

제약분야 기술이전 및 독점라이선스 계약서 중에서 진술보증 조항 REPRESENTATIONS, WARRANTIES AND COVEANTS – 권리진술 및 독점권 보장의무 등 상세한 내용을 매우 구체적으로 기재하는 방식의 계약조항 샘플



## 10. REPRESENTATIONS, WARRANTIES, AND COVENANTS.

10.1 **Mutual Representations and Warranties.** Licensor and Licensee (each, a “Representing Party”) each hereby represents and warrants to each other, as of the Effective Date and except as otherwise set forth in Schedule 10.2 (in the case of Licensor) and Schedule 10.3 (the case of Licensee), that:

(a) such Representing Party is a corporation or limited liability company, as

applicable, duly organized and subsisting under the laws of its jurisdiction of organization;

(b) such Representing Party has the power, authority, and legal right, and is free, to enter into this Agreement on behalf of itself and its Affiliates and to perform its respective obligations hereunder and to cause its Affiliates to perform their respective obligations hereunder;

(c) such Representing Party has the power, authority, and legal right to own and operate its property and assets and to carry on its business as it is now being conducted and as it is contemplated to be conducted by this Agreement;

(d) this Agreement constitutes a legal, valid, and binding obligation of such Representing Party and is enforceable against it in accordance with its terms, subject to the effects of bankruptcy, insolvency, or other laws of general application affecting the enforcement of creditor rights and judicial principles affecting the availability of specific performance and general principles of equity, whether enforceability is considered a proceeding at law or equity;

(e) the execution and delivery of this Agreement and the performance of such Representing Party's and its Affiliates' obligations hereunder (i) have been duly authorized and approved by all necessary action by such Representing Party, and all necessary

consents, approvals, and authorizations of all Regulatory Authorities and other Third Parties required to be obtained by such Representing Party in connection with the execution and delivery of this Agreement and the performance of its obligations hereunder have been obtained; (ii) do not conflict with or violate any requirement of Applicable Laws or any provision of the articles of incorporation, bylaws, limited partnership agreement, or any similar instrument of such Representing Party, as applicable, in any material way; and (iii) do not, and will not, conflict with or otherwise interfere with in such a manner as to result in a violation, breach, or default under or require any consent that has not been obtained under any contract between such Representing Party and any Third Party;

(f) there are no, and shall be no, liens, conveyances, mortgages, assignments, encumbrances, or other agreements that would prevent or impair such Representing Party's or any of its Affiliates' full and complete exercise of the terms and conditions of the Agreement;

(g) such Representing Party and its Affiliates shall at all times comply with all Applicable Laws relating or pertaining to their obligations under the Agreement;

(h) with respect to the services provided hereunder to the other Party, its Affiliates, and their respective employees, officers, contractors and agents who perform such services

have the experience, capability, and resources to efficiently and skillfully perform the services, and shall perform, where applicable, all such services in a professional and workmanlike manner and in accordance with the generally accepted then-current standards, forms, procedures, and techniques established from time to time by the industry;

(i) all of such Representing Party's employees, officers, contractors, and consultants have executed agreements requiring assignment to such Representing Party of all inventions created by such persons in the course of their employment by such Representing Party and obligating each such employee, officer, contractor, and consultant to maintain and safeguard the confidentiality of (i) any information that is confidential to such Representing Party or (ii) any information that is confidential to any other Person and that such Representing Party is obligated to maintain and safeguard as confidential; and

(j) neither such Representing Party, nor any of its employees, officers, subcontractors, or consultants who have rendered or will render services relating to the Product: (i) has ever been debarred or is subject or debarment or convicted of a crime for which an entity or person could be debarred under 21 U.S.C. Section 335a or (ii) has ever been under indictment for a crime for which a person or entity could be debarred under said Section 335a.

10.2 **Additional Representations, Warranties, and Covenants of Licensor.** Licensor hereby represents, warrants, and covenants to Licensee, as of the Effective Date and except as otherwise set forth in Schedule 10.2, that:

(a) Licensor is entitled to grant the rights and licenses purported to be granted to Licensee under this Agreement, and to assign the rights purported to be assigned to Licensee under this Agreement, and is not currently bound by any agreement with any Third Party, or by any outstanding order, judgment, or decree of any court or administrative agency, that restricts it from granting to Licensee the rights, licenses and sublicenses purported to be so granted in this Agreement;

(b) Licensor is the sole and exclusive owner of all right, title, and interest, in, to, and under the Licensed Rights and has the right under the Licensed CPEX Patent Rights and the Licensed Reprise Patent Rights to grant the sublicenses thereunder in accordance with Section 2.2;

(c) the Licensed Rights are free and clear of any liens, charges, encumbrances, or judgments, and Licensor has sufficient rights to grant the licenses and rights purported to be granted herein, free and clear of any security interests, claims, encumbrances, or charges

of any kind;

(d) Licensor has not granted, and will not grant during the term of this Agreement, any right, option, license, or interest in or to any of the Licensed Rights that is in conflict with the rights assigned or granted to Licensee under this Agreement;

