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For the Pharmaceutical Licensing Groups

Biotech turns to strategic alliances as VCs flee

Licensing deals: make provision for termination

'Small pharma' may offer better partnerships

Striking a balance on off-label and unlicensed use

Early termination of license agreements

As is often the case with marriage, the possibility of an early termination and its potential consequences are often disregarded when entering into a license agreement. Addressing the possibility of divorce in advance may point to a lack of confidence in a joint future, but provision for license termination and its repercussions is critical.

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Parties entering into a license agreement are enthusiastic about concluding the deal and working together, and do not want to think about termination. But the majority of all collaboration and license agreements for a compound in pre-clinical or clinical development are being terminated before any commercial sales. The licensee will ask for flexibility in order to be able to move away from its performance obligations. The licensor, on the other hand, will want to ensure that the licensed technology is not devaluated by an early termination and that the development project or the marketing of the licensed technology is not delayed.

Several different types of events may trigger a termination, and each has a different potential remedy.

Termination at will

In these circumstances, the licensee will want to have the flexibility to terminate a license agreement, either at any time and without any cause, or for defined reasons, such as commercial or scientific viability of the licensed technology. A licensee that loses interest in the licensed technology or no longer believes that the technology will be successful does not want to remain bound by the agreement, namely by the duty to meet certain performance obligations. It may not be advisable for the licensor to bind the licensee to a technology they are no longer interested in. In such situation a commercial solution should be found.

For the licensor, a termination at will can have severe negative consequences. Finding a new licensee tends to be difficult if the first licensee when terminating has documented its diminished interest in the technology. To mitigate such negative consequences, the licensor may want the termination agreement to allow a statement that the licensor has reacquired the technology, rather than received a notice of termination.

Furthermore, the licensor should ask for compensation for losses incurred as a result of such termination. Since it tends to be difficult to prove the damages actually incurred, providing for an exit fee to be paid upon termination is advisable. This fee could either be specified, or at least the formula to calculate it, in the license agreement.

The licensor, on the other hand, typically does not have a right to terminate at will. The licensee cannot agree to the risk of losing access to the licensed rights in the event that the licensor finds a better way to exploit the technology.

Termination for material breach

In this scenario, the licensor has the right to terminate if the licensee is in material breach of obligations under the agreement and does not make good such a breach within the agreed rectification period. The licensee may be in material breach if it does not make agreed payments on time or if it does not meet performance obligations, for example not commencing the studies or the marketing required to exploit the technology.

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In order to avoid disputes over whether there is a material breach, the license agreement should specify the obligations considered material and set out the conditions under which such obligations would be seen as breached. Otherwise, depending on the applicable law, standard practice is that it would be unreasonable for the licensor (the terminating party) to remain bound to the license agreement (under German law, for example), or that the breach deprives the licensor of the essential benefits of the license agreement (under the laws of England and Wales, for example).

The license agreement should provide rectification periods, giving the licensee the chance to rectify the breach to avoid termination. Only if this 'last chance' period expires without the material breach having been addressed is it reasonable for the licensor to terminate. The length of such periods may depend on the specific obligations – the license agreement may, for example, specify a rectification period of 15 days for payment obligations, while the period for breach of performance obligations may be as long as six months.

In practice, the termination of the license agreement by the licensor after licensee breach is often not accepted by the licensee. There may be dispute over whether the licensee is in breach and/or whether the breach is material. Such dispute results in an unfavourable situation for both parties, with uncertainty as to whether termination has come into effect. The licensor may not be able to find a new licensee willing to take the risk that the original license is void, while the licensee will not want to make further investments into the technology if there is a risk that it no longer owns the license. Either party would have to file suit or commence arbitration proceedings (whatever dispute resolution process is agreed) to obtain a declaratory judgment on termination. This may take years and therefore has the potential to destroy the commercial value of the technology.

The license agreement should address this possibility. A solution may be to specify that if the licensee disputes the validity of termination for breach, it must promptly begin dispute resolution proceedings, that an expedited process is to apply and that the license in such event remains effective pending a decision. Furthermore, if the termination is subsequently declared valid, the licensee would have to compensate the licensor for damages incurred through delaying the effective date of termination.

