Negotiating performance clauses in licensing contracts

Trusting a prized technology asset to another company will always require a number of guarantees, particularly if the licence granted is going to be an exclusive one. Of course actually agreeing the performance measure is only the first step – there are then the penalties or possibly incentives for adhering to the agreed performance measures.

by Roger Davies, Pharmaceutical Licensing Group (UK)

Background

Does every licence include a performance clause? The level of performance required will to some extent depend on whether the licence is an exclusive licence or a non-exclusive agreement. For an exclusive licence the licensee is the only party able to develop and commercialise the asset. Failure to do so can be catastrophic because the return of the asset to the licensor carries with it a sense of damage, ie the originally perceived value of the asset is diminished and valuable time may be lost. This can make it difficult for the licensor to secure another licensee that will deliver the same degree of return as the original one. This effect is seen not only in licence agreements but also where options are granted and the acquiring party elects not to take up the rights. So it is well accepted as a basic principle that it is inequitable to have an exclusive licence without any performance obligations.

For non-exclusive licensees, the position is different. However there is a need, where there are several licensees, that each has parity of commercial terms with the other. This can range across a number of clauses, including the ability to call on supply of product when supply is short. The clause most frequently used to achieve this is referred to as a most favoured nation clause and prohibits the licensor from granting other licensees more favourable terms than those agreed with another party. This clause can occasionally be used to achieve an exclusive licence without paying the level of fees usually associated with exclusive licensees.

These clauses become increasingly important when taken in conjunction with the merger possibilities – a product asset that was viable for a company pre-merger may become less viable to the newly merged company with higher sales thresholds.

In this case, the first licensee offers above average terms which no other party would be able to accept, thus achieving an exclusive position. This can be extremely damaging for the licensor, especially if the company is trying to get a wide uptake, for example a platform technology.

Characteristics of performance clauses

Typically these clauses are being used to measure performance across a range of parameters – measuring performance in pre-clinical and clinical development, regulatory, supply and sales and marketing. To be truly effective, these measures need to be both independent and objective as well as being easily auditable from an external perspective. Achieving this is not easy and clauses therefore tend to be general, ie the company will use its best or reasonable efforts (or similar words to that effect) to achieve the specified objective.

Non-specific performance clauses

The most widely accepted clauses are 'best efforts' and 'commercially reasonable efforts'. In practical terms, best efforts are interpreted as meaning an obligation to do the utmost to achieve the desired results. In contrast, commercially reasonable efforts are taken to mean an obligation to undertake what is deemed reasonable. This obligation is often qualified by reference to other products offering similar commercial potential to the licensee. The key difficulty in both of these clauses is that they are dependent on a subjective judgement.

These clauses are most often used in a typical biotech (licensor)–big pharma (licensee) deal where the concern from the licensor is that the licensee does not in-license the asset defensively, ie acquire the rights and then do nothing with them. Fortunately in the current climate, with the strong drive to fill pipelines, such defensive licensing is now rare, but there remains the concern that the asset should receive equal priority to the licensee's in-house projects, which may offer a better return to the company.

In contrast, the major pharmaceutical company may not want to accept an obligation that forces it to develop a product with the same priority and resources as their in-house projects especially if the product profile is found to be suboptimal or the project is no longer a core strategic interest. Hence, the freedom to be able to manage its own portfolio will be paramount and consequently accepting anything too specific becomes unworkable.

These clauses become increasingly important when taken in conjunction with the merger possibilities – a product asset that was viable for a company pre-merger may become less viable to the newly merged company with higher sales thresholds or a different strategic focus. Delegates at the meetings in Madrid and Cambridge were asked to vote on the clauses they were prepared to accept, and the votes for the two types of non-specific clause are shown in Table 1.

Table 1: Votes for types of general performance clause

Clause	Votes	
	Madrid	Cambridge
Best efforts	40%	10%
Reasonable efforts	60%	90%

The results support the view that 'best efforts' clauses are generally less acceptable, although it is recognised that in some areas, eg maintenance of marketing authorisations, there should be an absolute obligation and both 'best efforts' and 'reasonable efforts' are not adequate. Delegates also commented that 'reasonable efforts' is difficult to enforce and few delegates had taken legal action, preferring instead to settle with the third party. The lack of enforceability of a non-specific 'reasonable efforts' or 'best efforts' clause usually results in 'specific' performance clauses also being included in the agreement.

Development performance clauses

With specific performance clauses there are three aspects to consider: the performance clause itself; the 'escape' clauses relating to the performance obligation; and the penalty for failure to achieve the required performance (or incentive for over-achievement!).

In the case of development, getting the product to market in a timely manner is critical – time is of the essence and every day's delay carries the cost of a day's lost revenue, earlier competition and increased development costs. However, in development, many factors that can delay the development fall outside the control of the licensee or licensor, for example regulatory delays, where it is difficult to penalise the licensee or licensor for matters outside their control and where both parties suffer. This is an example of an 'escape' clause (Table 2).

Where development is being entrusted to a licensee, the licensor can obtain some measure of control by the use of a joint development committee.

In the development phase, it may be appropriate to consider whether incentives (eg bonus payment for early registration) rather than penalties are more effective. Penalties can include the payment of a milestone irrespective of the milestone event being reached, a reduced milestone for delays within the developer's control or, as a last resort, termination.

