Request for Proposal (RFP)

Instructions to Recipients

Date: August 3, 2022

Subject: Request for Proposal for Cefiderocol Access and Stewardship Project

1. Summary

This Request for Proposal ("RFP") is to solicit competitive bids for a contract to manufacture, obtain regulatory approval (within countries in the Territory described below in Annex 2), obtain WHO prequalification of, and commercialize a cefiderocol 1g lyophilized powder for concentrate for solution for infusion meeting the specifications and for the indications specified in this RFP (the "Product") in the Territory (as defined below).

To be considered for a contract, each responding party (each, a "Responder") bidder must have a demonstrably viable plan to manufacture, obtain regulatory approval of, and commercialize the Product as well as prior experience in commercialization of sterile cephalosporin products for injection or infusion.

The goal of this proposal is to identify a pharmaceutical manufacturer ("Sublicensee") to manufacture, obtain regulatory approval, obtain WHO prequalification and market commercially viable Product in the Territory.

2. "Project Parties"

GARDP | The Global Antibiotic Research and Development Partnership (GARDP) is a Swiss not-for-profit organization developing new treatments for drug-resistant infections that pose the greatest threat to health. GARDP was created by the World Health Organization (WHO) and the Drugs for Neglected Diseases initiative (DNDi) in 2016 and legally founded in 2018 to ensure that everyone who needs antibiotics receives effective and affordable treatment. GARDP is registered in Geneva under the legal name "GARDP Foundation".

The **Clinton Health Access Initiative** | The Clinton Health Access Initiative, Inc. (CHAI) is a global health organization committed to saving lives and reducing the burden of disease in low-and middle-income countries. CHAI works with its partners to help strengthen the capabilities of governments and the private sector to create and sustain high-quality health systems.

Shionogi & Co., Ltd. | Shionogi & Co., Ltd. ("Shionogi") is a 143-year-old global, research-driven pharmaceutical company headquartered in Osaka, Japan, that is dedicated to bringing benefits to patients based on its corporate philosophy of "supplying the best possible medicine to protect the health and wellbeing of the patients we serve." The company currently markets products in several therapeutic areas including anti-infectives, pain, CNS disorders, cardiovascular diseases, and gastroenterology.

See Annex 1 for a summary of the parties' Press Release issued 15 June 2022.[1]

3. Summary of Target Product

[1] A complete copy of the referenced press release is available at https://www.shionogi.com/us/en/news/2022/06/shionogi-gardp-and-chai-announce-landmark-license-and-collaboration-agreements-to-treat-bacterial-infections-by-expanding-access-to-cefiderocol-in-135-countries.html

The Product is a cefiderocol sulfate tosylate 1g lyophilized powder for concentrate for solution for infusion meeting the specifications and for the indications specified in this RFP.

Cefiderocol, a siderophore cephalosporin, uses a novel "Trojan horse" mechanism to enable penetration of Gram-negative bacteria and is a potential treatment option for some antibiotic-resistant infections. Cefiderocol, first approved in 2019, is active against many types of Gram-negative bacteria and is approved for use in the United States (currently sold by Shionogi as "FETROJA®") and the European Union (currently sold by Shionogi as "FETCROJA®")[2].

Anti-microbial resistance (AMR) is a growing public health threat globally, directly leading to almost 1.3 million deaths each year.[3] The World Health Organization (WHO) has identified AMR as a leading risk to health and economic development and a barrier to reaching sustainable development goals.[4] The emergence, increase in incidence, and rapid dissemination of carbapenem-resistant infections is noted to be of critical concern by the WHO.[5] Cefiderocol has demonstrated clinical and *in vitro* activity against the large majority of carbapenem-resistant isolates, including for isolates that have become resistant to other antibiotics that are typically used for carbapenem-resistant infections. In 2021, G7 Health Ministers committed to making AMR a key strategic area for action.[6] Unlike COVID-19, which raised alarm as it swiftly moved across the globe, AMR is a silent pandemic that has gained ground in countries and hospitals with little public notice.[7] While the risk from AMR infections continues to increase, only a small number of new antibiotics have been developed in recent years. Growing demand for antibiotics targeting carbapenem-resistant infections is reflected in a study of eight countries. This study showed a 6.5% increase in volume of antibiotics purchased to treat carbapenem-resistant infections, with some countries demonstrating much more rapid growth (e.g., Bangladesh 61.3%, Brazil 28.4%, Mexico 37.8%, Pakistan 29.3%). Based on a study of procurement of antibiotics used for the extremely resistant infections that cefiderocol may be used for, procurement across eight representative countries included in the license territory (8 out of 135) was 3.27 million standard units in 2021. We anticipate the demand for the Product to be approximately 1 million units per year at launch and for the first few years of rollout.

