Controlling the risks of PARTNERING

The barriers to establishing an equitable partnership between biotechs and big pharma are high and many partnerships, once established, do not deliver the tangible and non-tangible value expected by the licensor. This article addresses how to develop and implement a partnering strategy that will deliver attractive value, avoid the erosion of current assets, be commercially defendable during the course of the negotiation and lead to a contract and partnership which will look as attractive in retrospect as it does on the day of signature.

By Dr Lynn Butler

Headline-grabbing deal announcements are often ends into themselves for Biotech management teams and shareholders, even in times of ample public and private funding. In the current climate of dwindling valuations and sparse cash, the drive to sign high value deals can distract even the most purposeful and exacting biotech management team from its need to nurture long-term as well as short-term objectives. In such climates, a sound and executable partnering strategy becomes an essential safeguard against corporate development errors. A press release announcing seemingly stupendous terms for a collaboration with Big Pharma X or Y is of little true value if the chances for long-term success of the partnership are low or if the conditions associated with the deal terms act to constrain the licensor from exploiting its retained assets. This article describes basic but powerful tools that a management team can use to mediate major partnering risks. The content is primarily focused on partnering of R&D projects by Biotechs with Big Pharma but is generally relevant as well to the partnering services and projects between companies of any size. A selection of partnering risks is listed in **Figure 1**.

A notable omission from this list is the risk of not receiving enough cash in return for the licensed rights. Deal value is undoubtedly of importance. A fat signature fee linked to the potential to gain stellar downstream milestone payments may generate short-term excitement and interest from the market. But the most important news events that a deal should eventually deliver are those that drive long-term corporate growth and shareholder value, eg successful project development and project launch, and continued growth of the licensee's retained and underlying assets, leading to new partnerships and new product launches.

Big Pharma as well as Biotech management teams can fall victim to the poor control of partnering risks. A worse case scenario is described in the story of a partnership between two pharmaceutical companies as summarised in **Figure 2**.

Basic but powerful tools to control the risks of partnering

Tailoring licensing strategies to corporate goals

It may seem obvious that corporate goals should

Figure 1: Partnering risks

- Lack of long-term commitment from the partner.
- Milestone payments that are linked to unachievable outcomes.
- Restrictions on the breadth of the licensor's retained rights and their use.
- An unintelligible contract which is difficult to monitor.
- Eventual collapse of the partnership.

Figure 2: A forced marriage that led to partnership failure

- The partners were not matched based on goodness of technical and commercial fit, but via 'the network' of management contacts.
- The deal negotiators had no scientific or commercial stake in the deal and did not seek the counsel or buy-in of those who would implement the deal.
- The partnership was signed and imposed on the development and commercial project teams.
- The project teams could not translate the contracted milestones into a plan of work and the deliverables linked to non-performance clauses were overlooked.
- When the licensee's portfolio strategy changed they scrutinised the contract for a way out and found it; the licensor had not met a key deliverable.
- The licensee cancelled the contract, sued for contract breach plus damages and settled on a multi-million Euro payment from the licensor.

Figure 3: Corporate goals and licensing strategies

- Partner selection: What are the prioritised corporate company goals and what skills and technology must a partner possess to support their attainment?
- Negotiating teams: Do all negotiation team members, decision makers and stakeholders understand and agree on the corporate goals and licensing strategy and can they convincingly support those elements in the context of a negotiation?
- Term sheets: How can a company's corporate goals be best expressed in term sheets and contracts?

Figure 4: What is required from a partnership?

- Retain rights for some indications, fields or territories.
- Option for active or passive co-development.
- Access to equipment and/or expertise.
- Asset swap for projects or patent rights.
- Cultural, geographical proximity.
- Retain manufacturing rights.
- Option for marketing rights.
- Partner hungry for growth or a market leader.
- Cash up front, royalties, equity.

form the blueprint for licensing strategies. But an examination of licensing practice demonstrates that this is not always the case, neither at Big Pharma nor at Biotechs. Many companies prefer and promote a level of autonomy and entrepreneurial spirit in their R&D and commercial directors whose views and actions may be at odds with those of decision makers. Even in the most hierarchical companies, renegade behaviour can result in independent initiatives that initially escape corporate surveillance. Controls usually exist within Big Pharma to prevent closure of licensing deals that do not fit with corporate goals. But many Biotechs, especially those under financial pressure, suffer from not matching licensing strategy to corporate goals. The risks associated with this lack of rigour are compounded when such Biotechs mix with the entrepreneurial or renegade members of Big Pharma.

