

EXCLUSIVE PATENT AND KNOW-HOW LICENSE AGREEMENT – LIFE SCIENCES TECHNOLOGY

by and between

Licensee

and

Licensor

Clause	Annotation
	<p>[1] This agreement example concerns a life sciences technology license wherein the licensor is licensing its patent rights and know-how for a drug candidate and the technology surrounding this drug candidate. The agreement is largely preferential to the licensee, while there are handful of provisions favor the licensor. Note that this agreement structure is common for transactions where a life sciences start-up is looking to out-license a drug program to Big Pharma. Under these deal structures, savvy start-ups understand and expect that if the API (active pharmaceutical ingredient) generates favorable clinical results, Big Pharma will often acquire the start-up or look to renegotiate the agreement to avoid or limit royalties.</p>
<p>This Agreement (this “Agreement”) is effective as of _____, 2016, (the “Effective Date”) and is entered into by and between Licensee, a corporation organized and existing under the laws of _____ (“Licensor”), and Licensee, a corporation organized and existing under the laws of _____ (“Licensee”).</p>	
<p>RECITALS:</p>	<p>[2] Recitals are typically not enforceable, but can provide assistance when construing ambiguous terms. Material terms should be included in the body of the agreement.</p>

<p>WHEREAS, Licensor has developed Licensor Know-How (as hereinafter defined) and has rights to Licensor Patent Rights (as hereinafter defined);</p> <p>WHEREAS, Licensee desires to obtain a license under the Licensor Patent Rights and Licensor Know-How, upon the terms and conditions set forth herein and Licensor desires to grant such a license;</p> <p>NOW, THEREFORE, in consideration of the foregoing premises and the mutual covenants herein contained, the receipt and sufficiency which are hereby acknowledged, Licensee and Licensor hereby agree as follows:</p>	
<p>ARTICLE 1 DEFINITIONS.</p> <p>Unless specifically set forth to the contrary herein, the following terms, whether used in the singular or plural, shall have the respective meanings set forth below.</p>	
<p>1.1 “Act” shall mean, as applicable, the United States Federal Food, Drug and Cosmetic Act, 21 U.S.C. §§ 301 et seq., and/or the Public Health Service Act, 42 U.S.C. §§ 262 et seq., as such may be amended from time to time.</p>	
<p>1.2 “Affiliate” shall mean (i) any corporation or business entity of which, now or hereafter, fifty (50%) or more of the securities or other ownership interests representing the equity, the voting stock or general partnership interest are owned, controlled or held, directly or indirectly, by Licensee or Licensor; or (ii) any corporation or business entity which, now or hereafter, directly or indirectly, owns, controls or holds fifty percent (50%) (or the maximum ownership interest permitted by law) or more of the securities or other ownership interests representing the equity, the voting stock or, if applicable, the general partnership interest, of Licensee or Licensor; or (iii) any corporation or business entity of which, now or hereafter, fifty percent (50%) or more of the securities or other ownership interests representing the equity, the</p>	<p>[3] When dealing with multinational entities, consider the language “or maximum ownership interest permitted by law”, because some countries do not permit majority ownership of a company by individuals who are not citizens of that country or by companies which are not headquartered in that country.</p>

<p>voting stock or general partnership interest are owned, controlled or held, directly or indirectly, by a corporation or business entity described in (i) or (ii).</p>	
<p>1.3 “Agreement” shall have the meaning given such term in the preamble to this document.</p>	
<p>1.4 “Licensor” shall have the meaning given such term in the preamble to this Agreement.</p>	
<p>1.5 “AIPLA A Analogs” shall mean a structural analog synthesized starting with AIPLA A as a starting material.</p>	
<p>1.6 “Licensor Compound” shall mean (i) AIPLA A Analogs that are claimed or disclosed in Licensor Patent Rights, or otherwise developed prior to the Effective Date using the Licensor Know-How, which in either case are set forth in <u>Schedule 1.6</u> and (ii) any free base form, metabolites, salts, esters, salt forms, racemates, stereoisomers, crystalline polymorphs, hydrates or solvates of a Licensor Compound described in the foregoing clause (i).</p>	<p>[4] Definition of “Licensor Compound” is limited to compounds disclosed in Schedule 1.6. Licensee may want to consider broadening the definition.</p>
<p>1.7 “Licensor Know-How” shall mean all Know-How which during the Term (i) are owned or Controlled by Licensor or its Affiliates, (ii) are not generally known and (iii) relate to the preparation, use, formulation, dosage, or means of delivery for AIPLA A Analogs.</p>	<p>[5a] Consider revising “generally known” to “publicly known” to conform with language in U.S. IP law.</p> <p>[5b] The term “relate to” in clause (iii) may lead to subjective interpretation. Licensor should consider defining ‘relate to’, using language that is more specific, or listing the information that is licensed Know-How.</p>
<p>1.8 “Licensor Patent Rights” shall mean Patent Rights related to AIPLA A analogs owned or Controlled by Licensor or its Affiliates or to which Licensor or its Affiliates through license or otherwise acquires rights during the Term of this Agreement that are necessary or useful for Licensee in the identification, research, development, manufacture, marketing, use or sale of Compound or Product, including, but not limited to, those listed on Schedule 1.366.</p>	<p>[6] Very broad definition. Licensor may consider amending “related to” to “Covering” where Covering means, with respect to a Product and a patent that, in the absence of a (sub)license under, or ownership of, such patent, the making, using, offering for sale, selling or importing of such Product would infringe a valid claim of such patent.</p>
<p>1.9 “Licensor Technology” shall mean the Licensor Know-How and Licensor Patent Rights.</p>	

<p>1.10 “Calendar Quarter” shall mean the respective periods of three (3) consecutive calendar months ending on March 31, June 30, September 30 and December 31.</p>	
<p>1.11 “Calendar Year” shall mean each successive period of twelve (12) months commencing on January 1 and ending on December 31.</p>	
<p>1.12 “Clinical Trial” shall mean a Phase I Clinical Trial, Phase II Clinical Trial, Phase III Clinical Trial, and/or Post-approval Clinical Trial.</p>	<p>[7] To avoid disputes the parties may also want to include other clinical trials such as Phase 1a/b clinical trials.</p>
<p>1.13 “Combination Product” shall mean a Product which includes one or more pharmaceutical active ingredients other than Compound in combination with Compound. All references to Product in this Agreement shall be deemed to include Combination Product.</p>	<p>[8] Important to include combination language even if initially there is no intention of using the product in combination with another product. There is a trend for Pharmaceutical companies to combine treatments.</p>
<p>1.14 “Commercially Reasonable Efforts” shall mean, with respect to the efforts to be expended by a Party with respect to any objective, the reasonable, diligent, good faith efforts to accomplish such objective as such Party would normally use to accomplish a similar objective under similar circumstances. It is understood and agreed that with respect to the research, development and sale of Product by either Party, such efforts shall be substantially equivalent to those efforts and resources commonly used by such Party for pharmaceutical products owned by it or to which it has rights, which product is at a similar stage in its development or product life and is of similar market potential taking into account efficacy, safety, approved labeling, the competitiveness of alternative products in the marketplace, the patent and other proprietary position of the product, the likelihood of regulatory approval given the Regulatory Authority involved, the profitability of the product including the amounts payable to licensors of patent or other intellectual property rights, alternative products and other relevant factors. Commercially Reasonable Efforts shall be determined on a market-by-market and Indication-by-Indication basis for a particular Product, and it is anticipated that the level of effort will be different for different markets, and will change over time, reflecting changes in the</p>	<p>[9a] This is a Licensee-friendly definition as it allows Licensee to take into account many extenuating circumstances when determining whether Licensee has used CRE</p> <p>[9b] Licensee preference in this definition could be effectively reduced by providing a condition that cancels the license rights if Licensee’s development efforts are shelved for some period of time. It may be difficult to determine whether the project has been mothballed, so consider a reporting requirement.</p>

<p>status of the Product and the market(s) involved. Commercially Reasonable Efforts shall further require as follows:</p>	
<p>1.14.1 Licensee shall and shall cause its Related Parties to use Diligent Efforts to develop, commercialize, manufacture, market, promote and sell the Product.</p>	<p>[10] Licensee should define the territory in which it is required to commercialize the Product e.g., consider adding the phrase “in the Territory”. Licensor may prefer “in each country in the Territory” such that Licensee is required to commercialize in every country in which it takes a license. Compromise could be reached by requiring commercialization in the Major EU Markets or another agreed upon territory.</p>
<p>1.14.2 Without limiting the foregoing, Licensee and its Related Parties shall not take or authorize any action designed to avoid or circumvent sales of the Product or payment of royalties to Licensor.</p>	<p>[11] This is a broad catch-all phrase that is very beneficial to a Licensor.</p>
<p>1.14.3 Licensee and its Related Parties shall not, directly or indirectly, by a sale or swap of assets, merger, reorganization, joint venture, lease, license or any other transaction or arrangement, sell, transfer, license, convey or otherwise dispose of all or a portion of their respective rights in and to the Product to a third party (collectively, a “Product Transfer”).</p>	<p>[12] When Licensee is a multinational or large entity, this provision may be innocuous. However, if Licensee is a small to mid-sized entity, this provision may be detrimental to its exit strategy.</p>
<p>1.14.4 Licensee and its Related Parties (or any of their permitted successors or assigns) shall not engage in any Product Transfer that would result in the sale, conveyance, transfer or other disposition of all or substantially all of Licensee’s and its Related Parties’ rights with respect to the Product to a third party, through one or more transactions or series of transactions, unless Licensor consents in writing to such Product Transfer and the transferee assumes and succeeds to all of the obligations of Licensee set forth in this Agreement and prior to or simultaneously with such Product Transfer delivers to Licensor an instrument of assumption for the benefit of Licensor effecting such assumption and succession. Any such</p>	<p>[13] Section 1.14.4 may create some redundancy with respect to Section 1.14.3. Consider adding a preface “Without limiting the generality of Section 1.14.3” .</p>

