

[국제계약실무] 신약물질 기술이전 Exclusive License 계약서 중 Termination 조항



일본제약회사와 다국적 제약회사가 체결한 신약의 물질특허에 대한 Exclusive License Agreement 중에서 Termination 조항을 간략하게 살펴보겠습니다. 신약개발은 최종 성공 가능성이 낮기 때문에 중간 Risk 관리가 무엇보다 중요합니다. 다른 License 계약보다 Termination 조항이 더욱 중요합니다.

Licensor 일본회사 Shionogi에서 신약물질 특허권을 보유하고, Licensee AstraZeneca에 대해 해당 특허의 전용실시권 허여 및 상업화 권리를 부여하는 기술이전 license 계약입니다. 발생 가능한 상황에 따라 Termination 조건을 달리 규정하고, 그에 따른 후속처리도 각각 규정하였습니다.

국내 라이선스 계약서에서 통상적으로 사용되는 계약해제, 해지 조항내용만으로 라이선스

스 이후 연구개발 진행에 따라 발생 가능한 Risk를 관리할 수 있다고 기대하는 것 자체가 비현실적입니다. 조금만 냉정하게 살펴보면 분명하게 알 수 있습니다. 정말 중요한 기술이전 및 라이선스 계약이라면 현재 흔히 사용되는 표준 계약서에 얽매이지 말고 필요한 조항을 새로 작성하는데 주저하지 말아야 할 것입니다.

Crestor License Agreement는 이미 상당한 시간이 지난 오래 된 계약서이지만, 실제 엄청난 성공을 거둔 신약개발 기술이전 프로젝트로서 실무자가 참고자료로 살펴볼 가치가 높다고 생각합니다.

Article 13. Term and Termination

13.1 This Agreement shall become effective as of the EFFECTIVE DATE and expires when ZENECA's obligations to pay running royalties according to Articles 4.2 and 4.3 expire.

13.2 If ZENECA determines that it is **not feasible** for ZENECA to pursue the development, launch or sale of LICENSED PRODUCTS **due to a scientific, technical, regulatory and/or commercial reason, including but not limited to** (i)

adverse events of the COMPOUNDS or LICENSED PRODUCTS or (ii) **marketability** of the LICENSED PRODUCTS or (iii) **reasons related to patent coverage**, ZENECA shall promptly notify SHIONOGI in writing of such determination and provide SHIONOGI with the pertinent information with respect thereto. Promptly following the receipt of such notice from ZENECA, the PARTIES shall discuss the situation in good faith. Following such discussion, ZENECA **may terminate** this Agreement upon ninety (90) days prior written notice.

13.3 Following launch of the LICENSED PRODUCTS in any country of the TERRITORY, ZENECA shall have the right to withdraw the LICENSED PRODUCTS from sale in such country, due to scientific, technical, regulatory and/or commercial reasons, including but not limited to adverse events of the COMPOUND or LICENSED PRODUCTS or marketability of the LICENSED PRODUCTS. ZENECA shall promptly notify SHIONOGI in writing of such determination and provide SHIONOGI with the pertinent information with respect thereto. Promptly following the receipt of such notice from ZENECA, the PARTIES shall discuss the situation in good faith. Following such discussion, ZENECA may withdraw the LICENSED PRODUCTS

from sale in such country; provided that ZENECA shall be entitled to withdraw the LICENSED PRODUCTS from sale without advance discussions with SHIONOGI if the withdrawal is for safety reasons.

13.4 After expiration of this Agreement pursuant to Article 13.1 above, **ZENECA's license shall be considered fully paid and become non-exclusive**, and ZENECA and its AFFILIATES and SUBLICENSEES shall be allowed to continue using all KNOW-HOW for the manufacture, sale or use of the COMPOUNDS and/or LICENSED PRODUCTS with no further consideration to SHIONOGI.

13.5 This Agreement shall be terminable by either PARTY at any time, upon the occurrence of any of the following events;

- (i) Should the other PARTY hereto become insolvent, or if proceedings in voluntary or involuntary bankruptcy or pursuant to any other insolvency law shall be instituted by, on behalf of or against the other PARTY, or if a trustee or receiver of the party's property shall be appointed; or

(ii) If the other PARTY commits any **material breach** of any of the terms of this Agreement and (a) fails to remedy such breach within sixty (60) days after written notice thereof has been given by the non-breaching PARTY, or (b) in the event that such breach is not capable of cure within such sixty (60) day period, fails to commence to cure such breach within such period and thereafter to prosecute such cure diligently to completion; provided, however, that in no event shall the period for such cure be greater than one hundred twenty (120) days after the non-breaching party's notice of such breach.

13.6 The termination of this Agreement shall not relieve the PARTIES from performing any obligations accrued prior to the date this Agreement terminates.

13.7 Upon termination of this Agreement pursuant to Article 3.8, 13.2 or 13.5, ZENECA shall promptly return all KNOW-HOW supplied from SHIONOGI and cease any activities allowed hereunder (including without limitation development, manufacture, use and/or sale of the COMPOUNDS and the LICENSED PRODUCTS);

provided however, that ZENECA, its AFFILIATES and SUBLICENSEES shall have the right, if applicable, to sell any remaining COMPOUNDS or LICENSED PRODUCTS made prior to said termination and shall pay to SHIONOGI any royalties owed to SHIONOGI with respect to such sales. ZENECA shall also transmit free of charge to SHIONOGI **registration data** generated by ZENECA up to the date of early termination without delay. Moreover, upon early termination (except the case that this Agreement is terminated by ZENECA in accordance with Article 13.5 above) and upon SHIONOGI's request, **ZENECA shall grant or cause to be granted to SHIONOGI a worldwide license**, with the right to sublicense to any THIRD PARTY, to manufacture, use and sell the COMPOUNDS and LICENSED PRODUCTS under any patent rights held or controlled by ZENECA, its AFFILIATES or SUBLICENSEES which cover the development, manufacture, use and/or sale of the COMPOUNDS and the LICENSED PRODUCTS, and utilizing ZENECA's registration data (including its AFFILIATES' and/or SUBLICENSEES' registration data) generated up to the date of early termination on the terms and conditions mutually agreed upon by the PARTIES. If the HEALTH REGISTRATION APPROVAL of any LICENSED PRODUCT is already held by ZENECA, its AFFILIATES and/or SUBLICENSEES at the date of early

termination of this Agreement (except the case that this Agreement is terminated by ZENECA in accordance with Article 13.5 above), ZENECA shall also take all reasonable steps to transfer or cause to be transferred, free of charge, such HEALTH REGISTRATION APPROVAL to SHIONOGI.

13.8 Early termination of this Agreement by the non-breaching PARTY shall in no way affect or limit such non-breaching party's right to claim against the breaching PARTY for any damages arising out of the breach of this Agreement.

13.9 ZENECA's payment obligation under Article 3.2 and Articles 5, 7, 8, 10, 13.4 and 13.7 shall survive the termination or expiration of this Agreement.

계약분쟁, 국제계약, 기업법무, 기술법무, 손해배상, Claim, License계약

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