A sound corporate development strategy that encompasses concise short and long-term goals is the most important tool for design of a risk-controlled and successful licensing strategy. These goals simplify the selection of potential partners, the prioritisation of objectives within individual partnerships as well as the preparation and negotiation of terms and conditions proposals and contracts. It is critical that all company representatives buy into the corporate goals and can articulate and defend them convincingly; without this capability, even the best-planned licensing campaign has little chance for success.

A review of the development of corporate strategy and its adaptation to emerging technical and market trends is beyond the scope of this article as is a treatise negotiation techniques and the execution of a full licensing campaign. But even advanced skills in negotiations and campaigns will fail in the absence of a targeted licensing strategy based on corporate goals.

Assuming that a sound corporate strategy with concise goals is in place, the answers to three fundamental questions (**Figure 3**) can provide a viable basis for building and executing a successful licensing strategy. The importance of these questions and their answers will be addressed in the following sections on partner selection, negotiating teams and term sheets.

Profiling and prioritising potential partners

What are the prioritised corporate company goals and what skills and technology must a partner possess to support their attainment?

Partnering risks can be substantially mediated by focusing partnering campaigns on those companies best placed to facilitate the attainment of corporate goals. A rigorous approach to partner selection will avoid wasting time with companies unlikely to progress to deal closure, unlikely to agree to the licensor's preferred deal terms and conditions, or those unlikely to retain sustained enthusiasm for the partnership following implementation.

The criteria used to screen for potential partners, and the prioritisation of these criteria, will vary depending on the clinical focus of the licensor, their technology and skills base, their needs for flexibility in exercising existing and future commercial and patent rights, and their management and resource requirements for progression of other projects in their portfolio. A mismatch of these criteria with the profile of potential partners can have a profound effect on opportunities for corporate growth. Examples of partner selection criteria are listed in **Figure 4**. Again, short-term deal value may feature as a low priority relative to those criteria a partner must fulfil to share a strong match with corporate goals and development strategy.

An example follows to illustrate the importance of matching corporate and licensing strategies. A Biotech sought to revise its market focus and to concentrate R&D funding in a select group of clinical areas. But the management was split on the decision to out-license non-core projects. A compromise was reached whereby the company sought co-development partnerships for the bulk of its non-core clinical pipeline. Numerous 50:50 co-development partnerships were established. The partner's budgets exceeded those of the licensor and the underlying contracts obliged the licensor to proscribed levels of investment. Cash resources at the Biotech were drained and human resources were diverted from core projects to the juggling of multiple collaborations. Ultimately the core project dossiers were sub-optimal, meetings with regulators and commercialisation partners floundered and share value declined.

Partner due diligence

The identification and prioritisation of partner selection criteria dramatically simplifies partner selection. A rigorous evaluation of actual versus perceived technical, development and commercial strengths of the potential partners can then commence. Likewise, a review of a company's partnering history can be instrumental in adapting terms and conditions to suit the licensing culture of a potential licensee. Examples of qualities to evaluate for potential partners are listed in **Figure 5**.

Partnering history – The licensor can refer to industry databases or interview contacts to assess the likelihood for a given company to be receptive to various deal constructs. For example, a potential partner may feature high on the list of candidates based on R&D and commercial strengths, but have no history of agreeing co-development arrangements or deals inclusive of equity investments. If these deal elements are critical to the achievement of corporate goals, this potential partner may merit contact but at a limited level to that reserved for others.

Perceived versus real R&D or commercial strengths – Many Biotech partnering campaigns focus on those companies having the biggest voice in a market of interest or those employing attractive enabling technologies. Yet such companies may not be those best positioned to complete a licensing negotiation or to demonstrate long-term commitment towards development and launch. For example, when seeking a research or early clinical development and commercialisation partner, a careful review of a company's existing development strengths and indication specific R&D investments more accurately signals the emerging marketing focus of a company than does their current marketed portfolio. A careful analysis should also be made of the potential for a licensed-in project to compete with a potential partner's existing portfolio; licensed-in projects are commonly the first to be ousted in times of budget constraints. Many licensors waste considerable time making presentations to and even entering negotiations with companies that are highly unlikely to complete negotiations and successfully implement a partnership.

Ownership of applicable technologies – Some partners may be attractive due to their use of sophisticated technologies, for example those that could enhance the physical properties of a drug or its production. The ownership any patents associated with these technologies should be confirmed. Are the relevant patents held by the potential partner or have rights been licensed; if the latter, what royalties are associated with the patent licence? A licensee will conventionally seek to share the burden for such third party royalties with the licensor, undermining the real cash in hand value of royalty rates as advertised in a partnering press release. This factor should be considered when ranking potential partners and must be accounted for when tailoring basic terms and conditions proposals.