The licensee typically does not want to terminate for a material breach by the licensor. Unless otherwise agreed, a termination would mean that the rights to the technology revert to the licensor. If there is a material breach by the licensor, for example if it does not prosecute, maintain or defend the licensed technology, or because the licensee is in breach of its confidentiality obligation by disclosing the licensed know-how to a third party, then the licensee may obtain a preliminary injunction and claim

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damages – but it would still not want to lose the license.

Alternatively, the license agreement can specify that, in such an event, the licensee retains the right to use the licensed technology, and that the terms and conditions of the license agreement are amended to reduce either party’s reciprocal obligations. However, such a structure needs to be considered carefully so that it does not provide incentives to improve the rights and obligations by way of a termination. Some agreements even provide that, in the event of a breach by the licensor, the licensee could retain the licensed technology and would no longer have to make payments to the licensor. This typically is not a fair and adequate response to licensor’s breach.

Insolvency

In looking at insolvency, a distinction needs to be made between the insolvency of the licensor and that of the licensee.

The licensor may want to terminate if the licensee is insolvent and therefore no longer in a position to invest in the technology and make the agreed payments. Depending on the applicable insolvency law – which is the insolvency law applicable at the residence of the insolvent company and not the law on which the parties agreed in the license agreement – there may be a ban on terminating the license agreement and/or the administrator in insolvency may have the option to assume the license and meet its obligations, or allow termination. It is advisable to act promptly and review what means need to be taken to mitigate the damages resulting from the insolvency of the licensee.

Insolvency of the licensor is the most critical situation, however. This is not because the licensee would want to terminate, but because the administrator in insolvency of the licensor may take the licensed technology away from the licensee. Under many laws (the insolvency laws of the insolvent licensor) the administrator in insolvency has an option to assume or reject the license. The licensee who has invested for years in a technology may be confronted with a situation in which the administrator decides that it is preferential for the creditors to have the technology exploited by someone else. Such a decision is possible, for example, in Germany, England, Switzerland, Austria and Sweden.

Often, one of the most difficult issues in negotiating license agreements is to find an acceptable mechanism to protect the licensee in the event of licensor insolvency. While the licensee will ask for a transfer of patent rights, the licensor cannot dispose of rights that would deprive them of other ways to exploit the technology (outside the licensed field, for example).

In the US, insolvency laws were amended in 1988 to protect the licensee. According to Sec. 365 (n) of the US Bankruptcy Code, the licensee may elect to retain its licensed rights provided payments continue to be made and waives all claims against the licensor under the agreement. Many other countries have

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recently amended their laws accordingly, including Canada and France. In Germany, an amendment to the Insolvency Act is being discussed in order to protect licensees.

Challenge of licensed patent rights

The licensor will want a right to terminate the license agreement if the licensee challenges the licensed patent rights. Non-challenge clauses in license agreements, stating that the licensee shall not challenge the rights, are not effective under applicable EU Block Exemption Regulations. However, a right to terminate in the event of such a challenge is effective – this provides almost the same protection to the licensor as a contractual ban on such challenges.

In the US, formerly it was not possible for a licensee to challenge the licensed technology. Under the principle of license estoppel, there was an implicit obligation of the licensee not to challenge. However, the Supreme Court decision Medimmune vs. Genentech 127 S.Ct. 764 (2007) changed this. Now, US license agreements also tend to provide for a right of the licensor to terminate if the licensee challenges the licensed patent rights.

Change of control

The licensor may want to terminate the license agreement if there is a change of control in the licensee – if its shares have been taken over by another company. The licensor will argue that it needs to avoid a situation in which its licensee is a competitor, or in which it becomes a company that has a history of failing to meet contractual obligations or infringing intellectual property rights.

For the licensee, such right to terminate is difficult to accept. First, the licensee will baulk at the risk of losing the licensed technology; second, any corporate transaction may become difficult as a potential buyer will be held up by such change of control provision.

The licensee will try to convince the licensor that a right to terminate for change of control is not required. Specific provisions can offer a compromise. For example, the license agreement may provide that, in the event the licensee is taken over by a competitor of the licensor, the licensor will no longer be obliged to make available improvements to the technology, and that the licensor has additional means to monitor the performance of the license agreement by the licensee.