(e) there is no legal, administrative, arbitration, or other proceeding, suit, claim, or action of any nature, judgment, decree, decision, injunction, writ, or order pending, or to Licensor's knowledge threatened by, against or involving Licensor, regarding the Licensed Rights, whether at law or in equity, before or by any Third Party, and Licensor has not received any written communications alleging that it has violated, through the manufacture, Development, import, or other exploitation of the Product, any intellectual property rights of any Third Party;

(f) to Licensor's knowledge:

(i) the patents in the issued Licensed Serenity Patent Rights, the Licensed CPEX Patent Rights, and the Licensed Reprise Patent Rights are valid and enforceable; and

(ii) no Third Party has asserted that any of the Licensed Rights or the Sublicensed Rights is invalid or unenforceable;

(g) all applications, registrations, maintenance and renewal fees due in respect of

any of the Licensed Serenity Patent Rights and, to Licensor's knowledge, the Licensed Reprise Patent Rights and the Licensed CPEX Patent Rights, have been paid and all documents and certificates required to be filed with the relevant agencies for the purpose of maintaining such Licensed Serenity Patent Rights, and to Licensor's knowledge, the Licensed Reprise Patent Rights and Licensed CPEX Patent Rights have been filed;

(h) none of the Licensed Serenity Patent Rights, the Licensed Serenity Know-How and, to Licensor's knowledge, none of the Licensed CPEX Patent Rights and the Licensed Reprise Patent Rights were developed with funding from any Governmental Authority such that any Governmental Authority has any march in rights or other rights to use the Licensed Serenity Patent Rights, the License Serenity Know-How, the Licensed Reprise Patent Rights, or the Licensed CPEX Patent Rights;

(i) to Licensor's knowledge, no Third Party has infringed or misappropriated any of the Licensed Rights or the Sublicensed Rights;

(j) all inventors of any inventions included within the Licensed Serenity Patent Rights and, to the knowledge of Licensor, the Licensed CPEX Patent Rights and the Licensed Reprise Patent Rights have assigned their entire right, title, and interest in and to such inventions and the corresponding patents and patent applications to Licensor, Reprise, or

CPEX, as applicable, and have been listed as inventors in the Licensed Serenity Patent Rights, the Licensed CPEX Patent Rights, and the Licensed Reprise Patent Rights, as applicable;

(k) no agreements that Licensor or its Affiliates may have with any Third Party provide such Third Party with any rights of first offer, rights of first refusal, or any other rights to make, have made, use, conduct Clinical Studies for, sell, offer for sale, have sold, import, export, or otherwise Exploit the Product in the Field in the Territory or the right to use the Licensed Rights or the Sublicensed Rights in connection with the Exploitation of the Product in the Field in the Territory; and Licensor has received no notice from a Third Party of any suit, action, proceeding, or arbitration pending or threatened against it that the proposed terms and conditions of this Agreement, and the Parties' performance in accordance therewith, do or shall conflict or interfere with in a manner resulting in a breach or default under, or other violation of, any agreements that Licensor or its Affiliates may have with any Third Party;

to Licensor's knowledge,

(i) each of the CPEX License Agreement and the Reprise License Agreement is valid and enforceable in accordance with its terms, is in full force and effect, and there are no



approvals or consents required to make it effective, (ii) Licensor has supplied Licensee with a true and correct copy of the CPEX License Agreement and the Reprise License Agreement , together with all amendments, waivers, or other changes thereto, (iii) Licensor has performed all material obligations required to be performed by it in connection with the CPEX License Agreement and the Reprise License Agreement, (iv) Licensor shall not materially breach and is not in material breach of the CPEX License Agreement or the Reprise License Agreement, (v) Licensor is not in receipt of any claim of default, cure notice, or show cause notice under the CPEX License Agreement or the Reprise License Agreement, and (vi) there is no current material breach or anticipated material breach by any other party to the CPEX License Agreement or the Reprise License Agreement;

(m) (i) Licensor is the named sponsor of the First Approved NDA for the Product; and (ii) with respect to all Regulatory Documentation to obtain Regulatory Approvals for the Product in the Field: (A) the data, information and/or all other documents in Licensor's or its Affiliates submissions were, are and shall be free from fraud or material falsity, and neither Licensor nor its Affiliates has made any material misrepresentation or omission in connection with such data; (B) the Regulatory Approvals have not been and will not be obtained either through bribery or the payment of illegal gratuities by Licensor; (C) the data, information and/or all other documents in Licensor's or its Affiliates' submissions are,

were and shall be accurate and reliable for purposes of supporting approval of the submissions; and (D) the Regulatory Approvals shall be obtained without illegal or unethical behavior of any kind by Licensor or its Affiliates; provided that Licensor shall not be deemed to be in breach of this Section 10.2(m) if the violation of this Section 10.2(m) results from the action or omission of Licensee or Licensee's Affiliates, Sublicensees, or contractors (other than Licensor);

(n) Licensor believes in good faith, based on the information set forth in Schedule 10.2(n), that FDA will consider amending or supplementing the First Approved NDA (or the related IND) in the manner described in Schedule 10.2(n); provided, however, that Licensor cannot assure that FDA will approve such amendment or supplement.