4. Scope of Work

The scope of work for this RFP includes the following activities:

- Sublicensee receives technical transfer[8] of Shionogi's manufacturing process for the Product and performs any necessary accompanying work such as manufacturing process scale-up, analytical

[2] https://www.ema.europa.eu/en/documents/product-information/fetcroja-epar-product-information_en.pdf
[3] Antimicrobial Resistance Collaborators. Global burden of bacterial antimicrobial resistance in 2019: a systematic analysis. Lancet. 2022 Feb 12;399(10325):629-655. doi: 10.1016/S0140-6736(21)02724-0. Epub 2022 Jan 19. PMID: 35065702; PMCID: PMC8841637.
[4] https://www.who.int/news-room/fact-sheets/detail/antimicrobial-resistance
[5] Global antimicrobial resistance and use surveillance system (GLASS) report 2021. Geneva: World Health Organization; 2021. Licence: CC BY-NC-SA 3.0 IGO
[6] https://www.who.int/news/item/09-06-2021-record-response-to-who-s-call-for-antimicrobial-resistance-surveillance-reports-in-2020
[7] https://www.who.int/news-room/fact-sheets/detail/antimicrobial-resistance
[8] The technical transfer package is optional to accept, but strongly encouraged.

method development and validation, physical product characterization, bioequivalence studies, and stability studies;

- Sublicensee prepares and submits a plan for regulatory filings in the Wave 1 subset of countries set forth in Annex 2 (the "Territory", the Wave 1 subset countries is the highlighted subset of the full Territory) and adheres to the elements of this plan, including clear timelines;
- Sublicensee prepares and submits a regulatory dossier for regulatory approval in each of the countries in the Wave 1 subset of countries as well as WHO prequalification; During the negotiation process for the final sublicense, this Wave 1 subset may change somewhat based on the successful applicant's commercialization geographic capacities; and,
- Sublicensee prepares a production and supply plan that ensures capacity to supply qualified orders (minimum size to be determined as part of the project plan) with manufacturing lead time of no more than 90 days.

A technical transfer package which includes the API process and FDF process will be provided by Shionogi to the Sublicensee if Sublicensee choses to accept such package.

Under the proposed agreement, the Sublicensee shall favor an access price and associated terms and supply conditions that is acceptable to public sector procurement groups in the Territory, including the countries themselves, which will be included in the contracts between the Sublicensee and GARDP. This access price should be immediately effective from the day an agreement is concluded and signed by GARDP and the Sublicensee.

During proposal evaluation and prior to start of contract negotiations, the Project Parties will consider the ability of a single Sublicensee to provide production of Product in addition to commercialization and distribution in the Territory and whether Sublicensee requires distribution partners in parts of the Territory. GARDP reserves the right to negotiate separate contracts for each of these activities.

5. Instructions to interested parties

CHAI will manage the RFP process for and on behalf of the Project Parties.

a. RFP

i. All proposals should be submitted in English and signed by an authorized representative of the Responder (Form A in Annex 3).
ii. Proposals should be submitted via email with the subject line RFP_CEF to: cefrfp@clintonhealthaccess.org.
iii. Proposals received after the stipulated due date will be deemed invalid.

b. **Timeline** The timeline for the RFP process is described below. Proposals received after the deadline will not be considered.