The licensee typically does not have – and will not need – a right to terminate the license agreement in the event of a change of control of the licensor. However, the licensee may request that his obligations to share development results with the licensor and to open his books to the licensor are to be amended and restricted if the licensor is taken over by a competitor of the licensee.

Consequences of termination

There are several possible consequences of termination as set out below:

(a) Reversion of rights

While the license agreement may provide

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> The agreement should expressly state that, in the event of a termination, the rights to the licensed technology automatically revert to the licensor.

that upon expiry of the license agreement the licensee retains a fully paid up license, in the event of a termination the licensee should not retain any rights to the licensed technology. The license agreement should expressly state that, in the event of a termination, the rights to the licensed technology automatically revert to the licensor. Otherwise and depending on the applicable law, it may be necessary to re-assign and re-transfer the licensed technology to the licensor.

(b) Transfer of the project to the licensor

The licensor or its new licensee will want to be in a position to continue the exploitation of the licensed technology without losing too much time or incurring additional costs and expenses. Consequently, the licensor will have to claim:

- access to the development results controlled by the licensee, including development data, marketing data and corresponding documentation;
- a license to improvements generated by the licensee and to any background intellectual property rights of licensee that are necessary to continue the development and marketing of the licensed technology;
- a license to any trademarks of the licensee under which the licensed technology is marketed;
- a transfer of regulatory approvals or the status as an applicant for regulatory approvals;
- a transfer of materials owned by the licensee, as the licensee will no longer be able to use such material; and
- a transfer of agreements with CROs and CMOs in order to be able to take over ongoing studies and/or the manufacture of products. To the extent a study cannot be assigned to the licensor, the agreement should provide that the licensee continues the study on behalf and at the cost of the licensor.

To avoid losing time, it may be advisable to exchange data and improvements during the term of the license agreement. Experience shows that, after termination of the license agreement, the licensee will have less incentive to meet its contractual obligations than during the time when the agreement was effective.

In negotiating these consequences of termination, the licensee often requests some financial compensation, for example a refund of its development costs, and/or a royalty on sales based on its technology. Whether such compensation is appropriate needs to be decided on a case-by-case basis. The licensor will argue that the licensee decided that it was no longer interested in the technology and should therefore not expect to benefit from a reversion of rights to the licensor. Furthermore, access to data, improvements and regulatory approvals may be perceived as a compensation for damages incurred by the licensor as a consequence of an early termination of the agreement.

> **Careful termination provision can be essential to protect the technology. If the parties need to revisit the terms of the agreement, the provisions on termination and its consequences tend to be the ones that are most frequently read and analysed.**

(c) Assumption of sublicense agreements

When entering into a sublicense agreement, the sublicensee needs to be concerned about a potential termination of the main license agreement. The sublicensee typically has no influence on the main agreement; if the main agreement terminates, the sublicensee also loses its rights to the licensed technology. The main agreement should address this issue and provide for protection of a sublicense. The licensor should agree to assume the sublicense (to enter into a direct license with the sublicensee if the main license terminates). The main license would provide that the licensor shall not be bound by any obligations of the sublicensor that go beyond the obligations of the licensor towards the licensee. Such obligation of the licensor under the main license will provide the reassurance a sublicensee is looking for. The clause in the license agreement could read:

Upon termination of this License Agreement – irrespective of the reasons for such termination – all sublicenses which the Licensee has granted in accordance with this License Agreement shall continue to exist and shall be transferred from Licensee to Licensor. However, the Licensor shall not be obliged to honour the Licensee's obligations from sublicenses if such obligations do not correspond to the Licensor's obligations in accordance with this License Agreement.

Conclusion

The reasons that may justify an early termination and the consequences of such termination must be fully considered when entering into a license agreement. Some creativity is required to capture all the different events that may occur, and negotiating provision for these is not easy as it requires the parties to address situations they never want to happen.

Carefully drafted termination provision can, however, be essential to protect the value of the licensed technology. Experience shows that, if the parties need to revisit the terms of the license agreement, the provisions on termination and consequences of termination tend to be the ones that are most frequently read and analysed. ■