(o) except as expressly permitted hereunder, Licensor agrees not to, and agrees to cause its Affiliates and Sublicensees not to (i) assign, transfer, convey or otherwise encumber any right, title or interest in or to the Licensed Rights, the Sublicensed Rights, or any Regulatory Approvals and Documentation in respect of the Product, (ii) grant in any manner any license or other right, title or interest in or to any of the Licensed Rights, the Sublicensed Rights, or the Regulatory Approvals and Documentation in respect of the Product, or (iii) agree to or otherwise become bound by any covenant not to sue for any infringement, misuse or other action or inaction with respect to any of the Licensed Rights,

the Sublicensed Rights, or the Regulatory Approvals and Documentation in respect of the Product; and

(p) other than the CPEX License Agreement, the Reprise License Agreement, the Renaissance Supply Agreements, and the other Third Party Supply Agreements, Licensor and/or its Affiliates have not entered into any agreements with any Third Party, pursuant to which any Third Party has granted to Licensor, or Licensor has granted to any Third Party, any rights to licenses to, in or under any of the Licensed Rights or the Sublicensed Rights or other intellectual property rights that relate to the Product, or relating to the manufacture of the Product.

10.3 **Additional Representations, Warranties, and Covenants of Licensee.** Licensee hereby represents, warrants, and covenants to Licensor, as of the Effective Date and except as otherwise stated in Schedule 10.3, that:

(a) if, during the term of this Agreement Licensee has reason to believe that it or any of its employees, officers, subcontractors, or consultants rendering services relating to the Product: (i) is or will be debarred or convicted of a crime under 21 U.S.C. Section 335a, or (ii) is or will be under indictment under said Section 335a, then Licensee shall

immediately notify Licensor in writing;

(b) as of the Effective Date, there is no legal, administrative, arbitration, or other proceeding, suit, claim, or action of any nature, judgment, decree, decision, injunction, writ, or order pending or, to the knowledge of Licensee's senior management, threatened by, against Licensee regarding this Agreement, whether at law or in equity, before or by any Third Party; and Licensee shall provide notice of any of the foregoing to the extent it affects Licensee's performance of its obligations under this Agreement;

(c) except for information provided by Licensor, its Affiliates or Sublicensees: (i) the data and information in Licensee's submissions and modifications of Regulatory Documentation relating to the Product shall be free from fraud or material falsity; (ii) Regulatory Approvals for the Product hereafter obtained will not be obtained either through bribery or the payment of illegal gratuities by Licensee; (iii) the data and information in Licensee's submissions and modifications of any Regulatory Documentation shall be accurate and reliable; and (iv) any such the Regulatory Approvals will be obtained without illegal or unethical behavior of any kind by Licensee; provided that Licensee shall not be deemed to be in breach of this Section 10.3(c) if the violation of this Section 10.3(c) results from the action or omission of Licensor or its Affiliates, Sublicensees (other than Licensee), or contractors; and

(d) except as expressly permitted hereunder, Licensee agrees not to, and agrees to cause its Affiliates and Sublicensees not to (i) assign, transfer, convey or otherwise encumber any right, title or interest in or to the Licensed Rights, the Sublicensed Rights, or any Regulatory Approvals and Documentation in respect of the Product, (ii) grant in any manner any license or other right, title or interest in or to any of the Licensed Rights, the Sublicensed Rights, or the Regulatory Approvals and Documentation in respect of the Product, (iii) agree to or otherwise become bound by any covenant not to sue for any infringement, misuse or other action or inaction with respect to any of the Licensed Rights, the Sublicensed Rights, or the Regulatory Approvals and Documentation in respect of the Product, or (iv) bring any action or proceeding or otherwise assert any claim under any Applicable Law in the event any licensee (or sublicensee or any entity or person acting on its behalf) initiates any proceeding or otherwise assert any claim in any court, administrative agency, or other forum with jurisdiction over such proceeding or claim, that any of the Licensed Rights or Sublicensed Rights are invalid, unenforceable, or not infringed, violated, or misappropriated. In the event that Licensee or any Affiliate or Sublicensee of Licensee initiates any proceeding or otherwise asserts any claim in violation of clause (iv) of this Section 10.3, and the result thereof is a final decision, ruling, holding, award, or other disposition to the effect that any of the Licensed Rights or Sublicensed Rights are

valid, enforceable, or infringed, violated, or misappropriated, then each of the royalty rates set forth in the table in Section 8.3(a) will each be increased by [\*] and the party initiating such proceeding or otherwise asserting such claim shall pay the attorneys' fees and expenses incurred by Licensor in defending against such proceeding or claim.

10.4 **Inaccuracies**. Without limiting either Party's rights and remedies at law, in equity or under this Agreement, if, at any point in time (not just at the times when the warranties are deemed granted), either Party becomes aware of any inaccuracies in the foregoing warranties and representations, such Party shall promptly notify the other Party of such inaccuracies, with a detailed written explanation.

국제계약, 영문계약, 계약분쟁, 손해배상, Claim, License, R&D 제휴계약

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