[국제계약실무] 신약 물질특허 기술이전 Exclusive License 계약서 중 Development 조항

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아래에서 일본제약회사와 다국적 제약회사가 체결한 신약의 물질특허에 대한 Exclusive

License Agreement 중 Development 조항을 간략하게 살펴보겠습니다. Licensor 일본회사 Shionogi에서 신약물질 특허권을 보유하고, Licensee AstraZeneca에 대해 해당 특허의 전용실시권 허여 및 상업화 권리를 부여하는 기술이전 license 계약입니다.

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참고로, 최근에는 양 당사자가 참여하는 Joint Steering Committee (JSC), Joint Development Committee (JDC)를 구성하여, 정기적 회의를 통해 후속 연구개발의 진행, 성과평가, 조정, 결정 등을 해나가는 방식이 자주 활용되고 있습니다. 이를 위해 처음부터 License Agreement에 이와 같은 JSC 등에 관한 계약조항을 두는 경우가 많습니다.

Article 3. Development

3.1 SHIONOGI shall disclose the KNOW-HOW, which is necessary, useful or advisable for ZENECA to obtain the HEALTH REGISTRATION APPROVAL and to develop, manufacture, use, distribute, market and sell the LICENSED PRODUCTS, in each

country of the TERRITORY, after the execution of this Agreement without delay to the extent not done so already. If the visits of SHIONOGI's representative(s) to ZENECA's facilities are reasonably requested by ZENECA relating to the disclosure of KNOW-HOW to ZENECA, SHIONOGI will send an appropriate representative(s) to ZENECA's facilities; provided that ZENECA shall bear the expenses of travel and accommodations for such representative(s).

SHIONOGI will provide ZENECA with all reasonable assistance required in order to transfer the KNOW-HOW to ZENECA in a timely manner. Such assistance will include, but shall not be limited to those items listed in the Schedule attached.

3.3 ZENECA shall develop and register the PRODUCTS in the TERRITORY on its sole responsibility as if the PRODUCTS had been derived from ZENECA's own research pipeline. Prior to October 31, 1998, ZENECA shall prepare a development schedule (hereinafter referred to as the "DEVELOPMENT SCHEDULE"), and shall allow SHIONOGI the opportunity to comment upon it. The DEVELOPMENT SCHEDULE shall contain the estimated time schedule of pre-clinical studies,

clinical trials, New Drug Application ("NDA") filings, launches and other related activities to be conducted by ZENECA with respect to the PRODUCTS in Europe, the U.S.A. and Japan. The first DEVELOPMENT SCHEDULE (hereinafter referred to as the "ORIGINAL DEVELOPMENT SCHEDULE") shall be attached to this Agreement as Appendix III.

3.4 ZENECA may also pursue the feasibility for the development and commercialization of the COMBINATION PRODUCTS. If ZENECA decides to carry out the development of any COMBINATION PRODUCTS leading to their commercialization, ZENECA shall promptly inform SHIONOGI of such intention in writing and provide SHIONOGI with the development schedule therefor.

3.5 If ZENECA reasonably foresees or becomes aware of any delay of six (6) months or more in the actual development of the PRODUCTS as compared with the timing set forth in the ORIGINAL DEVELOPMENT SCHEDULE or any later modified DEVELOPMENT SCHEDULE, ZENECA shall promptly inform SHIONOGI of such delay in writing. Whereupon ZENECA may modify such DEVELOPMENT

SCHEDULE upon consultation with SHIONOGI, but for the avoidance of doubt, such consultation shall be for information only and ZENECA will not be required to obtain SHIONOGI's approval to any such modification.

3.6 Any and all development costs for the LICENSED PRODUCTS in the TERRITORY shall be solely borne by ZENECA.

3.7 ZENECA shall provide SHIONOGI with a bi-annual report on the progress in the development of LICENSED PRODUCTS in the TERRITORY in order to keep SHIONOGI informed of the progress. ZENECA also agrees to have meetings with SHIONOGI in a timely manner (at least once a year) in order to report on the progress in the development of LICENSED PRODUCTS in the TERRITORY. If any application of Investigational New Drug ("IND"), Clinical Trial Exemption ("CTX") and/or NDA is filed with the competent authorities in Europe, the U.S.A. and Japan, ZENECA shall provide SHIONOGI with a summary of all dossier submitted to such authorities (including any amendments thereto). The provisions of Article 8.1 shall apply to any information disclosed hereunder, and SHIONOGI shall not

be permitted to use any such information for any purpose other than evaluating the progress of ZENECA's development of the LICENSED PRODUCTS.

3.8 Upon completion of phase II clinical trials for the LICENSED PRODUCTS, ZENECA shall have the right to terminate this Agreement by informing in writing SHIONOGI of its intention to terminate this Agreement as well as the background of such decision. On termination of this Agreement pursuant to this Article 3.8, ZENECA shall not be obliged to make any further payments under Article 4.

3.9 If and when the HEALTH REGISTRATION APPROVAL is obtained in any country of the TERRITORY, ZENECA shall promptly inform SHIONOGI of such HEALTH REGISTRATION APPROVAL and send to SHIONOGI a copy of the approval letter, along with an English translation thereof, of such HEALTH REGISTRATION APPROVAL issued by the competent health authority of such country. The provisions of Article 8.1 shall apply to any information disclosed hereunder, and SHIONOGI shall not be permitted to use any such information for any purpose other than evaluating the progress of ZENECA's development of the LICENSED

PRODUCTS.

3.10 If ZENECA chooses to market the LICENSED PRODUCTS in Japan and/or Taiwan with a partner other than ZENECA's AFFILIATE in such countries, ZENECA shall offer to SHIONOGI the first opportunity to be ZENECA's marketing partner for the LICENSED PRODUCTS in Japan and/or Taiwan. With regard to the terms and conditions of the marketing of LICENSED PRODUCTS in Japan and/or Taiwan, SHIONOGI and ZENECA shall negotiate such terms and conditions in good faith. If the PARTIES are unable to agree upon such terms and conditions, ZENECA shall be free to offer the opportunity to a THIRD PARTY on terms and conditions no more favorable than those offered to SHIONOGI.