<p>Product Transfer will not release Licensee from its obligations under this Agreement.</p>	
<p>1.14.5 If Licensee or any of its Related Parties acquires or develops alternative technology or products or products derived or otherwise invented, directly or indirectly, from or otherwise based upon such acquired or developed technology that replaces or directly competes with the Product, Licensee shall promptly (not less than thirty (30) days from the occurrence of such event) pay Licensor an amount equal to [_____] Dollars (\$[_____]), less all royalties that have been previously paid to Licensor under this Agreement.</p>	<p>[14] Licensee may seek to limit this clause to any sale of competing products rather than development or acquisition of competing products. Consider including a definition of “competing product”.</p>
<p>1.15 “Compound” shall mean a Licensee Compound or a Licensor Compound.</p>	
<p>1.16 “Control”, “Controls” or “Controlled by” shall mean with respect to any item of or right under Licensor Patent Rights or Licensor Know-How, the possession of (whether by ownership or license, other than pursuant to this Agreement) or the ability of a Party to grant access to, or a license or sublicense of, such items or right as provided for herein without violating the terms of any agreement or other arrangement with any Third Party existing at the time such Party would be required hereunder to grant the other Party such access or license or sublicense.</p>	
<p>1.17 “Diligent Efforts” shall mean, with respect to Licensee’s and its Related Parties’ efforts to be expended to develop, commercialize, manufacture, market, promote and sell the Product, the carrying out of such activities using Commercially Reasonable Efforts, that level, caliber and quality of efforts and resources reasonably and normally used in the development and commercialization by major pharmaceutical companies for a product or compound that is of similar market potential, at a similar stage in its development or product life, and that has a similar potential market opportunity, as the Product, taking into account, without limitation, with respect to the Product, issues of safety, efficacy, target product profile and proprietary position of the Product, and other relevant</p>	<p>[15] It may be difficult to interpret the definition of “Diligent Efforts” in light of the fact that it includes the definition of “Commercially Reasonable Efforts” which has a slightly different standard. Consider using one term or the other and modifying the definition as needed.</p>

<p>scientific, technical, business, marketing, return on investment and other commercial factors, including the cost-effectiveness of efforts or resources, the competitiveness of alternative compounds or products that are or are expected to be in the marketplace, the patent and other proprietary position of the Product, the profitability of the Product and alternative products. For purpose of this definition, milestones or royalty payments required to be paid to Licensor under this Agreement shall not be considered in evaluating profitability or other economic factors.</p>	
<p>1.18 “Field” shall mean all therapeutic, prophylactic and diagnostic uses in humans and animals.</p>	<p>[16] This is a broad field of use.</p>
<p>1.19 “Filing” of an NDA shall mean the acceptance by a Regulatory Authority of an NDA for filing.</p>	<p>[17] This definition is Licensee-friendly, since if a milestone is attached to a Filing, such milestone will not be triggered by the submission of an NDA application but rather acceptance by FDA.</p>
<p>1.20 “First Commercial Sale” shall mean, with respect to any Product, the first sale for end use or consumption of such Product in a country, excluding, however, any sale or other distribution for use in a Clinical Trial.</p>	<p>[18] This definition differentiates between “end use” and clinical trial use. Licensee may also wish to exclude other pre-approval uses of Product, e.g. compassionate use.</p>
<p>1.21 “IND” shall mean an Investigational New Drug application, Clinical Study Application, Clinical Trial Exemption, or similar application or submission for approval to conduct human clinical investigations filed with or submitted to a Regulatory Authority in conformance with the requirements of such Regulatory Authority.</p>	
<p>1.22 “Indication” shall mean a separate and distinct disease or medical condition in humans for which a Product that is in Clinical Trials is intended to treat, prevent and/or diagnose and/or for which a Product has received Marketing Authorization.</p>	
<p>1.23 “Information” shall mean any and all information and data, including without limitation all Licensee Know-How, all Licensor Know-How, and all other scientific, pre-clinical, clinical, regulatory, manufacturing, marketing, financial and commercial information or data, whether communicated in writing or orally or by any other method, which is provided by one Party</p>	

<p>to the other Party in connection with this Agreement.</p>	
<p>1.24 “Initiates”, “Initiated” or “Initiation” shall mean, with respect to a Clinical Trial, the administration of the first dose to a patient in such Clinical Trial.</p>	
<p>1.25 “Invention” shall mean any process, method, composition of matter, article of manufacture, discovery or finding that is conceived and/or reduced to practice during the Term as a result of the research, development and commercialization of a Product or Compound.</p>	<p>[19] The phrase “is conceived <u>and/or</u> reduced to practice” is broader than the definition of invention in the statute which only includes “conceived <u>and</u> reduced to practice”</p>
<p>1.26 “Know-How” shall mean all information, compounds, materials and trade secrets, including but not limited to, discoveries, improvements, processes, methods, protocols, formulas, data and results, inventions, ideas, know-how, patentable or otherwise.</p>	<p>[20] Consider combining the definitions of Information and Know-How, or alternatively, to further differentiate them from one another.</p>
<p>1.27 “Major EU Market” shall mean any of the United Kingdom, France, Italy, Spain or Germany.</p>	
<p>1.28 “Marketing Authorization” shall mean all approvals from the relevant Regulatory Authority necessary to market and sell a Product in any country (including without limitation all applicable pricing and governmental reimbursement approvals even if not legally required to sell Product in a country).</p>	
<p>1.29 “Licensee” shall have the meaning given such term in the preamble to this Agreement.</p>	
<p>1.30 “Licensee Compound” shall mean AIPLA A Analogs that have been identified or optimized by Licensee (or Third Parties working on behalf of Licensee or an Affiliate of Licensee) during the Term that is claimed or covered by an Licensor Patent Right or otherwise uses or incorporates Licensor Know-How. Licensee Compounds do not include Licensor Compounds.</p>	<p>[21] The definition of Licensee Compound may be ambiguous. It would be difficult to know whether the compound was covered by Licensor Know-How and may lead to disputes over royalties. There may be overlap between Licensor Compounds and Licensee Compounds, if, prior to execution of the license both parties had been developing AIPLA A technology (or any technology that may be used in the Product).</p>

<p>1.31 “Licensee Know-How” means any Know-How owned or Controlled by Licensee or its Affiliates as of the Effective Date and during the Term which Licensee or its Affiliates chooses to use in the research, development, manufacture, marketing, use or sale of Compound or Product in the Territory.</p>	<p>[22] Definition of “Control” includes ownership so the word “owned” is redundant.</p>
<p>1.32 “Licensee Patent Rights” shall mean all Patent Rights claiming or disclosing an Invention.</p>	<p>[23] Because the license granted by Licensor is exclusive even as to Licensor, there shouldn’t be any overlap with Licensor Patent Rights. However, in licensing transactions where the Licensor retains rights under the license, the drafter should draft this definition to clearly divide Licensee Patent Rights and Licensor Patent Rights.</p>
<p>1.33 “NDA” shall mean a New Drug Application, Biologics License Application, Worldwide Marketing Application, Marketing Application Authorization, filing pursuant to Section 510(k) of the Act, or similar application or submission for Marketing Authorization of a Product filed with a Regulatory Authority to obtain marketing approval for a biological, pharmaceutical or diagnostic product in that country or in that group of countries.</p>	
<p>1.34 “Net Sales” shall mean the gross invoice price (not including value added taxes, sales taxes, or similar taxes) of Product sold by Licensee or its Related Parties to the first Third Party after deducting, if not previously deducted, from the amount invoiced or received, but only to the extent such deductions are specifically and solely allocated to such Product and actually taken, paid, accrued, allowed, included or allocated based on good faith estimates in the gross invoice price (and consistently applied as set forth below):</p>	<p>[24a] Licensee may wish to limit the definition of Net Sales to post-approval sales in order to exclude pre-approval sales e.g. compassionate use sales, however, in this license, Section 4.3.1(d)(iv) addresses this issue by excluding such use of Product from royalty payments.</p> <p>[24b] In this instance, “first Third Party” is intended clarify the definition of “Net Sales” in the event that a drug is sold to a non-Affiliate distributor.</p>
<p>1.34.1 customary trade and quantity discounts other than early payment cash discounts;</p>	
<p>1.34.2 customary returns, rebates, chargebacks and other allowances;</p>	

<p>1.34.3 retroactive price reductions that are actually allowed or granted;</p>	
<p>1.34.4 deductions for Health Care Reform fees and similar deductions to gross invoice price of Product imposed by Regulatory Authorities or other governmental entities; and</p>	
<p>1.34.5 the standard inventory cost of devices or delivery systems used for dispensing or administering Product.</p>	
<p>With respect to sales of Combination Products, Net Sales shall be calculated on the basis of the gross invoice price of Product(s) containing the Compound sold without other active ingredients. In the event that Product is sold only as a Combination Product, Net Sales shall be calculated on the basis of the gross invoice price of the Combination Product multiplied by a fraction, the numerator of which shall be the inventory cost of Compound in the Product and the denominator of which shall be the inventory cost of all of the active ingredients in the Combination Product. Inventory cost shall be determined in accordance with Licensee's regular accounting methods, consistently applied. The deductions set forth in Sections 1.34.1 through 1.34.4 will be applied in calculating Net Sales for a Combination Product. In the event that Product is sold only as a Combination Product and either Party reasonably believes that the calculation set forth in this Paragraph does not fairly reflect the value of the Product relative to the other active ingredients in the Combination Product, the Parties shall negotiate, in good faith, other means of calculating Net Sales with respect to Combination Products.</p>	<p>[25] It is important that the definition of “Net Sales” or other language in the agreement contemplates the determination of Net Sales for combination products.</p>
<p>The deductions set forth in Sections 1.34.1 through 1.34.5 shall not exceed ten percent (10%) of the gross invoice price of Product during any three (3) month period. No deductions from Net Sales shall be made for commissions paid to individuals whether they are with independent sales agencies or regularly employed by Licensee or its Related Parties and on their payroll, or for cost of collections. Product shall be considered “sold” when billed or invoiced.</p>	<p>[26] It is important to limit the total percentage of deductions from Net Sales to ensure that Licensor receives adequate royalties.</p>

