Once formal negotiations to develop a license are underway, a number of issues need to be considered to ensure a profitable relationship for both parties.

**Relationship development**

The relationship between the parties will have been building throughout the first-round non-confidential meetings and the due diligence process. It is important to create a sense of trust and be objective during any and all discussions. Enthusiasm, motivation, tenacity and commitment to concluding the arrangement are essential characteristics of successful deals. Deals often go through difficult stages but, by creatively seeking solutions, these can be overcome.

**Progress and timing of negotiations**

At the outset, it is helpful to set objectives for each meeting, planning and communicating the agenda ahead of each round of discussions. It is useful to keep a record of the progress of the deal throughout the negotiations. This can be most useful when one party has a sense of constantly conceding points, as it will be possible to review the balance of the discussions and determine how much each party has moved from its primary position.

Whilst it is necessary to be realistic about the length of time it takes to conclude a full contract, it is important to ensure that the negotiations maintain a reasonable pace. If there are long unexplained delays, these can be construed as a lack of commitment. Larger pharmaceutical companies can have a complex evaluation and approval procedure via a series of committees which will need to 'sign off' on each stage of a negotiation. It is important to be aware of the time frames that are required for such committee approvals and to ensure that the right information will be available for appropriate decisions to be made.

Often, biotechnology companies can have a very urgent need for cash at specific times (e.g. to pay for ongoing development) or the financing of a deal needs to take into account the financial year planning of one partner. Heads of agreement or letters of intent can be put in place prior to a full contract being concluded to allow payments to be released from a budget before the full agreement is signed.

**Mid-negotiation review**

Mid-term reviews during negotiation are useful to take stock of a situation. One can also break out to discuss the ramifications of any novel concepts that are introduced into the negotiation. The designated team observer may offer some insights on different aspects to an issue that are not immediately evident on first consideration.
The priority given to the deal by either party may well change during the course of the discussions. Occasionally, the deal can be completely overturned by events such as a change of ownership of one of the parties or a discontinuation of activity in a given therapeutic field. In the latter case, if a therapeutic area appears to be of declining interest, this can be addressed by including appropriate performance criteria.

It is always prudent to consider the alternative to a negotiated agreement as a potential fallback position. In this regard, it is important to keep a check on what other opportunities there are available and to be aware that the other party may well be running other evaluations and negotiations in parallel. This may influence the financial side of the negotiations, for example if the price for accessing the technology is perceived as being too high then this may close the negotiations.

Reality checks are necessary to review the terms against current market intelligence. There is a continuous flow of press releases giving outline terms for pharmaceutical licensing arrangements, which can be used to reinforce the valuation of the technology.

Common problems in negotiation

Problems do arise during negotiations and, because of the pressure to conclude agreements, difficulties can get blown out of proportion. 'Off-the-record' discussions should be very frequently employed to get around an impasse and to ensure that there are no miscommunications between the parties.

These private communication links can be used to establish the rationale behind key issues that might not otherwise be openly discussed, as well as to explore any lateral approaches as to what can and cannot work within the deal structure.

Hopefully, most of the potential difficulties will have been identified in advance during the due diligence. However, other problems will inevitably arise during the course of the negotiations as the relationship between the companies develops. It is important to identify problem areas early and to tackle the issue quickly. Once identified, the problem needs to be considered objectively; for example, is the problem a matter of opinion or one of fact?

If the former, then external opinions can be sought. If the latter, how accurate are the facts concerned? Further data can be sought to verify the contentious issue. Occasionally, problems occur within one team and need to be resolved within the team before the negotiation can progress. Creativity in reviewing a wide range of different options with commensurate outcomes can bring about a rapid solution.

Inevitably there will be issues that cannot be solved without 'off-line' discussion, possibly with additional experts. Rather than dwell on a negative issue during discussions it is preferable to defer the matter, if necessary calling a specific parallel meeting to address the issue, allowing the main negotiation to focus on other, more constructive, areas.
Changing the negotiating platform

This occurs when one other party apparently keeps changing its negotiating position. If this happens frequently, constantly adjusting the deal structure to meet the new criteria and new objectives gets very wearing. It implies a lack of commitment and uses up significant amounts of goodwill if there is no apparent logical reason (a change of management structure would, for example, be a reasonable basis for changing the negotiating platform). One way to address the problem is to put forward a proposal on a ‘last offer’ basis. This usually has the effect of forcing a definitive response from the other company.

Changing the negotiation team

Switching the authority within the team or negotiating with a team with insufficient or no authority can cause difficulties. One can try to access the senior persons above the existing team but this does not win favours with the team involved in the face-to-face discussions, who may need to recommend the deal or who will hold responsibility for its implementation. Similarly, changing the team representatives, so a matter can be discussed repetitively, is a tactic employed when a company is loathe to concede an issue.

Insisting on gaining prior approval for the main Head of Terms can ameliorate this problem.

Occasionally, a case may arise where one side is clearly poorly advised or does not have access to the right experts to assess a specific aspect. This situation most commonly occurs with start-up or biotechnology companies or universities.

Although there may be an obvious and immediate negotiation advantage in the short term, long term it may become clear that one party has unfairly exploited this weakness. This may have an adverse effect on the relationship during the implementation stages and may even prevent the parties from doing business again in the future.

Problems of detail

Despite having agreed the basic key terms, some discussions move on to become horrendously complex at a very fine level of detail. This can occur when one party makes a request, for example of transfer back of rights when one party is no longer interested in pursuing development. Because this appears a major concession to the other party, it is then conceded only on very limiting terms. These terms then require a complex supplementary agreement to cover pay back formulae on situations that might be highly unlikely ever to occur.

This can be an unnecessary use of negotiation efforts but it occurs because there is insecurity about the balance of the agreement overall. It is generally better to focus on achieving an equitable main agreement covering realistic issues. There will always be situations that occur post-signature for which one can negotiate, in good faith, further terms, with the added security of improved knowledge of the possible outcomes.

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