Table 2: Examples of development performance and escape clauses

Performance clause	Escape clause
Milestone achievement and timing by developer	Delay caused by non-developing party, eg change in programme
Minimum development resources (FTEs, $ spend)	Delay caused by factors outside developer's control

Sales and marketing performance clauses

In setting appropriate sales and marketing performance measures it is important to consider what the key objective of the deal is. Revenue generation? Establishing a new chemical entity (NCE) in the market? Maintaining market sector dominance? The objective and the type of deal will influence the choice of measure, for example in a co-promotion deal it will be critical to specify the level of detail for the product. In an NCE licence agreement it may be the market coverage; in a generic deal establishing and holding a level of market share may be key.

Sales and marketing minimum performance clauses are the most complex, have the most escape clauses and the most creative penalties!

Table 3 indicates the voting in Madrid and Cambridge. As the clauses are not mutually exclusive, the number of votes is shown rather than a percentage. The number reflects the terms that are most acceptable.

Table 3: Examples of marketing performance clauses

Clause example	Madrid	Cambridge
Minimum level of royalties	21	14
Minimum sales volume	32	14
Minimum purchase volumes	42	11
Minimum sales value	35	11
Minimum number of reps and detail priority	22	8
Minimum promotional spend	11	2
Achieving % market share	12	2

As expected, the most popular clauses are those that relate to product sales in one form or another, whether measured as royalties, volumes, values or purchases. Marketing resource minimums are less popular. Only the last criterion – achieving market share – is a performance measure that takes into

account the competitive position of the product in the sector but has the drawback for the licensee that, even if the sales target is achieved, other changes in the market may prevent the market share being achieved. When asked what should be the level of minimum sales (measured as a ratio of the licensee sales forecast), the delegates in Madrid responded as shown in Table 4.

Table 4: Minimum sales forecast levels

Minimum sales forecast (% of target)	Licensee position	Licensor position
25%	0	1
50%	46	15
75%	9	29

As expected, the licensors expected a higher percentage but of course the percentage is dependent on the degree of optimism of the original sales forecast!

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On signing a licence agreement, there will remain a high degree of uncertainty over many aspects of the technology, and most licensees will seek to mitigate their marketing performance obligations by including a variety of 'escape' clauses as noted in Table 5. The number of votes reflects the acceptability of the clause.

The escape clauses relevant to each of the minimum performance targets are shown in Table 6.

Table 5: Examples of marketing escape clauses

Escape clause	Madrid	Cambridge
Supply failure	39	12
Patent challenge or failure	31	9
Regulatory delays	30	8
Target profile not achieved	23	1
Government-imposed price reductions	15	1
Unexpected direct competition	10	5
Economic hardship	4	4
Parallel imports	1	

Other reasons for failure to achieve marketing minimums were cited, such as a product defect or a catastrophic market failure. Not surprisingly, the least acceptable escape clauses to a licensor were the hardship clause, the impact of competition and the effect of parallel imports.

Penalties

In setting performance criteria and escape clauses one needs to give close consideration to the penalties for failing to adhere to the agreed criteria.

There are several choices to be made in relation to the failure to perform – it is always possible to put a monetary value to the loss of income. For example, in a situation where a licensee has failed to achieve the minimum royalties it may be preferable to allow the licensee to make a shortfall payment rather than to terminate the licence. If it is an exclusive licence, it is always possible to alter the degree of exclusivity to non-exclusive. However, in practice, this is not a very meaningful penalty. If one company is not performing well with a given product then it is difficult to encourage another company to enter the market with the same product. Termination of the agreement (with the full and complete return of all of the rights) may appear more draconian but may be more appropriate. Other measures will depend on the benefits in the contract. For example, if there are co-promotion rights included then these can be withdrawn. The grant of any future options can also be removed. These penalties are not mutually exclusive and an agreement may contain different penalties, dependent on different circumstances. Also it may be the licensee rather than the licensor who can choose which penalty to accept. In the workshops the delegates voted fairly evenly between the three options presented (Table 7).

Other performance measures apply to the manufacturing and supply aspects of the licensing agreement. Performance measures will include timeliness of supply and that the product meets the precise quality specification. Batch failures do occur, more frequently with biological products. The immediate remedy is to replace the stock free of charge. However, long-term failure to supply can lead to a transfer of manufacturing know-how. Clearly this is not an effective remedy unless there is a second manufacturing site included on the product licence.

In conclusion, performance clauses are an essential part of an exclusive licence. The negotiation of these clauses can cause a lot of anguish to both sides because of the focus on negative 'what if' scenarios. To prepare for this negotiation it is recommended that both sides prepare a hierarchy of performance clauses, escape clauses and penalties that they would like to apply in each 'what if' scenario and critically consider which of these, if any, are 'deal-breakers'.

Table 6: Relevance of escape clauses to performance targets

Clause	Market share target	Sales or royalties target	Sales volume target	Promotion target	Launch target
Product profile	✔	✔	✔	✔	
Approval delay	✔	✔	✔		✔
Price reduction		✔			
Competition	✔	✔	✔	✔	
Parallel imports		✔	✔	✔	
Supply failure		✔	✔		✔
Hardship				✔	

Table 7: Penalties on termination

Penalty	Madrid	Cambridge
Termination	43	7
Loss of exclusivity	30	9
Shortfall payment	25	n/a

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