<p>For purposes of calculating Net Sales, all such calculations shall be in accordance with United States generally accepted accounting principles consistently applied and based on, or valued as if based on, bona fide arms' length transactions and not on any bundled, loss-leading or other blended or artificial selling or transfer price.</p>	<p>[27] The application of GAAP accounting principles can assuage auditing. If Licensee follows non-GAAP accounting procedures, auditors may have to spend added time learning the Licensee's accounting practices and backing out Net Sales figures from these records. Consider providing for this added expense in the auditing rights terms.</p>
<p>1.35 “Party” shall mean Licensee or Licensor, individually, and “Parties” shall mean Licensee and Licensor, collectively.</p>	
<p>1.36 “Patent Rights” shall mean any and all patents and patent applications in the Territory (which for the purpose of this Agreement shall be deemed to include certificates of invention and applications for certificates of invention), including divisionals, continuations, continuations-in-part, reissues, renewals, substitutions, registrations, re-examinations, revalidations, extensions, supplementary protection certificates, pediatric exclusivity periods and the like of any such patents and patent applications, and foreign equivalents of the foregoing.</p>	<p>[28] The “and the like” language may be too general if the material exclusivity periods (e.g., patent term extension or pediatric exclusivity) are not listed.</p>
<p>1.37 “Phase I Clinical Trial” shall mean a human clinical trial in any country that would satisfy the requirements of 21 CFR 312.21(a).</p>	<p>[29a] Consider adding Phase 1a/b clinical trials.</p> <p>[29b] The definitions of various phases of clinical trials under 21 CFR may not be sufficiently detailed. Many disputes arise over whether a clinical trial is a Phase I or Phase II trial e.g. Phase I trials may include elements of efficacy and not only safety and Phase II trials will also include elements of safety.</p>
<p>1.38 “Phase II Clinical Trial” shall mean a human clinical trial in any country that would satisfy the requirements of 21 CFR 312.21(b).</p>	
<p>1.39 “Phase III Clinical Trial” shall mean a human clinical trial in any country that would satisfy the requirements of 21 CFR 312.21(c).</p>	
<p>1.40 “Product(s)” shall mean any pharmaceutical or biological preparation in final form containing either a Licensee Compound or a Licensor Compound (i) for sale by prescription, over-the-counter or any other method; or (ii) for administration to human patients in a Clinical</p>	

<p>Trial, for any and all uses in the Field, including without limitation any Combination Product.</p>	
<p>1.41 “Regulatory Authority” shall mean any applicable government regulatory authority involved in granting approvals for the manufacturing, marketing, reimbursement and/or pricing of a Product in the Territory, including, in the United States, the United States Food and Drug Administration and any successor governmental authority having substantially the same function.</p>	
<p>1.42 “Related Party” shall mean each of Licensee, its Affiliates, and their respective sublicensees (which term does not include distributors), as applicable.</p>	
<p>1.43 “Term” shall have the meaning set forth in Section 7.1.</p>	
<p>1.44 “Territory” shall mean all of the countries in the world, and their territories and possessions.</p>	
<p>1.45 “Third Party” shall mean an entity other than Licensee and its Related Parties, and Licensor and its Affiliates.</p>	
<p>1.46 “Valid Patent Claim” shall mean a claim of an issued and unexpired patent that is in force included within the Licensor Patent Rights which claims Compound or Product as a composition of matter, which has not been revoked or held unenforceable or invalid by a decision of a court or other governmental agency of competent jurisdiction (which decision is not appealable or has not been appealed within the time allowed for appeal), and which claim has not been disclaimed, denied or admitted to be invalid or unenforceable through reissue, re-examination or disclaimer or otherwise.</p>	<p>[30] This definition is limited to patents and does not include patent applications. An alternative definition is set out below: “Valid Claim” means either (a) a claim of an issued and unexpired patent which has not been held permanently revoked, unenforceable or invalid by a decision of a court or other governmental agency of competent jurisdiction, unappealable or unappealed within the time allowed for appeal and that is not admitted to be invalid or unenforceable through reissue, post-grant proceeding, disclaimer or otherwise (<i>i.e.</i>, only to the extent the subject matter is disclaimed or is sought to be deleted or amended through reissue), or (b) a claim of a pending patent application that has not been abandoned, finally rejected or expired without the possibility of appeal or refiling, <i>provided, however</i>, that Valid Claim will exclude any such pending claim in an application that has not been granted within five (5) years</p>

	<p>following the earliest non-provisional priority filing date for such claim (provided that, if such pending claim is granted after five (5) years, it shall be a Valid Claim in accordance with (a) above).</p>
<p>1.47 “Violation” shall mean that either Licensor, or any of its officers or directors has been: (a) convicted of any of the felonies identified among the exclusion authorities listed on the U.S. Department of Health and Human Services, Office of Inspector General (OIG) website, including 42 U.S.C. 1320a-7(a) (https://oig.hhs.gov/exclusions/index.asp); and/or (b) identified in the OIG List of Excluded Individuals/Entities (LEIE) database (https://oig.hhs.gov/exclusions/exclusions_list.asp) or the U.S. General Services Administration's list of Parties Excluded from Federal Programs (https://www.sam.gov/portal/public/SAM/) (each of (a) and (b), singly and collectively, the “Exclusions Lists”).</p>	
<p>ARTICLE 2 LICENSE; EXCHANGE OF INFORMATION; DEVELOPMENT AND COMMERCIALIZATION.</p>	
<p>2.1 License Grant. 2.1.1 Licensor hereby grants to Licensee an exclusive license (even as to Licensor) in the Territory under Licensor Patent Rights, with a right to grant and authorize sublicenses, for any and all uses in the Field, including but not limited to: (i) to make, have made, use, offer to sell, sell or import Compound(s) and Product(s) and (ii) to make, have made, use, offer to sell, sell or import any invention claimed in or covered by Licensor Patent Rights.</p> <p>Licensor hereby grants to Licensee an exclusive license (even as to Licensor) in the Territory under Licensor Know-How, with a right to grant and authorize sublicenses, for any and all uses in the Field, including but not limited to make, have made, use, offer to sell, sell or import Compound(s), Product(s) or any</p>	<p>[31a] Note that Licensor is giving up its rights to practice its Patent Rights and Know-How.</p> <p>[31b] As mentioned above, the term “covered” is not clearly defined, so its meaning is open to interpretation. Under some interpretations, Licensor may not have the right to grant a license to inventions “covered” in the Licensor Patent Rights.</p> <p>[31c] Licensor may not have the right to grant an exclusive license to the Know-How. Consider including “to the extent Licensor is legally able to do so”</p>

<p>invention claimed in or covered by Licensor Patent Rights.</p>	
<p>2.2 Non-Exclusive License Grant. In the event that the making, having made, use, offer for sale, sale or import by Licensee, or Licensee’s Related Parties, of Compound(s) or Product(s) would infringe during the Term of this Agreement a claim of issued letters patent which Licensor owns or has the rights to license and which patents are not covered by the grant in Section 2.1, Licensor hereby grants to Licensee, to the extent Licensor is legally able to do so, a non-exclusive, sublicensable, royalty-free license in the Territory under such issued letters patent for Licensee and its Related Parties to develop, make, have made, use, sell, offer for sale or import Compound(s) and Product(s) in the Territory.</p>	
<p>2.3 No Implied Licenses. Except as set forth in Sections 2.1 and 2.2, neither Party shall acquire any license or other intellectual property interest, by implication or otherwise, in any Information disclosed to it under this Agreement or under any patents or patent applications owned or controlled by the other Party or its Affiliates.</p>	
<p>2.4 Exclusivity. During the Term, neither Licensor nor any of its Affiliates shall (itself or together with any Third Party), directly or indirectly, research, discover, develop (including generation, formatting, testing, expression, production or formulation), make or commercialize any AIPLA A analogs. Without limiting the foregoing, during the Term neither Licensor nor any of its Affiliates shall grant any rights or licenses to any Third Party under any Patent Rights, Know-How or other intellectual property owned or otherwise Controlled by Licensor or any of its Affiliates to research, discover, develop (including generation, formatting, testing, expression, production or formulation), make or commercialize any AIPLA A analogs.</p>	<p>[32] This is a very broad license and amounts to the sale by the Licensor of all its technology relating to the AIPLA A compound. Licensor should conduct due diligence to ensure that the research of Licensor’s remaining products would not violate this obligation.</p>
<p>2.5 Technology Transfer. As soon as reasonably practicable following the Effective Date (but in all cases within thirty-five (35) days after the Effective Date), and thereafter on an ongoing</p>	<p>[33] To be read consistently with the exclusivity obligation in Section 2.4, Section 2.5 may obligate Licensor to provide on-going technical support after an initial transmittal of</p>

<p>basis during the Term (to the extent not previously disclosed or provided), Licensor shall disclose and provide to Licensee (in writing and in electronic format in English, or other tangible form, as applicable) the Licensor Know-How including by providing in tangible form the Licensor Compounds in the amounts set forth in <u>Schedule 2.5</u> and such other Licensor Know-How as set forth on <u>Schedule 2.5</u>.</p>	<p>its Know-How, but only that Know-How existing as of the Effective Date.</p>
<p>2.6 Development and Commercialization. Licensee shall use Commercially Reasonable Efforts, at its own expense, to develop and commercialize a Product. In connection therewith, on no less frequently than a quarterly basis, Licensee shall provide to Licensor a written progress report, detailing Licensee's progress in the development and commercialization of a Product that incorporates or is derived from Licensor Technology.</p>	<p>[34] This reporting obligation for Licensee could provide Licensor with some ability to assess whether the licensed technology has been shelved. However, Licensor must take the report on faith. Consider requiring a certification by an officer similarly situated manager to protect against inaccurate reporting.</p>
<p>2.7 Excused Performance. In addition to the provisions of Article 5, the obligation of Licensee with respect to any Product under Section 2.6 are expressly conditioned upon the continuing absence of any adverse condition or event relating to the safety or efficacy of the Product, and the obligation of Licensee to develop or market any such Product shall be delayed or suspended so long as in Licensee's opinion any such condition or event exists. In the event that Licensee delays or suspends its obligation under this Section 2.7, Licensee shall provide Licensor a written description of the perceived adverse condition or event relating to the safety or efficacy of the Product and the circumstances under which the perceived adverse condition or event arose within thirty (30) days of Licensee's perception of the adverse condition or event.</p>	<p>[35] This provision is very Licensee-friendly. Licensor may wish to define which adverse events or conditions would qualify for excused performance</p>
<p>ARTICLE 3 CONFIDENTIALITY AND PUBLICATION.</p>	
<p>3.1 Nondisclosure Obligation. All Information disclosed by one Party to the other Party hereunder shall be maintained in confidence by the receiving Party and shall not be disclosed to any Third Party or used for any purpose except as set forth herein without the prior written consent</p>	