Marketing infrastructure – Most licensors will assess the potential partner's marketed portfolios and revenues for relevant indications. A detailed review of the nature and level of a company's investments in market sectors is warranted. Does the company invest in building and maintaining relationships with clinical opinion leaders, regulators and payors? The results of such analyses provide a prognosis to a company's ability and commitment to compete in a given market. To what

Figure 5: Partner due diligence

- Partnering history.
- Perceived versus real R&D or commercial strengths.
- Ownership of applicable technologies.
- Marketing infrastructure.

Figure 6: The licensor's negotiating team

- Speak with one voice.
- Reticent stakeholders, one point of main contact.
- Technical or commercial representative to participate negotiations and contract drafting.

Figure 7: The licensee's negotiating team

- Confirm that the team has a corporate mandate.
- Identify and cater to the project champion.

extent does the company rely on marketing partnerships for product sales? The payments due to marketing partners can have a major negative impact on the licensor's residual royalties if not addressed in the partnering contract.

Negotiating teams – the licensor's and the licensee's

The licensor's negotiating team

Do all negotiation team members, decision makers and stakeholders understand and agree the corporate goals and licensing strategy and can they convincingly support these elements in the context of a negotiation?

Speak with one voice – The success of a partnering campaign is at risk if team members do not deliver identical messages regarding the corporate goals and licensing strategy in all internal and external communications. A frequently used and quite effective negotiating tool is to exacerbate perceived differences of opinion or competition between members of a negotiating team, even to the point of flattering selected team members to induce their allegiance to the licensee's position. Insuring buy-in and trust among team members is the best means to avoid this trap.

Reticent stakeholders, one main point of contact – This responsibility for consistency and clarity of message extends to stakeholders not directly involved in the negotiation. The resistance of these stakeholders to be lured into detailed discussions of ongoing negotiations with external contacts can prove a powerful negotiation tool and strengthen the effectiveness of the negotiating team. For example, it can be decidedly useful for the negotiating team to refuse concession on critical points by referring to the unswerving will of a CEO or board member external to the negotiation. This advantage can be diluted if stakeholders are insufficiently reticent in conversations with external parties. Even the best intended 'parallel discussions' could have serious negative consequences on negotiations.

A case in point based on negotiations between a major Pharma company and a Biotech with a particularly ambitious and gregarious CEO illustrates the sensitive nature of parallel discussions. The CEO sought social contacts with Pharma commercial directors and investors via membership in social and sports clubs. These contacts provided pivotal insights into corporate culture and industry trends and paved the way for introductions to key decision makers. The CEO's company then entered advanced negotiations with one of these companies on a deal that involved an equity stake for the licensor. The CEO failed to restrain his enthusiasm with his club contacts and information on the nature of the impending deal found its way to the press. The Biotech's share value surged upwards. In response, the licensor's Managing Director demanded that the negotiations be terminated, but ultimately agreed to closure only given removal of the equity component. This effectively halved the signature fee and did little for the reputation of the Biotech CEO.

Technical or commercial representative – Both in the case of technology platform licensing as well as R&D or commercial projects, the negotiating team should include a person well versed in the technical and commercial aspects of the licensed project. Their expert advice is needed not only for technical presentations and the design of workplans, but importantly, for the review of draft contracts. Their role is to insure the technical feasibility of contract milestones and deliverables. As such individuals are usually not contract law experts, they can also play a role in insuring that the contract is understandable by laymen. Top quality contracts are those that the general management of the company can use as a readily comprehensible guide to monitor contract obligations and deliverables. In the event that the licensor will have an ongoing responsibility for the licensed project after deal closure, the technical representative is a prime candidate for the role of partnership project manager or inter-company liaison.

The licensee's negotiating team

Two critical qualities of the licensee's team merit attention to gauge the potential likelihood for success in a negotiation (**Figure** 7).

Confirm that the team has a corporate mandate – It is important to seek clarification on the decision making structure of a potential partner to identify the internal champion who will back or sign any eventual contract and to confirm that the licensee's team has a strong mandate from the ultimate decision makers to proceed with negotiations. This is essential to avoid wasting time in ultimately futile negotiations which collapse or result in provisions that will eventually be rejected by senior management. Potential licensors are advised to request that a line of contact between a member of their negotiating team be established with a senior decision maker in the licensee's organisation from the time of entering formal full due diligence onwards. If serious doubts over the licensees commitment surface, it is wise to request a Letter of Intent signed by a member of the potential licensees senior management. Such documents may have little legal value depending on the prevailing national law, but they can be used to confirm that the negotiations have the attention and support of those who will 'sign the check'.

