectionable in principle because it implies that they are preparing for failure even before they begin. My experience suggests otherwise. As human beings we are fallible, so our constructions are likewise fallible. Fighter plane pilots are comforted by the presence of a parachute even though they certainly hope they never have to use it.

We need to recognize that the disparate needs of the two entities are likely to cause some degree of dissatisfaction on one side or the other. Small bio may be late in providing promised deliverables. Big pharma may be unable to reproduce small bio's results or may be slow (in small bio's view, at least) in using the deliverables provided to move the product or technology along to the next stage.

Thus, it is important to provide a safety valve for the times when — not if — such problems arise. A useful safety valve is to allow each party to reproduce some portion of the other party's work or to use the other party's finished work in a different area.

### Reserved Markets

A common and useful safety valve technique is to reserve a small market area for the small bio to exploit. Not only does this channel small bio's frustration in a positive direction, it can also produce positive results that might goad the big pharma partner into quicker action.

Inherent in the concept of the entrepreneurial small bio is the strength of its belief in its technology or product. The constant narrow focus on a single technology or product is likely to push a small bio's efforts ahead more quickly then those of the more diffusely focused big pharma. This reality should be recognized and built into the structure of the agreements and timing of the work.

Big pharma may not be ready to absorb the results provided by small bio, or it may feel required to confirm the parameters of the process to determine its ultimate scope or to refine or optimize a process whereas small bio may be satisfied with proof in principle and wonders why big pharma is taking so long to react.

Reserved markets serve a useful purpose for small bio because it can test its products directly in limited markets without a major marketing effort. They provide a chance to experience the commercial realities of selling the product/process/technology and develop an appreciation of what is necessary to exploit the marketplace. Big pharma is also served by yielding a reserved market because that can provide another direction for small bio's

efforts. It minimizes small bio's feelings of powerlessness, of not being the master of the technology's destiny. And the nimbleness of small bio's efforts may show big pharma what the market thinks without it needing to be directly involved.

### Change in Interest

Consider these scenarios: Small biotech CEO and division VP of big pharma negotiate an arrangement. Small biotech CEO is likely to be an entrepreneur/founder and will probably be in the same position for a long time. Not so for the large pharma negotiator. A new manager is appointed, and at its next annual internal strategy meeting, big pharma decides that it has less interest in the arrangement. Its corporate outlook requires retrenchment. Or the big pharma division dealing with small bio's technology/product is sold to a new company with less interest — or even worse, competing technology.

These aren't hypothetical situations. They have occurred and resulted in huge lawsuits and huge judgments, such as in *IGEN v. Roche* (**1**) and *Enzo v. J&J* (**2**).

For a small pile of gold, most of it contingent on a product being developed and marketed, small bio has given away its jewels. What to do? After the fact, there aren't many options. So both parties are well served by considering those possibilities during the formation stage and providing a structure for dealing with such unforeseen circumstances.

The first step is acknowledging that neither party has a crystal ball. The second step is to consider techniques for ameliorating the consequences of such changes in direction. Then comes the even harder step of adopting appropriate techniques.

**Technique 1:** Big pharma often makes milestone payments to the small bio as steps are completed. An analogous concept can be applied in reverse: Big pharma must make an effort to bring the technology/product to the point where it can be exploited.

The underlying concept that must be articulated and expressly agreed upon is that big pharma is not buying a technology to do with it what it pleases. The price paid is for the development and marketing rights and those are expressly dependent on the expenditure of a specified minimum effort. That effort could be expressed in effort-days or in expense terms (somewhat artificial) or in terms of accomplishments (submission for regulatory approval, commencement of marketing, and so on).

This technique may be adopted as a negotiated number of days of work by employees of specified type on the project or as an additional payment to small bio to allow it to perform at least some of the missing work (if it can) or as the relinquishment of certain rights to small bio's technology/product. In any case, the monetary value of the consequence of big pharma's inadequate performance should be expressed and removed from the big pharma department's overall research budget.

It should be identified as an amount contractually required to be funded and paid. Removal of the funding decision from the annual R&D budgeting process is a powerful technique in small bio's arsenal because it transforms an easily made ordinary budgeting decision into a decision to breach a contract. In some instances, it might also be viewed with some favor by big pharma divisional representatives because it assures them of consistent funding during their annual budget battles.

This option is rather severe and will generally be objected to by big pharma.

**Technique 2:** This technique involves a negotiated narrowing of big pharma's exploitation rights.

A technique often specified in these arrangements is for the conversion of big pharma's exclusive rights to nonexclusive rights. This technique should be resisted by small bio in almost all cases.

