

제약, 바이오 분야의 기술이전 라이선스 계약의 조기 종료 Early Termination 관련 실무적 포인트 몇 가지



신약개발 관련 기술이전 라이선스 계약서에 시판허가를 받고 상업적 판매를 하는 것까지 약정했다고 실제 그 때까지 계속되는 경우는 많지 않습니다. 대다수는 다양한 이유로 중단도 해지, 라이선스 반환 등 조기 종료되는 경우가 많습니다.

따라서 계약 실무적으로는 라이선스 계약의 조기 종료, 즉 early termination of license agreement를 예상하고 이에 대한 합리적 대응방안을 고민하고, 반드시 필요한 사항을 라이선스 계약서에 반영해 두는 것이 바람직합니다. 또한 termination agreement을 잘 협의하고 작성하는 것도 매우 중요합니다.

제약, 바이오 분야의 라이선스 계약의 조기 종료와 관련한 실무적 포인트를 정리한 자료를 참고로 첨부합니다. 그 중에서 licensee의 임의해지 조항에 관한 사항과 termination

후 처리사항에 관한 부분을 그대로 인용하면 다음과 같습니다. 최근 자료는 아니지만 한번 일독해 보시기 바랍니다.

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 – 임의해지

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.

Consequences of termination – 조기종료 후 처리

(a) Reversion of rights

While the license agreement may provide 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:

(1) access to the development results controlled by the licensee, including development data, marketing data and corresponding documentation;

(2) 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;

(3) a license to any trademarks of the licensee under which the licensed technology is marketed;

(4) a transfer of regulatory approvals or the status as an applicant for regulatory approvals;

(5) a transfer of materials owned by the licensee, as the licensee will no longer be able to use such material; and

(6) 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.

(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.

첨부: 발표자료

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