Identify and cater to the project champion – Many negotiations and partnerships falter or fail because the licensee lacks a deep understanding of the licensed technology or its marketable applications. This risk can be controlled by identifying the individual who will champion the project within the licensee's organisation. The champion's satisfaction with, and comprehension of, project related materials, term sheets and relevant portions of draft contracts should be closely monitored. Ideally, the project champion or their representative will participate directly in the contract negotiations. It is likely that this individual will be responsible for implementing the licensed project after contract signature. To a large extend the initial success of the partnership thereafter will reside with the licensee's project champion and their supporting team.

Corporate goals and the term sheet

How can a company's corporate goals be best expressed in term sheets and contracts? Basic principles are described below and summarised in **Figure 8**.

Adapt core terms and conditions to each potential partner – With the commercial goals prioritised and translated into a licensing strategy, the potential partner's required attributes defined and target companies identified and ranked, the negotiating team is well placed to design a core terms and condition proposal. Adaptation of core term sheets, within the parameters of the key licensing objectives, is usually required to enhance receptivity by each potential partner. These adaptations will be based upon information gathered during partner due diligence.

Opening terms and conditions proposals often encapsulate the key objectives of the licensor, embellished with points that are intended as 'throw-aways' to concede as required. This approach can be effective, but it is most productive if the overall complexion of the proposal is generally viable for the targeted partner, even if the magnitude of the individual terms is not.

For example, the licensor's corporate goals may include a short-term cash infusion for use in acquiring key enabling technologies or early stage research projects. These goals may be reflected in a proposal via the request for a sizable signature fee and early milestone payments for potential licensees having a history of such deals. For other potential licensees having a large range of enabling technologies or projects, a portion of these early payments could be met by the grant of a licence against the technologies or an asset swap in lieu of cash.

Avoid logical inconsistencies in term sheets – Many negotiating teams yield to the pressures of market conditions and include overly ambitious terms in their opening proposals. Some teams base the structure of their terms on published deals. Both approaches can lead to logically inconsistent components within term sheets if corporate goals and the commercial viability of the terms are not considered. Much time, credibility and trust can be lost debating ill-conceived proposals with potential partners. The ensuing confusion can lead the licensor to lose sight of the key strategic goals of a partnership and can confound their ability to clearly communicate these goals during negotiations. This leads in turn to misdirected counter-proposals from the potential licensee and further loss of time and good faith.

Rigorously debate and proof-check the legal and commercial defensibility of the terms – Extensive internal debates on the defensibility of

Figure 8: Corporate goals and the term sheet

- Adapt for each potential partner.
- Avoid logical inconsistencies.
- Rigorously debate and proof-check the legal and commercial defensibility of the terms.
- Protect the licensor's residual and underlying rights.

individual points within terms and conditions proposals, and the interrelationships of the individual components, greatly assists successful negotiation outcomes. The team must be prepared to present a united front on the commercial rationale for each component of the term sheet and the relationships of related components within the term sheet. Their negotiating position will not be compelling or sustainable if it is clear that individual team members place different weights on the various deal components. For example, what limitations on the field or territory of use will the licensor be willing to concede in return for an increase in royalty levels or milestone fees? Is the licensor's clinical representative able to argue this point with the same fervour as their CFO if cornered by the licensee's representative during a break in the negotiations?

Protect the licensor's residual and underlying rights – An applicable cliché is that 'if you are not careful you may get what you ask for'. Many Biotechs are keen to realise the PR and cash that result from a major collaboration but they are reluctant to lose control of what is often their most advanced project. In response, they may seek to retain development rights for some indications or applications of the licensed intellectual property or project. Given well-developed skills and discipline in portfolio management, retaining partial rights can be a boon to corporate development options and enhance company valuations. If portfolio management skills and discipline are lacking, the retained rights can instead become an alluring perceived 'safe bet' into which a disproportionate percentage of resources are sunk, depriving the remaining portfolio from much needed investment.

Another partnering risk is particularly high in companies which offer technology platform services in parallel with development of their own R&D pipeline. Judicious monitoring of resources against corporate goals and licensing strategies is required to insure sufficient human and financial resource for both sides of the business. A second and more pernicious challenge for such companies relates to potential conflict of interest between the service and R&D components of their business. Execution of service contracts often involves disclosure of confidential and patentable information by the client, which can constrain the licensor's freedom to progress internal research related to that information. Clear corporate goals must be in place to insure that licensing strategies account for and are valued against the potential loss in freedom that service deals may impose on R&D development plans.

Conclusion

Experience is the best tool for success in the design and execution of a successful and profitable licensing campaign. Yet attention to the basic tools described above has been proven to substantially enhance the control of partnering risks, simplify the partnering process and assist in the realisation of corporate goals and long-term shareholder value. DDW

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