<p>of the disclosing Party, except to the extent that such Information:</p>	
<p>3.1.1 is known by the receiving Party at the time of its receipt, and not through a prior disclosure by the disclosing Party, as documented by the receiving Party’s business records;</p>	
<p>3.1.2 is in the public domain by use and/or publication before its receipt from the disclosing Party, or thereafter enters the public domain through no fault of the receiving Party;</p>	
<p>3.1.3 is subsequently disclosed to the receiving Party by a Third Party who may lawfully do so and is not under an obligation of confidentiality to the disclosing Party;</p>	
<p>3.1.4 is developed by the receiving Party independently of Information received from the disclosing Party, as documented by the receiving Party’s business records;</p>	<p>[36] Consider amending to “receiving Party’s <u>contemporaneous</u> business records” to exclude business records created after the event</p>
<p>3.1.5 is disclosed to governmental or other regulatory agencies in order to obtain patents or to gain or maintain approval to conduct clinical trials or to market Product, but such disclosure may be only to the extent reasonably necessary to obtain patents or authorizations;</p>	<p>[37] The provider of the Information may want to ensure that disclosures under Section 3.1.5 are only made following approval.</p>
<p>3.1.6 is deemed necessary by the receiving Party to be disclosed to Affiliates, Related Parties, agent(s), consultant(s), and/or other Third Parties for any and all purposes such Party deems necessary or advisable in the ordinary course of business in accordance with this Agreement on the condition that such Third Parties agree to be bound by confidentiality and non-use obligations that substantially are no less stringent than those confidentiality and non-use provisions contained in this Agreement; <u>provided, however,</u> that the term of</p>	

<p>confidentiality for such Third Parties shall be no less than ten (10) years; or</p>	
<p>3.1.7 is deemed necessary by counsel to the receiving Party to be disclosed to such Party’s attorneys, independent accountants or financial advisors for the sole purpose of enabling such attorneys, independent accountants or financial advisors to provide advice to the receiving Party, on the condition that such attorneys, independent accountants and financial advisors agree to be bound by the confidentiality and non-use obligations contained in this Agreement; <u>provided, however,</u> that the term of confidentiality for such attorneys, independent accountants and financial advisors shall be no less than ten (10) years.</p>	
<p>Any combination of features or disclosures shall not be deemed to fall within the foregoing exclusions merely because individual features are published or available to the general public or in the rightful possession of the receiving Party unless the combination itself and principle of operation are published or available to the general public or in the rightful possession of the receiving Party.</p>	
<p>If a Party is required by judicial or administrative process to disclose Information that is subject to the non-disclosure provisions of this Section 3.1 or Section 3.3, such Party shall promptly inform the other Party of the disclosure that is being sought in order to provide the other Party an opportunity to challenge or limit the disclosure obligations. Information that is disclosed by judicial or administrative process shall remain otherwise subject to the confidentiality and non-use provisions of this Section 3.1 and Section 3.3, and the Party disclosing Information pursuant to law or court order shall take all steps reasonably necessary, including without limitation obtaining an order of confidentiality, to ensure the continued confidential treatment of such Information.</p>	
<p>3.2 Prior Non-Disclosure Agreements. As of the Effective Date, the terms of this Article 3 shall</p>	

<p>supersede the Confidential Disclosure Agreement, effective April 6, 2012, by and between Licensee and Licensor, and shall apply to any confidential information disclosed by a Party (or its Affiliate) thereunder.</p>	
<p>3.3 Licensor Know-How. Licensor agrees to keep all Licensor Know-How confidential subject to Section 3.1.2.</p>	<p>[38] This provision could operate to protect the trade secret value of Licensor's Know-How and limit Licensor's ability to generate prior art for Licensee's future patent applications. This may be unnecessary considering other protective terms in the agreement.</p>
<p>3.4 Publication. Licensor shall have no right to publish with respect to AIPLA A Analogues, Products or Compounds. Licensee shall have the right to publish results of its research regarding AIPLA A Analogues, Products and Compounds to the extent that such publications do not disclose Licensor's Confidential Information.</p>	
<p>3.5 Publicity/Use of Names. No disclosure of the existence, or the terms, of this Agreement may be made by either Party, and no Party shall use the name, trademark, trade name or logo of the other Party, its Affiliates or their respective employee(s) in any publicity, promotion, news release or disclosure relating to this Agreement or its subject matter, without the prior express written permission of the other Party, except as may be required by law.</p>	<p>[39] Licensor should be careful to obtain prior approval for any press-releases relating to the license agreement.</p>
<p>ARTICLE 4 PAYMENTS; ROYALTIES AND REPORTS.</p>	
<p>4.1 Upfront Payment. In consideration for the licenses granted to Licensee herein, Licensee shall pay to Licensor an up-front fee in the aggregate amount of Twenty Million Dollars (\$20,000,000) within thirty (30) days following the Effective Date which amount shall be non-refundable.</p>	

<p>4.2 Milestone Payments. The following milestones payments shall be payable only one time for the first Product to achieve such milestone (and for clarity a given milestone payment shall not be payable more than one time even if more than one Product achieves such milestone):</p> <table border="1" data-bbox="305 428 885 1056"> <tr> <td data-bbox="305 428 885 491">Milestone Event</td> </tr> <tr> <td data-bbox="305 491 885 583">Initiation of the first IND enabling study with a Compound</td> </tr> <tr> <td data-bbox="305 583 885 676">Initiation of the first Phase I Clinical Trial for a Product</td> </tr> <tr> <td data-bbox="305 676 885 768">Initiation of the first Phase II Clinical Trial for the first Product</td> </tr> <tr> <td data-bbox="305 768 885 861">Initiation of the first Phase III Clinical Trial for the first Product</td> </tr> <tr> <td data-bbox="305 861 885 953">FDA approval of the NDA for the first Product in the US</td> </tr> <tr> <td data-bbox="305 953 885 1056">EMEA Approval of the Marketing for the first Product in three of the five Major EU Markets</td> </tr> </table>	Milestone Event	Initiation of the first IND enabling study with a Compound	Initiation of the first Phase I Clinical Trial for a Product	Initiation of the first Phase II Clinical Trial for the first Product	Initiation of the first Phase III Clinical Trial for the first Product	FDA approval of the NDA for the first Product in the US	EMEA Approval of the Marketing for the first Product in three of the five Major EU Markets	<p>[40] Note that even if multiple products are generated from Licensor Technology, milestones are payable only for the first product.</p>
Milestone Event								
Initiation of the first IND enabling study with a Compound								
Initiation of the first Phase I Clinical Trial for a Product								
Initiation of the first Phase II Clinical Trial for the first Product								
Initiation of the first Phase III Clinical Trial for the first Product								
FDA approval of the NDA for the first Product in the US								
EMEA Approval of the Marketing for the first Product in three of the five Major EU Markets								
<p>4.2.1 Licensee shall notify Licensor in writing within thirty (30) days following the achievement of each milestone, and shall make the appropriate milestone payment within thirty (30) days after the achievement of such milestone. The milestone payment shall be payable only upon the initial achievement of such milestone and no amounts shall be due hereunder for subsequent or repeated achievement of such milestone.</p>								
<p>4.3 Royalties.</p>								
<p>4.3.1 <u>Royalties Payable By Licensee.</u> Subject to the terms and conditions of this Agreement, Licensee shall pay Licensor royalties, calculated on a Product-by-Product basis, as set forth in this Section 4.3.</p>								
<p>(a) <u>Patent Royalties.</u></p>								

<p>(i) <u>ROYALTY PERCENTAGE.</u> Subject to the provisions of Section 4.3.1(b) Licensee shall pay Licensor royalties in an amount equal to the following percentage of Net Sales of Products by Licensee or its Related Parties:</p>	
<p>(1) Four percent (4%) of worldwide Net Sales in the Territory in each Calendar Year if the Product contains an Licensor Compound (including any Combination Product that contains both a Licensee Compound(s) and an Licensor Compound); provided, that the sale of such Product would infringe a Valid Patent Claim in the country of sale; and</p>	<p>[41] Licensee-friendly definition. Licensor may wish to receive royalties for Combination Products that include a Licensor Compound in combination with a Licensee Compound <u>or a third party compound.</u></p>
<p>(2) Two percent (2%) of worldwide Net Sales in the Territory in each Calendar Year for those Products that contain a Licensee Compound;</p>	<p>[42] This provision accounts for situations where Licensee produces a Licensee Compound that is not included in any of Licensor's Patent Rights, but its process chemistry or use is covered by Licensor Patent Rights.</p>

	provided, that the sale of such Product would infringe a Valid Patent Claim in the country of sale.	
(b)	<u>Know-How Royalty.</u> Notwithstanding the provisions of Section 4.3.1(a), in countries where the sale of Product by Licensee or its Related Parties would not infringe a Valid Patent Claim, Licensee shall pay royalty rates that shall be set at fifty percent (50%) of the applicable royalty rate determined according to 4.3.1(a). Such royalties shall be calculated after first calculating royalties under Section 4.3.1(a).	[43] It is important to include a step-down royalty rate for Know-How to avoid claims of patent misuse.
(c)	Royalties pursuant to Section 4.3.1(a) shall be calculated based on worldwide Net Sales of each Product in the Territory. Royalties on each Product at the rates set forth above shall continue on a country-by-country basis until the expiration of the later of: (i) the last-to-expire Valid Patent Claim or (ii) for a period of ten (10) years after First Commercial Sale of such Product in such country (the “ Royalty Period ”).	
(d)	All royalties are subject to the following conditions: (i) that only one royalty shall be due with respect to the same unit of Product;	
	(ii) that no royalties shall be due upon the sale or other transfer among	