RFP Released	August 3, 2022
RFP Information Session Posted	August 11, 2022, 6:30pm IST/3:00pm CEST/9:00am EDT
Q&A Period for Manufacturers	August 3-19, 2022
Q&A Response Document Released	August 26, 2022
Proposals Due	September 19, 2022, 5pm EDT

c. Question and answer

i. A formal period during which questions regarding this RFP are answered will be held for eighteen days following the posting of the RFP on CHAI's website. Questions should be addressed to: cefrfp@clintonhealthaccess.org.
ii. A presentation to describe the RFP process will be released on August 11, 2022, at 6:30pm IST/3:00pm CEST/9:00am EDT.
iii. Inquiries must be received by the stipulated deadline. To the extent possible, questions and answers will be published on the CHAI website.
iv. Telephone inquiries are not permitted.

d. Eligibility

The RFP is open to companies who meet the following criteria:

- Manufacturers have previously submitted dossiers to an SRA regulatory authority or WHO PQ and received full approval for submitted products (not limited to cephalosporin products);
- Manufacturers use an on-site cephalosporin facility for production of the final dosage form. A contract manufacturer of the final dosage form will not be considered.
- Manufacturers have previously submitted dossiers to a regulatory authority and received full approval for sterile cephalosporin products for injection or infusion;
- Manufacturers' production facilities operate under current Good Manufacturing Practice (cGMP) as established by the International Conference on Harmonization (ICH);
- Manufacturers must agree to share any recent regulatory authority inspection reports (e.g., from an SRA or WHO PQ) and subsequent correspondence related to major or critical observations, including corrective and preventative action plans, if they are selected as a finalist for the sublicense agreement;
- Manufacturers must agree to host and pass an independent quality audit if they are selected as a finalist for the sublicense agreement;
- Manufacturers must provide documentary confirmation of adherence to PSCI Principles and agree to host and pass an independent EHS audit if they are selected as a finalist for the sublicense agreement; and
- Manufacturers will agree to establish a project team structure that includes CHAI participation as well as host regular meetings (in person or via telecom) as/when required.

e. Costs of preparing documents

All costs associated with preparing and submitting a proposal will be borne by the Responder.

f. Confidentiality of submitted proposals

Responder agrees that CHAI, GARDP and Shionogi are not undertaking any confidentiality obligations with respect to the submitted proposals.

If the disclosure of confidential information is required for Responder to submit a proposal, the Project Parties may enter into a separate confidentiality agreement at the request of Responder.

g. Disclosure
Information relating to the examination, clarification, and evaluation of responses shall not be disclosed to Responders or any other persons not part of the project team with this process.

h. Terms and Conditions of Agreement
Although terms and conditions for the contract will be finalized during the negotiation process after final Sublicensee(s) have been selected, some of the required terms and conditions has been attached to this document (Annex 4) for reference. The formal agreement will be the sublicensing agreement between the Sublicensee and GARDP.

6. Proposal requirements

Responders should provide the following information in the proposal response to this RFP:

a. Completed forms found in Annex 3: A (Response to RFP), B (Quality Audit Agreement) and C (EHS Audit Agreement);
b. Completed RFP Excel questionnaire – separate attachment to RFP; and
c. Separate Word document outlining the Responder's plan and timeline for the activities described in Section 4 above. Included in this document should be a discussion of the Responder's capacity to manufacture Product, a timeline (or Gantt chart) highlighting the milestones indicated in the Timeline tab of the RFP questionnaire, and the strategy for ensuring sustained supply in the target countries. This document should be no longer than five pages in length.

CHAI reserves the right to request additional information, arrange interviews with the Responder, visit the Responder's premises and facilities, and conduct an audit to verify the information provided.

7. Evaluation Criteria

To be considered for the contract, the Responder must demonstrate the necessary experience of manufacturing in its own facilities cephalosporin-based product, commercializing injectable cephalosporin antibiotic products in single vials, necessary experience of commercializing products manufactured with the intended technology, and experience registering and supplying cephalosporin drugs to the Wave 1 subset of countries within the Territories (or an adjusted list according to Responder's capacities).

CHAI and GARDP will assess each eligible proposal based on selection criteria that includes the overall quality of the development and commercialization plan provided, timelines, corporate capabilities and demonstrated expertise with similar products. CHAI and GARDP anticipate that several companies will be identified for further discussions to refine project plans, timelines, and cost estimates. Sublicense agreement will be between GARDP and sublicensee.