Consider the likelihood of another company paying for nonexclusive rights to a product or technology that is still under development and for which it has to share future exploitation with the first partner (who allowed its rights to become nonexclusive). The questions the second partner will ask are "Why did the first company relinquish exclusive rights? Why should I work on a product/technology where the first partner has a long head start? Why should the first company have the right to compete with me when I've invested the time and cost of development?"

The likelihood of finding a strong interested second licensee is very low. Therefore, the value to a small bio of converting an exclusive license to a nonexclusive license is of little real value.

A variation on this technique that has more commercial reality and benefit to small bio is to narrow the rights of big pharma by narrowing the field of exploitation and totally excluding certain uses. In this scenario, the big pharma partner continues to maintain exclusivity in its areas of primary focus, but smaller, still valuable minisegments are returned to small bio to exploit by itself or to offer exclusively to another partner.

### Equity Investment and Its Use By Small Bio

On the whole, small bio benefits from the sale of equity to big pharma. There is the obvious benefit of receiving unallocated cash not subject to the requirement that it be used for the advancement of the licensed technology or product. Receiving an equity investment is especially important when small bio has been able to retain exploitation rights in selected market segments. It is hard to find funding, except from an equity investor, for further development in relatively small retained market segments. Unallocated funding allows small bio to determine for itself how and when to fund the development of its retained markets. The income might be used to develop opportunities in the retained fields of use or market niches without reporting to the big pharma partner.

But an equity investment can also be limiting to small bio because, as a large shareholder, big pharma can be perceived as exercising some degree of control. Also, other companies may be reluctant to partner with a small bio once a big pharma company has established an ownership position.

For these reasons, it is desirable to avoid is the installation of a big pharma representative on small bio's board of directors. If the equity investment is large enough, big pharma may insist on such representation; if big pharma obtains a controlling interest, it will be the norm. In some instances, big pharma, for reasons of its own, won't want to take a minority equity position.

### Potential Problems to Consider

Along side all the benefits associated with retaining market segments, small bio must recognize its accounting responsibilities when performing research and development using earmarked funds for which it is accountable to big pharma, along with its own funds. How will it allocate the resources of its limited number of scientists? On which project do its most creative scientists work? Unless the products or technologies are

distinctive enough to easily distinguish between them, problems will arise regarding payments and allocations.

Another question to consider is how many hours the scientists should spend on the joint projects. If a milestone is not met, is it because the scientists were working on small bio's own projects? These problems are not unsolvable, but they do require consideration and creativity by negotiators and agreement drafters.

The problems multiply when the creative scientists working on in-house projects in addition to the joint project make patentable improvements. It is curious how the inventions always seem to be made during the work done on in-house projects. Should there be a difference in how inventions are handled from the ownership standpoint if they are made during work on the joint project rather than while doing in-house work? Has small bio effectively opened itself to the claim that all future inventions made by its scientists belong to big pharma? How does big pharma police the other research activities of scientists assigned to its project?

## Ownership of Improvements

Big pharma makes a multimillion-dollar investment in small bio for certain rights to exploit small bio's technology or product. Invariably in human therapeutics, a marketable product (one that has passed regulatory review) will not be available, although in human diagnostics or animal health, the product may not need approval or may have already been approved for sale. So in human therapeutics, big pharma is expected to perform and fund the work necessary to advance a product to market.

If the technology or product is narrow — a single compound or a specific research tool — the additional work may not lead to additional patentable information. But if the product universe is wider or the tool has multiple uses, follow-on information may be developed by either big pharma or by small bio as it performs its assigned duties. The arrangement should address the question of rights to after-developed technology.

I suggest that logic ordains that regardless of ownership, big pharma should obtain exploitation rights in its market areas and small bio in its retained market niches.

## Plan Ahead

The areas discussed here are merely some of the many that can subtly promote or retard the proper functioning of an otherwise beneficial joint arrangement between companies of different size, different needs, and different expectations. The stresses inherent in relationships between such partners can be minimized and the likelihood of success maximized by taking the time to recognize the changes that occur over time and to build into the initial arrangement a structure designed to relieve some of those stresses.

## References


**1** *IGEN International, Incorporated v. Roche Diagnostics GmbH et al.*, 02-1537 (Fourth Circuit, 2003); http://pacer.ca4.uscourts.gov/opinion.pdf/021537.P.pdf.

**2** *Enzo Biochem, Inc. v. Johnson & Johnson, DC SDNY* 870.v6125 (Ro), settled before decision.



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