	<p>Licensee or its Related Parties, but in such cases the royalty shall be due and calculated upon Licensee's or its Related Party's Net Sales to the first independent Third Party;</p>
<p>(iii)</p>	<p>no royalties shall accrue on the sale or other disposition of Product by Licensee or its Related Parties for use in a Clinical Trial; and</p>
<p>(iv)</p>	<p>no royalties shall accrue on the disposition of Product in reasonable quantities by Licensee or its Related Parties as samples (promotion or otherwise) or as donations (for example, to non-profit institutions or government agencies for a non-commercial purpose).</p>
<p>4.3.2 <u>Royalties for Bulk Compound.</u> In those cases in which Licensee sells bulk Compound rather than Product in packaged form to an independent Third Party, the royalty obligations of this Section 4.3 shall be applicable to the bulk Compound.</p>	<p>[44] Important provision for the Licensee to include in order to avoid paying higher royalty rates.</p>
<p>4.3.3 <u>Compulsory Licenses.</u> If a compulsory license is granted to a Third Party with respect to Product in any country in the Territory with a royalty rate lower than the royalty rate provided by Section 4.3.1, then the royalty rate to be paid by Licensee on Net Sales in that country under Section 4.3.1 shall be reduced to the rate paid by the compulsory licensee.</p>	<p>[45] Important provision for the Licensee to include in order to avoid paying higher royalty rates.</p>

<p>4.3.4 Third Party Licenses. In the event that one or more patent licenses from Third Parties are required by Licensee or its Related Parties in order to make, have made, use, offer to sell, sell or import Compound or Product(s) (hereinafter “Third Party Patent Licenses”), fifty percent (50%) of the consideration actually paid under such Third Party Patent Licenses by Licensee or its Related Parties for sale of such Compound or Product in a country for a Calendar Quarter shall be creditable against the royalty payments due Licensor by Licensee with respect to the sale of such Compound or Products in such country; <u>provided, however</u>, that in no event shall the royalties owed by Licensee to Licensor for such Calendar Quarter in such country be reduced by more than fifty percent (50%).</p>	<p>[46] Licensee should include this provision in case it is required to pay third party royalties on the product. Licensor should ensure that the reduction is limited, e.g. 50%, to some fraction of the royalty rate.</p>
<p>4.4 REPORTS; PAYMENT OF ROYALTY. During the Term of this Agreement following the First Commercial Sale of a Product, Licensee shall furnish to Licensor a quarterly written report for the Calendar Quarter showing the Net Sales of all Products subject to royalty payments sold by Licensee and its Related Parties in the Territory during the reporting period and the royalties payable under this Agreement. Reports shall be due on the sixtieth (60th) day following the close of each Calendar Quarter. Royalties shown to have accrued by each royalty report shall be due and payable on the date such royalty report is due. Licensee shall keep complete and accurate records in sufficient detail to enable the royalties payable hereunder to be determined.</p>	
<p>4.5 Audits.</p>	
<p>4.5.1 Upon the written request of Licensor and not more than once in each Calendar Year, Licensee shall permit an independent certified public accounting firm of nationally recognized standing selected by Licensor and reasonably acceptable to Licensee, at Licensor’s expense, to have access during normal business hours to such of the records of</p>	<p>[47a] This provision limits audit rights to one time per year. Any more might be onerous on Licensee. Licensee should include a limitation on the length of the audit e.g. 2 days since audits can be disruptive to the business.</p> <p>[47b] It is important that Licensee limit the transmission of its confidential information, via the auditors, to Licensor.</p>

<p>Licensee as may be reasonably necessary to verify the accuracy of the royalty reports hereunder for any Calendar Year ending not more than twenty-four (24) months prior to the date of such request. The accounting firm shall disclose to Licensor only whether the royalty reports are correct or incorrect and the amount of any discrepancy. No other information shall be provided to Licensor.</p>	
<p>4.5.2 If such accounting firm correctly identifies a discrepancy of ten percent (10%) or more of the payment(s) audited for such period, the appropriate Party shall pay the other Party the amount of the discrepancy within thirty (30) days of the date Licensor delivers to Licensee such accounting firm's written report so correctly concluding, or as otherwise agreed upon by the Parties. The fees charged by such accounting firm shall be paid by Licensee.</p>	<p>[48] Licensor may argue that it will only correct discrepancies in favor of Licensor and will not repay any overpayments by Licensee to Licensor.</p>
<p>4.5.3 Licensee shall include in each sublicense granted by it pursuant to this Agreement a provision requiring the sublicensee to make reports to Licensee, to keep and maintain records of sales made pursuant to such sublicense and to grant access to such records by Licensor's independent accountant to the same extent required of Licensee under this Agreement.</p>	<p>[49] Licensor may wish to require any sublicenses to include certain critical provisions of the license e.g. confidentiality, liability, insurance, etc.</p>
<p>4.5.4 Upon the expiration of twenty-four (24) months following the end of any Calendar Year, the calculation of royalties payable with respect to such Calendar Year shall be binding and conclusive upon Licensor, and Licensee and its Related Parties shall be released from any liability or accountability with respect to royalties for such Calendar Year.</p>	<p>[50] This provision favors the Licensee and does not consider potential patent litigation relating to disputed royalties that may extend over multiple years. Licensor should consider situations where Royalties may not be accurately determined due to such complications.</p>
<p>4.5.5 Licensor shall treat all financial information subject to review under this</p>	

<p>Section 4.5 or under any sublicense agreement in accordance with the confidentiality and non-use provisions of this Agreement, and shall cause its accounting firm to enter into an acceptable confidentiality agreement with Licensee and/or its Related Parties obligating it to retain all such information in confidence pursuant to such confidentiality agreement.</p>	
<p>4.6 Payment Exchange Rate. All payments to be made by Licensee to Licensor under this Agreement shall be made in United States dollars and may be paid by check made to the order of Licensor or bank wire transfer in immediately available funds to such bank account in the United States as may be designated in writing by Licensor from time to time. In the case of sales outside the United States, the rate of exchange to be used in computing the monthly amount of currency equivalent in United States dollars due Licensor shall be made at the monthly rate of exchange utilized by Licensee in its worldwide accounting system.</p>	<p>[51] The parties may wish to include a more recognized exchange rate than that utilized by the Licensee’s accounting system.</p>
<p>4.7 Income Tax Withholding. Licensor shall be liable for all income and other taxes (including interest) (“Taxes”) imposed upon any payments made by Licensee to Licensor under this Article Article 4 (“Agreement Payments”). If applicable laws, rules or regulations require the withholding of Taxes, Licensee shall make such withholding payments and shall subtract the amount thereof from the Agreement Payments. Licensee shall submit to Licensor appropriate proof of payment of the withheld Taxes as well as the official receipts within a reasonable period of time. Licensee shall provide Licensor reasonable assistance in order to allow Licensor to obtain the benefit of any present or future treaty against double taxation which may apply to the Agreement Payments.</p>	<p>[52] This is an important clause to include as Licensee may be required to withhold taxes and would not want to have to pay the full amount and the withholding taxes</p>
<p>ARTICLE 5 REPRESENTATIONS AND WARRANTIES.</p>	
<p>5.1 REPRESENTATIONS AND WARRANTIES OF EACH PARTY. Each Party represents and</p>	

warrants to the other Party that as of the Effective Date:	
5.1.1 it has the full right, power and authority to enter into this Agreement and to perform its obligations hereunder; and	
5.1.2 this Agreement has been duly executed by it and is legally binding upon it, enforceable in accordance with its terms, and does not conflict with any agreement, instrument or understanding, oral or written, to which it is a party or by which it may be bound, nor violate any material law or regulation of any court, governmental body or administrative or other agency having jurisdiction over it.	
5.2 LICENSOR REPRESENTATIONS AND WARRANTIES. Licensor represents and warrants to Licensee that as of the date of this Agreement:	[53] When know-how is licensed, consider applicable reps/warranties that are commonly included in trade secret licenses.
5.2.1 to the best of Licensor’s knowledge, the Licensor Patent Rights and Licensor Know-How exist and are not invalid or unenforceable, in whole or in part;	[54] Important to include “to the best of Licensor’s knowledge” qualifier if Licensor is required to rep/warrant validity of licensed IP.
5.2.2 it has the full right, power and authority to enter into this Agreement and to grant the licenses granted under Article 4;	
5.2.3 it has not previously assigned, transferred, conveyed or otherwise encumbered its right, title and interest in Licensor Patent Rights or Licensor Know-How;	
5.2.4 to the best of Licensor’s knowledge, it is the sole and exclusive owner of the Licensor Patent Rights and Licensor Know-How, all of which are free and clear of any liens, charges and encumbrances, and no other person, corporate or other private entity, or governmental entity or subdivision thereof, has any claim of ownership	[55] Knowledge qualifier may not be necessary in this subsection in view of the other terms.

	whatsoever with respect to the Licensor Patent Rights and Licensor Know-How;	
5.2.5	to the best of Licensor’s knowledge, the exercise of the license granted to Licensee under the Licensor Patent Rights and Licensor Know-How, including without limitation the development, manufacture, use, sale and import of Compound and Products do not interfere with or infringe any intellectual property rights owned or possessed by any Third Party;	[56] Licensor should insist on a knowledge qualifier for this rep/warranty.
5.2.6	there are no claims, judgments or settlements against or owed by Licensor and, to the best of Licensor’s knowledge, there are no pending or threatened claims or litigation relating to the Licensor Patent Rights and Licensor Know-How; and	[57] Knowledge qualifier may not be necessary in this subsection in view of the other terms. Consider adding a rep/warranty that Licensor has not been notified by any Third Parties of any potential IP claims.
5.2.7	Licensor has disclosed to Licensee all reasonably relevant information regarding the Licensor Patent Rights and Licensor Know-How licensed under this Agreement.	[58] This is a useful catch-all for Licensee but may be onerous on Licensor.
5.2.8	Licensor has disclosed to Licensee the existence of any patent opinions related to the Licensor Patent Rights and Licensor Know-How licensed under this Agreement.	
ARTICLE 6 PATENT PROVISIONS.		
6.1	Ownership of Inventions, Disclosure, Assignment of Interests.	
6.1.1	Ownership. Licensee shall own all right, title and interest in any and all Licensee Patent Rights and Inventions. Licensor shall own all right, title and interest in any and all Licensor Patent Rights.	
6.1.2	Disclosure. Licensor shall promptly disclose to Licensee in writing the development, making, conception or reduction to practice of any Invention	[59] The term “for clarity” may imply that the previous sentence is unclear. Consider using alternative language, e.g., as an illustration or by way of example.