CHAI will engage with a third party to perform a quality audit and an EHS audit of the selected Sublicensee. CHAI anticipates one Sublicensee would be selected for the Territory in Q4 2022 after which a contract would be signed between that party and GARDP. Based on the current anticipated

timeline, it is expected that the contracted manufacturer will file for regulatory approval by 2024, although this is subject to change.

Annex 1

Shionogi, GARDP and CHAI Announce Landmark License and Collaboration Agreements To Treat Bacterial Infections by Expanding Access to Cefiderocol in 135 Countries

Osaka (Japan), Geneva (Switzerland), Boston (USA), 15 June 2022 – Shionogi & Co., Ltd. (Shionogi) and the Global Antibiotic Research and Development Partnership (GARDP) have today announced the execution of a license and technology transfer agreement and, with the Clinton Health Access Initiative (CHAI), a collaboration agreement that aim to significantly transform the landscape of access to antibiotics for countries around the world.

The agreements will provide access to cefiderocol, an antibiotic for the treatment of serious Gram-negative bacterial infections, which may be resistant to other antibiotic treatments. Cefiderocol was recently added to the World Health Organization (WHO) Model List of Essential Medicines and targets a number of Gram-negative WHO priority pathogens. It was approved by the European Medicines Agency in 2020 and, separately, by the U.S. Food and Drug Administration in 2019. Please refer to the detailed U.S. indications and Important Safety Information for cefiderocol found below.

This is the first license agreement for an antibiotic to treat serious bacterial infections between a pharmaceutical company and a non-profit organization driven by public health priorities. Under this agreement, GARDP will manufacture and commercialize cefiderocol through sub-licensees in a large range of countries that have delayed access (if any) to newer antibiotics. The license territory includes all low-income countries, most lower middle- and upper middle-income countries, and select high-income countries (135 countries total, almost 70% of countries worldwide). It includes a significant proportion of the world's population living in areas most affected by antibiotic resistance.

NOTE: This is an abbreviated version of the Press Release. The full document is available at https://www.shionogi.com/us/en/news/2022/06/shionogi-gardp-and-chai-announce-landmark-license-and-collaboration-agreements-to-treat-bacterial-infections-by-expanding-access-to-cefiderocol-in-135-countries.html

Annex 2

List of countries included in the Territory

Wave 1 countries for early submission of regulatory dossiers are highlighted in bold underlined font

High Income	Upper Middle Income		Lower Middle Income		Low Income
Antigua	Albania	Marshall Isl.	Algeria	Nepal	Afghanistan
Bahamas	Argentina	**Mexico**	Angola	Nicaragua	Burkina Faso
Barbados	Armenia	Montenegro	**Bangladesh**	**Nigeria**	Burundi
Chile	Azerbaijan	Namibia	Benin	**Pakistan**	Central African Republic
Mauritius	Belarus	N. Macedonia	Bhutan	Papua NG	Chad
Nauru	Belize	Paraguay	Bolivia	São Tomé	Dem. Rep. of Congo
Palau	Bosnia, Herz.	Peru	Cabo Verde	Senegal	Eritrea
Panama	Botswana	Samoa	Cambodia	Solomon Isl.	**Ethiopia**
Uruguay	Brazil	Serbia	Cameroon	**Sri Lanka**	Gambia
Seychelles	**Colombia**	**South Africa**	Comoros	Tanzania	Guinea
St. Kitts	Costa Rica	St. Lucia	Congo, Rep.	Timor-Leste	Guinea-Bissau
Trinidad/Tobago	Cuba	St. Vincent	Côte d'Ivoire	Tunisia	Haiti
	Dominica	Suriname	Djibouti	Ukraine	Dem. People's Rep. of Korea
	Dominican Rep	Tonga	**Egypt**	Uzbekistan	Liberia
	Ecuador	Turkmenistan	El Salvador	Vanuatu	Madagascar
	Eq. Guinea	Tuvalu	Eswatini	Zambia	Malawi
	Fiji	Venezuela	Ghana	Zimbabwe	Mali
	Gabon		Honduras		Mozambique
	Georgia		**India**		Niger
	Grenada		**Kenya**		Rwanda
	Guatemala		Kiribati		Sierra Leone
	Guyana		Kyrgyz Rep.		Somalia
	Iran		Lao PDR		South Sudan
	Iraq		Lesotho		Sudan
	Jamaica		Mauritania		Syrian Arab Republic
	Jordan		Micronesia		Tajikistan
	Kazakhstan		Moldova		Togo
	Lebanon		Mongolia		Uganda
	Libya		Morocco		Yemen
	Maldives		Myanmar		

Annex 3

Forms to be Completed by Responders

FORM A: Response to RFP

This form must be completed, signed, and returned to CHAI at cefrfp@clintonhealthaccess.org .

DECLARATION

We, the undersigned, having read the RFP for cefiderocol 1g lyophilized powder for concentrate for solution for infusion, submit our proposal, which includes the information requested in Section 6. We confirm that all the information provided is correct.

We confirm that we are interested in entering into discussions for a possible sublicense agreement with GARDP on the manufacture, filing to appropriate SRAs and regulatory authorities, and commercialization of the Product (as defined above).

We understand that Partners' issue of the RFP and the proposal we submit is not a commitment by either party to enter into such discussions or agreement. We further understand that parties reserve the right to discuss and collaborate with one or multiple parties, no parties, or to cancel the RFP at their discretion.

This RFP and any proposals submitted hereunder may be used by CHAI, GARDP and Shionogi in their discretion, subject to any confidentiality agreement that may be agreed upon between the Project Parties and Responder.

Name of authorized representative:

Title:

Signature:

Date:

Company name:

Postal Address:

Telephone No.:

Email Address:

FORM B: Quality Audit Agreement

This form must be completed, signed, and returned to CHAI at cefrfp@clintonhealthaccess.org

DECLARATION

Responder agrees that if selected for the RFP award, permission will be given to conduct a quality audit in order to assess that the supplier is operating under cGMP.[1] This will be a general GMP and Quality Systems audit performed by an independent third-party consultant. This audit will be scheduled directly with the finalist prior to any contract negotiations.

Name of authorized representative:

Title:

Signature:

Date:

Company name:

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[1] Valid cGMP authorities include SRAs and regulatory authorities participating in the Pharmaceutical Inspection Cooperation Scheme (PIC/S). For PIC/S, please refer to www.picscheme.org. An SRA is defined as a regulatory authority that is (1) a Founding (USA, European Commission, Japan) or Standing (Canada, Switzerland) Regulatory Member of the International Conference on Harmonisation (ICH); or (2) a Standing Observer (WHO, The International Federation of Pharmaceutical Manufacturers and Associations (IFPMA)) as specified on www.ich.org. In addition, countries that have mutual recognition with one of the Founding Regulatory Members (e.g., EMA has mutual recognition with Australia and New Zealand) are considered SRA.

FORM C: EHS Audit Agreement

This form must be completed, signed, and returned to CHAI at cefrfp@clintonhealthaccess.org

DECLARATION

Responder agrees that if selected for the RFP award, permission will be given to conduct an EHS audit in order to assess that the supplier is operating under the appropriate standards. This will be performed by an independent third-party consultant. This audit will be scheduled directly with the finalist prior to contract negotiations.

Name of authorized representative:

_____

Title:

_____

Signature:

_____

Date:

_____

Company name:

_____

Annex 4

Non limitative list of required provisions for the GARDP Sublicense Agreement

Schedule F Provisions for Sublicense Agreement

This Sublicense Agreement ("**Sublicense Agreement**" or "**Agreement**"), effective as of [DATE] (the "**Effective Date**"), is by and between **GARDP Foundation**, a non-profit research and development organization registered under the laws of Switzerland, and having a principle place of business at 15 Chemin Camille-Vidart 1202 Geneva, Switzerland ("**Sublicensor**"), and [SUBLICENSEE], a [STATE OF ORGANIZATION] [ENTITY TYPE] ("**Sublicensee**"). Sublicensor and Sublicensee may be referred to herein collectively as the "**Parties**" or individually as a "**Party**".