<p>which is conceived, discovered, made and/or reduced to practice by or on behalf of Licensor (or its employees, agents or consultants). For clarity, in accordance with Section 2.4 it is anticipated that Licensor will not make any Inventions.</p>	
<p>6.1.3 Assignment of Interests to Effectuate Ownership. In the event that Licensor makes Inventions despite Section 2.4, Licensee shall exclusively own such Inventions. Licensor shall, and hereby does, on behalf of itself and each of its Affiliates, employees, assign to Licensee (without the payment of additional consideration, and the Parties hereby acknowledge and agree that the consideration as set forth in this Agreement is sufficient), in perpetuity throughout the world, ownership of all rights, title and interest in and to such Inventions to effect the ownership of such Inventions. In furtherance of the foregoing, Licensor shall, upon request by Licensee, promptly undertake and perform (and /or cause its Affiliates and their respective employees and/or agents to promptly undertake and perform) such further actions as are reasonably necessary for Licensee to, as between the Parties, perfect its title in any such Inventions, as applicable, including by causing the execution of any assignments or other legal documentation, and/or providing Licensee or its patent counsel with reasonable access to any employees or agents who may be inventors of such Invention.</p>	
<p>6.2 Filing, Prosecution and Maintenance of Patents. Licensor agrees to file patent applications claiming Licensor Know-How generated as of the Effective Date or Licensor Compounds, and to prosecute and maintain in the Territory, upon appropriate consultation with Licensee, the Licensor Patent Rights licensed to Licensee under this Agreement. Licensor shall give Licensee an opportunity to review the text of any patent application before filing, shall consult</p>	<p>[60] In the context of this license, since Licensor is precluded from doing any research, development or sale of the AIPLA A compound, Licensee may wish to have full control of Licensor Patent prosecution. Licensor may agree to this provided Licensor is afforded the opportunity to review and comment on the filing and prosecution strategy.</p>

<p>with Licensee with respect thereto, and shall supply Licensee with a copy of the application as filed, together with notice of its filing date and serial number. Licensor shall keep Licensee advised of the status of the actual and prospective patent filings and, upon Licensee's request, shall provide advance copies of any papers related to the prosecution and maintenance of Licensor Patent Rights. Licensor shall promptly give notice to Licensee of the grant, lapse, revocation, surrender, invalidation or abandonment of any Licensor Patent Rights licensed to Licensee for which Licensor is responsible for the filing, prosecution and maintenance. For the avoidance of doubt, Licensee shall have the sole right to file, prosecute and maintain patent applications and patents claiming Licensee Patent Rights. With respect to all filings, prosecution and maintenance of Licensor Patent Rights, Licensee shall be responsible for payment of fifty (50%) of all related costs and expenses.</p>	
<p>6.3 Option of Licensee to File, Prosecute and Maintain Licensor Patent Rights. Licensor may elect not to file patent applications claiming Licensor Know-How generated as of the Effective Date or Licensor Compounds and, if so, Licensor shall notify Licensee and Licensee shall have the right to file such patent applications. Licensor shall give notice to Licensee of any desire to cease prosecution and/or maintenance of Licensor Patent Rights on a country-by-country basis in the Territory and, in such case, shall permit Licensee, in its sole discretion, to continue prosecution or maintenance of such Licensor Patent Rights at its own expense. In such events, if Licensee elects to file patent applications claiming Licensor Know-How generated as of the Effective Date or Licensor Compounds, or to continue prosecution or maintenance of Licensor Patent Rights, Licensor shall execute in a timely manner and at Licensor's expense (i) an assignment of such Licensor Patent Rights to Licensee and (ii) additional documents as may be reasonably necessary to allow Licensee to continue such filing, prosecution or maintenance. Any patents or patent applications so assigned shall not be considered Licensor Patent Rights.</p>	

<p>6.4 Derivation, Interference, Inter Partes Review, Invalidation, Opposition, Post-grant Review, Reexamination and Reissue of Licensor Patent Rights.</p>	
<p>6.4.1 Licensor shall, within ten (10) days of learning any request for, or filing or declaration of, any derivation, interference, inter partes review, invalidation, opposition, post-grant review, reexamination or similar administrative proceeding initiated by a Third Party relating to Licensor Patent Rights, inform Licensee of such event. Licensee and Licensor shall thereafter consult and cooperate fully to determine a course of action with respect to any such proceeding. Licensee shall have the right to review and approve any submission to be made in connection with such proceeding.</p>	
<p>6.4.2 Licensor shall not initiate any derivation, supplemental examination, reexamination, interference or reissue proceeding relating to Licensor Patent Rights without the prior written consent of Licensee, which consent shall not be unreasonably withheld.</p>	
<p>6.4.3 In connection with any derivation, interference, supplemental examination, inter partes review, invalidation, opposition, post-grant review, reissue, reexamination, or similar administrative proceeding relating to Licensor Patent Rights, Licensee and Licensor will cooperate fully and will provide each other with any information or assistance that either may reasonably request. Licensor shall keep Licensee informed of developments in any such action or proceeding, including, to the extent permissible by law, consultation and approval of any settlement, the status of any settlement negotiations and the terms of any offer related thereto.</p>	

<p>6.4.4 Licensor shall bear the expense of any derivation, interference, supplemental examination, inter partes review, invalidation, opposition, post-grant review, reexamination, reissue, or similar administrative proceeding relating to Licensor Patent Rights.</p>	<p>[61] Consider cost sharing between Licensor and Licensee for patent challenges.</p>
<p>6.5 Enforcement and Defense.</p>	
<p>6.5.1 Licensor shall give Licensee notice of either (i) any infringement of Licensor Patent Rights, or (ii) any misappropriation or misuse of Licensor Know-How, that may come to Licensor’s attention. Licensee and Licensor shall thereafter consult and cooperate fully to determine a course of action, including but not limited to the commencement of legal action by either or both Licensee and Licensor, to terminate any infringement of Licensor Patent Rights or any misappropriation or misuse of Licensor Know-How. Licensee, upon notice to Licensor, shall have the first right to initiate and prosecute such legal action at its own expense and in the name of Licensor and Licensee, or to control the defense of any declaratory judgment action relating to Licensor Patent Rights or Licensor Know-How. Licensee shall <u>promptly</u> inform Licensor if it elects not to exercise such first right and Licensor shall thereafter have the right to either initiate and prosecute such action or to control the defense of such declaratory judgment action in the name of Licensor and, if necessary, Licensee. Each Party shall have the right to be represented by counsel of its own choice.</p>	<p>[62a] The obligation to notify of any infringement or misappropriation should be reciprocal. Licensee would be more likely to here of this type of activity given that Licensor would no longer be commercializing AIPLA A.</p> <p>[62b] The term “promptly” is open to subjective interpretation. Consider specifying a time limit.</p> <p>[62c] Some Licensees may wish to prevent the Licensor from enforcing its IP rights if Licensee elects not to do so.</p>
<p>6.5.2 In the event that Licensee elects not to initiate and prosecute an action as provided in Section 6.5.1, and Licensor elects to do so, the costs of any agreed-upon course of action to terminate infringement of Licensor Patent Rights or misappropriation or misuse of Licensor Know-How, including without</p>	

<p>limitation the costs of any legal action commenced or the defense of any declaratory judgment, shall be shared equally by Licensor and Licensee.</p>	
<p>6.5.3 For any action to terminate any infringement of Licensor Patent Rights or any misappropriation or misuse of Licensor Know-How, in the event that Licensee is unable to initiate or prosecute such action solely in its own name, Licensor will join such action voluntarily and will execute and cause its Affiliates to execute all documents necessary for Licensee to initiate litigation to prosecute and maintain such action. In connection with any action, Licensee and Licensor will cooperate fully and will provide each other with any information or assistance that either may reasonably request. Each Party shall keep the other informed of developments in any action or proceeding, including, to the extent permissible by law, consultation on and approval of any settlement, the status of any settlement negotiations and the terms of any offer related thereto.</p>	
<p>6.5.4 Any recovery obtained by either or both Licensee and Licensor in connection with or as a result of any action contemplated by this Section, whether by settlement or otherwise, shall be shared in order as follows:</p>	
<p>(a) the Party which initiated and prosecuted the action shall recoup all of its costs and expenses incurred in connection with the action;</p>	
<p>(b) the other Party shall then, to the extent possible, recover its costs and expenses incurred in connection with the action; and</p>	
<p>(c) the amount of any recovery remaining shall then be allocated between the Parties on a pro rata</p>	

<p>basis taking into consideration the relative economic losses suffered by each Party.</p>	
<p>6.5.5 Licensor shall inform Licensee of any certification regarding any Licensor Patent Rights it has received pursuant to either 21 U.S.C. §§355(b)(2)(A)(iv) or (j)(2)(A)(vii)(IV) or its successor provisions or any similar provisions in a country in the Territory other than the United States, and shall provide Licensee with a copy of such certification within five (5) days of receipt. Licensor's and Licensee's rights with respect to the initiation and prosecution of any legal action as a result of such certification or any recovery obtained as a result of such legal action shall be as defined in Sections 6.5.1 through 6.5.4; <u>provided, however</u>, that Licensee shall exercise its first right to initiate and prosecute any action and shall inform Licensor of such decision within ten (10) days of receipt of the certification, after which time Licensor shall have the right to initiate and prosecute such action. Regardless of which Party has the right to initiate and prosecute such action, both Parties shall, as soon as practicable after receiving notice of such certification, convene and consult with each other regarding the appropriate course of conduct for such action. The non-initiating Party shall have the right to be kept fully informed and participate in decisions regarding the appropriate course of conduct for such action, and the right to join and participate in such action.</p>	<p>[63] Provision is specific to drug products for which FDA market approval is required. A generic drug company can obtain 180 days of market exclusivity for its generic drug product if it is the first to file its ANDA and Paragraph IV certification, which certifies that the generic company's drug product does not infringe the (orange book listed) patents of the branded drug company, and usually alleges that the branded drug company's patents are unenforceable.</p> <p>The filing of the ANDA is an act of infringement, and unless the branded drug company files an infringement suit within 45 days, the FDA will approve the ANDA. If an infringement claim is asserted against a generic drug company, the FDA will suspend approval of the ANDA for the earlier of 30 months or until the court rules on the suit.</p> <p>Accordingly, ANDA litigation could heavily impact the value and market share of a branded drug. This provision obliges the parties to cooperate in the event that such litigation strategy becomes necessary due to an ANDA filing. This is to both parties' benefit.</p>
<p>6.6 Patent Term Restoration And Extension. The Parties shall cooperate fully with each other to provide necessary information and assistance, as the other Party may reasonably request, in obtaining patent term extension or supplemental protection certificates or their equivalents in any country in the Territory where applicable to Licensor Patent Rights and Licensee Patent Rights. In the event that elections with respect to</p>	

<p>obtaining such patent term extension are to be made, Licensee shall have the right to make the election and Licensor agrees to abide by such election.</p>	
<p>6.7 Other Cooperation. The Parties agree to cooperate fully and provide any information and assistance that either may reasonably request for the filing, prosecution and maintenance of Licensor Patent Rights and/or Licensee Patent Rights. The Parties further agree to take reasonable actions to maximize the protections available under the safe harbor provisions of 35 U.S.C. 102(c) for U.S. patents and patent applications</p>	
<p>ARTICLE 7 TERM AND TERMINATION.</p>	
<p>7.1 Term And Expiration. This Agreement shall be effective as of the Effective Date and unless terminated earlier pursuant to Sections 7.2 or 7.3, this Agreement shall continue in full force and effect until one or more Products has received Marketing Authorization and, thereafter, until expiration of all royalty obligations hereunder (the “Term”). Upon expiration of this Agreement, Licensee's licenses pursuant to Section 2.1 and 2.2 shall become fully paid-up, perpetual licenses.</p>	<p>[64] “Marketing Authorization” may be unnecessary because it doesn’t serve as a metric to measure the term.</p>
<p>7.2 Termination By Licensee. Notwithstanding anything contained herein to the contrary, Licensee shall have the right to terminate this Agreement at any time in its sole discretion by giving ninety (90) days’ advance written notice to Licensor. No later than thirty (30) days after the effective date of such termination, each Party shall return or cause to be returned to the other Party all Information in tangible form received from the other Party and all copies thereof; <u>provided, however,</u> that each Party may retain any Information reasonably necessary for such Party’s continued practice under any license(s) which do not terminate pursuant to this Section, and may keep one copy of Information received from the other Party in its confidential files for record purposes. In the event of termination under this Section 7.2: (i) each Party shall pay all amounts then due and owing as of the termination date; and (ii) except for the surviving provisions</p>	<p>[65] This clause seems somewhat bulky and could imply that Licensee has the right to terminate only certain parts of the license but leave other parts in force. Licensor should resist this type of piecemeal termination because Licensor may find it difficult to find an alternative licensee if Licensee still retains certain rights to AIPLA A.</p>

<p>set forth in Section 7.4, the rights and obligations of the Parties hereunder shall terminate as of the date of such termination.</p>	
<p>7.3 Termination for Cause.</p>	
<p>7.3.1 Cause for Termination. This Agreement may be terminated at any time during the Term of this Agreement:</p>	
<p>(a) upon written notice by either Party if the other Party is in breach of its material obligations hereunder by causes and reasons within its control and has not cured such breach within ninety (90) days after notice requesting cure of the breach; <u>provided, however,</u> in the event of a good faith dispute with respect to the existence of a material breach, the ninety (90) day cure period shall be tolled until such time as the dispute is resolved pursuant to Section 9.6.</p>	<p>[66] Licensee may try to include language that tolls the 90 day cure period in the event of a dispute that cannot reasonably be cured within 90 days.</p>
<p>(b) immediately upon written notice by Licensor if Licensor determines in its reasonable discretion that Licensee has failed to satisfy its obligations under Section 2.6; or</p>	<p>[67] Most licensees would not accept such broad discretion on the part of a licensor to terminate a license. This clause may conflict with Section 9.6.5, depending on the circumstances and what is deemed to be “good faith”.</p>
<p>(c) by either Party upon the filing or institution of bankruptcy, reorganization, liquidation or receivership proceedings, or upon an assignment of a substantial portion of the assets for the benefit of creditors by the other Party; <u>provided, however,</u> that in the case of any involuntary bankruptcy proceeding such right to terminate shall only become effective if the Party consents to the involuntary bankruptcy or such proceeding is not dismissed</p>	

<p>within ninety (90) days after the filing thereof.</p>	
<p>7.3.2 <u>Effect of Termination for Cause on License.</u></p>	<p>[68] This section does not address (i) sublicenses or (ii) Licensee Patent Rights in the case of termination.</p> <p>As to sublicenses - Licensee should consider including language that retains sublicensees rights in the event of breach by Licensee. Failure to include such language would make a sublicense unpalatable to a potential sublicensee</p> <p>As to Licensee Patent Rights – the Licensor may argue that Licensee should transfer to Licensor all Licensee Patents in the case of termination for breach by Licensee given that Licensee would not have been able to develop the technology without using confidential information and know-how of licensor. This may be a contentious provision to negotiate but without it, there could be a messy situation with Licensor retaining valuable rights to AIPLA A</p>
<p>(a) If this Agreement is terminated under Section 7.3.1(a) or (b): (i) Licensee’s license pursuant to Sections 2.1 and 2.2 shall terminate as of such termination date; (ii) Licensee shall, within thirty (30) days after the effective date of such termination, return or cause to be returned to Licensor all Information in tangible form and substances or compositions delivered or provided by Licensor, as well as any other material provided by Licensor in any medium; and (iii) Licensor shall, within thirty (30) days after the effective date of such termination, return or cause to be returned to Licensee all Information in tangible form, and all substances or compositions delivered or provided by Licensee, as well as</p>	<p>[69] Subsection (a)(iii) is probably unnecessary (as written) given that the flow of Information and compounds are directed to the Licensee. It could potentially require the Licensor to return the quarterly status reports that Licensee is obligated to provide.</p>

<p>any other material provided by Licensee in any medium.</p>	
<p>(b) Upon termination of this Agreement by Licensee pursuant to Section 7.2, or by Licensor pursuant to Section 7.3.1(b), Licensee and its Affiliates, sublicensees and distributors shall be entitled, during the twelve (12) month period immediately following the effective date of termination, to finish any work-in-progress and to sell any Products or Compound remaining in inventory, in accordance with the terms of this Agreement.</p>	<p>[70] Consider revising this language to consider the effect of termination at different stages of drug development.</p>
<p>(c) If this Agreement is terminated by Licensee pursuant to Section 7.3.1(c) due to the rejection of this Agreement by or on behalf of Licensor under Section 365 of the United States Bankruptcy Code (the “Code”), all licenses and rights to licenses granted under or pursuant to this Agreement by Licensor to Licensee are, and shall otherwise be deemed to be, for purposes of Section 365(n) of the Code, licenses of rights to “intellectual property” as defined under Section 101(35A) of the Code. The Parties agree that Licensee, as a licensee of such rights under this Agreement, shall retain and may fully exercise all of its rights and elections under the Code, and that upon commencement of a bankruptcy proceeding by or against Licensor under the Code, Licensee shall be entitled to a complete duplicate of or complete access to (as Licensee deems appropriate), any such intellectual property and all embodiments of such intellectual property. Such</p>	<p>[71a] Important to include a provision that protects Licensee’s interests in the event that Licensor enters bankruptcy.</p> <p>[71b] Licensor should also consider adding protective language in the event that Licensee causes, in any way, Licensor’s bankruptcy.</p>

<p>intellectual property and all embodiments thereof shall be promptly delivered to Licensee (i) upon any such commencement of a bankruptcy proceeding upon written request therefore by Licensee, unless Licensor elects to continue to perform all of its obligations under this Agreement or (ii) if not delivered under (i) above, upon the rejection of this Agreement by or on behalf of Licensor upon written request therefore by Licensee.</p>	
<p>The foregoing provisions of Section 7.3.2(c) are without prejudice to any rights Licensee may have arising under the Code or other applicable law.</p>	
<p>7.4 Effect of Expiration or Termination; Survival. Expiration or termination of this Agreement shall not relieve the Parties of any obligation accruing prior to such expiration or termination. Any expiration or termination of this Agreement shall be without prejudice to the rights of either Party against the other accrued or accruing under this Agreement prior to expiration or termination, including without limitation the obligation to pay royalties for Product(s) or Compound sold prior to such expiration or termination. The provisions of _____ shall survive the expiration or termination of this Agreement and shall continue in effect for ten (10) years. In addition, the provisions of Article, _____ and Sections ____, ____, ____, and ____ shall survive any expiration or termination of this Agreement.</p>	<p>[72] Important to ensure that any confidentiality and other long lived provisions survive the termination or expiration of the agreement.</p>
<p>ARTICLE 8 INDEMNIFICATION.</p>	
<p>8.1 Licensee Indemnification. Licensee shall indemnify, defend and hold harmless Licensor and its Affiliates, and each of Licensor’s and its Affiliates’ respective officers, directors, employees, agents, successors and assigns against all losses arising out of or resulting from any third party claim, suit, action or other proceeding related to or arising out of or resulting</p>	<p>[73a] Favors Licensee. Licensee may wish to require Licensor to indemnify Licensee for any breach of confidentiality (which may lead to loss of patent rights) or for any third party claims related to the use by Licensor of the Licensor Patent Rights or Know-How.</p> <p>[73b] Consider imposing comparative negligence standard for indemnification. For</p>

<p>from (a) Licensee’s or its Related Parties’ breach of any representation, warranty, covenant or obligation under this Agreement, or (b) use by Licensee or its Related Parties of the Licensor Patent Rights or Licensor Know-How, or (c) any use, sale, transfer or other disposition by Licensee or its Related Parties of the Product or any other products made by use of the Licensor Patent Rights or Licensor Know-How (each an “Action”).</p>	<p>example, consider the following exception language: “except that these obligations to indemnify (both subsections ___ and ___) shall apply only to the extent that any such breach, misconduct, gross or other negligence or other fault was attributable to Licensee (and not attributable in whole or in part to any breach, misconduct, negligence of fault as to the Licensor)”</p>
<p>8.2 Indemnification Procedure. Licensor shall promptly notify Licensee in writing of any Action and cooperate with Licensee at Licensee’s sole cost and expense. Subject to Section 6.5, Licensee shall immediately take control of the defense and investigation of the Action and shall employ counsel reasonably acceptable to Licensor to handle and defend the Action, at Licensee’s sole cost and expense. Licensee shall not settle any Action in a manner that adversely affects the rights of Licensor or its Affiliates without Licensor’s prior written consent, which consent shall not be unreasonably withheld or delayed. Licensor’s failure to perform any obligations under this Section 8.2 shall not relieve Licensee of its obligations under Article 8 except to the extent that Licensee can demonstrate that it has been materially prejudiced as a result of the failure. Licensor may participate in and observe the proceedings at its own cost and expense with counsel of its own choosing.</p>	<p>[74] Important to include an indemnification procedure that allocates responsibilities for defense and related costs.</p>
<p>ARTICLE 9 MISCELLANEOUS.</p>	
<p>9.1 Force Majeure. Neither Party shall be held liable to the other Party nor be deemed to have defaulted under or breached this Agreement for failure or delay in performing any obligation under this Agreement to the extent such failure or delay is caused by or results from causes beyond the reasonable control of the affected Party, potentially including, but not limited to, embargoes, war, acts of war (whether war be declared or not), acts of terrorism, insurrections, riots, civil commotions, strikes, lockouts or other labor disturbances, fire, floods, or other acts of God, or acts, omissions or delays in acting by any governmental authority or the other Party. The</p>	<p>[75] Licensor may wish to exclude monetary obligations from this clause.</p>

<p>affected Party shall notify the other Party of such force majeure circumstances as soon as reasonably practical, and shall promptly undertake all reasonable efforts necessary to cure such force majeure circumstances</p>	
<p>9.2 Assignment. Except as provided in this Section 9.2, this Agreement may not be assigned or otherwise transferred, nor may any right or obligation hereunder be assigned or transferred, by either Party without the consent of the other Party, which consent shall not be unreasonably withheld or delayed. Any attempted assignment not in accordance with this Section 9.2 shall be void.</p>	<p>[76] Consider the parties' respective exit strategies when drafting this term.</p>
<p>9.3 Severability. If any one or more of the provisions contained in this Agreement is held invalid, illegal or unenforceable in any respect, the validity, legality and enforceability of the remaining provisions contained herein shall not in any way be affected or impaired thereby, unless the absence of the invalidated provision(s) adversely affects the substantive rights of the Parties. The Parties shall in such an instance use reasonable efforts to replace the invalid, illegal or unenforceable provision(s) with valid, legal and enforceable provision(s) which, insofar as practical, implement the purposes of this Agreement.</p>	
<p>9.4 Notices. All notices which are required or permitted hereunder shall be in writing and sufficient if delivered personally, sent by facsimile (and promptly confirmed by personal delivery, registered or certified mail or overnight courier), sent by nationally-recognized overnight courier or sent by registered or certified mail, postage prepaid, return receipt requested, addressed as follows:</p> <p style="margin-left: 40px;">if to Licensor, to: Licensor</p> <p style="margin-left: 100px;">_____</p> <p style="margin-left: 100px;">_____</p> <p style="margin-left: 100px;">_____</p>	

<p>if to Licensee, to:</p> <p style="margin-left: 100px;">Licensee</p> <p style="margin-left: 100px;">_____</p> <p style="margin-left: 100px;">_____</p> <p style="margin-left: 100px;">_____</p> <p>or to such other address(es) as the Party to whom notice is to be given may have furnished to the other Party in writing in accordance herewith. Any such notice shall be deemed to have been given: (a) when delivered if personally delivered or sent by facsimile on a business day (or if delivered or sent on a non-business day, then on the next business day); (b) on the business day after dispatch if sent by nationally-recognized overnight courier; or (c) on the fifth (5th) business day following the date of mailing, if sent by mail.</p>	
<p>9.5 Applicable Law. This Agreement shall be governed by and construed in accordance with the laws of the State of New Jersey and the patent laws of the United States without reference to any rules of conflict of laws or renvoi.</p>	<p>[77] If dispute resolution does not require binding arbitration, consider including a jury waiver and venue provision.</p>
<p>9.6 Dispute Resolution.</p>	
<p>9.6.1 The Parties shall negotiate in good faith and use reasonable efforts to settle any dispute, controversy or claim arising from or related to this Agreement or the breach thereof. If the Parties do not fully settle, and a Party wishes to pursue the matter, each such dispute, controversy or claim that is not an “Excluded Claim” shall be finally resolved by binding arbitration in accordance with the Commercial Arbitration Rules and Supplementary Procedures for Large Complex Disputes of the American Arbitration Association (“AAA”), and judgment on the arbitration award may be entered in any court having jurisdiction thereof.</p>	
<p>9.6.2 The arbitration shall be conducted by a panel of three persons experienced in the pharmaceutical business: within thirty (30) days after initiation of arbitration, each Party shall select one</p>	

<p>person to act as arbitrator and the two Party-selected arbitrators shall select a third arbitrator within thirty (30) days of their appointment. If the arbitrators selected by the Parties are unable or fail to agree upon the third arbitrator, the third arbitrator shall be appointed by the AAA. The place of arbitration shall be New York, New York, and all proceedings and communications shall be in English.</p>	
<p>9.6.3 Either Party may apply to the arbitrators for interim injunctive relief until the arbitration award is rendered or the controversy is otherwise resolved. Either Party also may, without waiving any remedy under this Agreement, seek from any court having jurisdiction any injunctive or provisional relief necessary to protect the rights or property of that Party pending the arbitration award. The arbitrators shall have no authority to award punitive or any other type of damages not measured by a Party's compensatory damages. Each Party shall bear its own costs and expenses and attorneys' fees and an equal share of the arbitrators' fees and any administrative fees of arbitration.</p>	
<p>9.6.4 Except to the extent necessary to confirm an award or as may be required by law, neither a Party nor an arbitrator may disclose the existence, content, or results of an arbitration without the prior written consent of both Parties. In no event shall an arbitration be initiated after the date when commencement of a legal or equitable proceeding based on the dispute, controversy or claim would be barred by the applicable New Jersey statute of limitations.</p>	
<p>9.6.5 The Parties agree that, in the event of a good faith dispute over the nature or quality of performance under this Agreement, neither Party may terminate this Agreement until final resolution of the dispute through arbitration or other</p>	<p>[78] This provision could favor Licensee to the extent that Licensee is permitted to extend the dispute resolution. This provision may also conflict with the 7.3.1(b).</p>

<p>judicial determination. The Parties further agree that any payments made pursuant to this Agreement pending resolution of the dispute shall be refunded if an arbitrator or court determines that such payments are not due.</p>	
<p>9.6.6 As used in this Section, the term “EXCLUDED CLAIM” shall mean a dispute, controversy or claim that concerns (a) the validity or infringement of a patent, trademark or copyright; or (b) any antitrust, anti-monopoly or competition law or regulation, whether or not statutory.</p>	<p>[79] Consider including dispute resolution provisions related to Excluded Claims. It may be unclear how disputes over such claims would be resolved.</p>
<p>9.7 Entire Agreement; Amendments. This Agreement, together with the Schedules and Exhibits hereto, contains the entire understanding of the Parties with respect to the subject matter hereof. Any other express or implied agreements and understandings, negotiations, writings and commitments, either oral or written, in respect to the subject matter hereof are superseded by the terms of this Agreement. The Schedules and Exhibits to this Agreement are incorporated herein by reference and shall be deemed a part of this Agreement. This Agreement may be amended, or any term hereof modified, only by a written instrument duly executed by authorized representative(s) of both Parties hereto.</p>	
<p>9.8 Headings. The captions to the several Articles, Sections and subsections hereof are not a part of this Agreement, but are merely for convenience to assist in locating and reading the several Articles and Sections hereof.</p>	
<p>9.9 Independent Contractors. It is expressly agreed that Licensor and Licensee shall be independent contractors and that the relationship between the two Parties shall not constitute a partnership, joint venture or agency. Neither Licensor nor Licensee shall have the authority to make any statements, representations or commitments of any kind, or to take any action, which shall be binding on the other Party, without the prior written consent of the other Party.</p>	

<p>9.10 Waiver. The waiver by either Party hereto of any right hereunder, or of any failure of the other Party to perform, or of any breach by the other Party, shall not be deemed a waiver of any other right hereunder or of any other breach by or failure of such other Party whether of a similar nature or otherwise.</p>	<p>[80] Any waiver should be in writing.</p>
<p>9.11 Cumulative Remedies. No remedy referred to in this Agreement is intended to be exclusive, but each shall be cumulative and in addition to any other remedy referred to in this Agreement or otherwise available under law.</p>	
<p>9.12 Waiver of Rule of Construction. Each Party has had the opportunity to consult with counsel in connection with the review, drafting and negotiation of this Agreement. Accordingly, the rule of construction that any ambiguity in this Agreement shall be construed against the drafting Party shall not apply.</p>	
<p>9.13 Certain Conventions. Any reference in this Agreement to an Article, Section, subsection, paragraph, clause, Schedule or Exhibit shall be deemed to be a reference to an Article, Section, subsection, paragraph, clause, Schedule or Exhibit, of or to, as the case may be, this Agreement, unless otherwise indicated. Unless the context of this Agreement otherwise requires, (a) words of any gender include each other gender, (b) words such as “herein”, “hereof”, and “hereunder” refer to this Agreement as a whole and not merely to the particular provision in which such words appear, (c) words using the singular shall include the plural, and vice versa.</p>	
<p>9.14 Business Day Requirements. In the event that any notice or other action or omission is required to be taken by a Party under this Agreement on a day that is not a business day then such notice or other action or omission shall be deemed to be required to be taken on the next occurring business day.</p>	
<p>9.15 Counterparts. This Agreement may be signed in any number of counterparts (facsimile and electronic transmission included), each of which shall be deemed an original, but all of which shall constitute one and the same instrument. After</p>	

<p>facsimile or electronic transmission, the parties agree to execute and exchange documents with original signatures.</p>	
<p>IN WITNESS WHEREOF, the Parties have executed this Agreement as of the Effective Date.</p>	
<p>LICENSEE</p> <p>BY: _____ [NAME]</p> <p>TITLE: <i>XXX</i></p>	<p>LICENSOR</p> <p>BY: _____ [NAME]</p> <p>TITLE: <i>XXX</i></p>

<u>SCHEDULES</u>	
SCHEDULE 1.6	LICENSOR COMPOUNDS
SCHEDULE 1.366	PATENT RIGHTS