WHEREAS, Sublicensor is a party to the License and Technology Transfer Agreement, dated as of [DATE] ("**License Agreement**"), with Shionogi & Co., Ltd. ("**Licensor**"), under which Licensor granted Sublicensor a license under certain rights of Licensor; and

WHEREAS, Sublicensee desires to obtain, and Sublicensor agrees to grant, a sublicense under Sublicensor's rights in and to the Sublicensed Rights, on the terms and conditions of this Agreement and subject to all applicable restrictions and limitations on the rights granted to Sublicensor under the License Agreement.

NOW, THEREFORE, in consideration of the mutual covenants, terms, and conditions set forth herein, and for other good and valuable consideration, the receipt and sufficiency of which are hereby acknowledged, the Parties agree as follows:

1. Sublicensee Commitment. Sublicensee hereby agrees to use commercially reasonable efforts to implement an agreed registration and commercialization plan (the **Sublicense Access Plan**), that includes specific target dates for various registration and commercialization objectives, and that furthers the Access and Stewardship Objectives. The Sublicense Access Plan shall be agreed to by Licensor, Sublicensor and Sublicensee.

2. License Agreement. Sublicensor has provided to Sublicensee, attached as Exhibit [LETTER], a true and complete copy of the License Agreement in effect as of the Effective Date, including all amendments thereto, except those terms and conditions that have been redacted as reasonably necessary to protect Licensor's commercially sensitive information. Sublicensee acknowledges and agrees that this Agreement and Sublicensee's rights and obligations under it are subject to, and Sublicensee shall comply with, all terms and conditions of the License Agreement applicable to Sublicensor's sublicensees. To the extent that the License Agreement explicitly requires that any terms or conditions be included in any agreement granting a sublicense under the License Agreement, such terms and conditions are deemed to be incorporated by reference in this Agreement. For the avoidance of doubt, any right of Sublicensor under the License Agreement not

expressly sublicensed to Sublicensee under this Agreement remains the right of Sublicensor and is not implicitly sublicensed to Sublicensee.

3. Sublicensee Acknowledgement. Sublicensee hereby acknowledges that Licensor has made no representations or warranties to Sublicensee regarding the Licensed Rights or the Licensed Product, and that the Sublicensee has independently evaluated any information supplied by or on behalf of Licensor or Sublicensor before making its decision to enter into the Sublicense Agreement and undertake the commitments and obligations set forth herein.

4. Sublicensor Commitment [OPTIONAL]. So long as Sublicensee is complying with its diligence obligations, Sublicensor hereby agrees not to seek another market access partner for the country(ies) covered by this Agreement. For the avoidance of doubt, nothing herein shall restrict Licensor or its agents' development, manufacture, registration, or commercialization of the Licensed Product in the Territory.

5. Adverse Event Reporting. Sublicensee shall, in accordance with its standard protocols, maintain effective and reliable systems for receiving and tabulating any reports of adverse reactions to the Licensed Product commercialized by Sublicensee and to report such information on a timely basis to the relevant regulatory authorities in accordance with applicable laws and regulations in the countries in which it is commercializing Licensed Product. Sublicensee shall be responsible for fulfilling all required pharmacovigilance reporting responsibilities, and managing inquiries related to the safety of Licensed Product, in accordance with applicable laws and regulations in the countries in which it is commercializing Licensed Product. Sublicensee acknowledges that Licensor is responsible for maintaining the global pharmacovigilance database for Licensed Product. Simultaneously with the execution of this Agreement, Sublicensee and Licensor are entering into a safety data exchange agreement on terms reasonably acceptable to Licensor (the "**SDEA**") governing the exchange of Licensed Product safety information between Sublicensee and Licensor and the conduct of inquiries relating to adverse events reported by Sublicensee as set forth in Schedule X attached hereto. Any breach by Sublicensee of its obligations under the SDEA shall be deemed to constitute a breach by the Sublicensee of its obligations under this Sublicense Agreement.

Sublicensee and Sublicensor will ensure that appropriate standard operating procedures regarding events are established, maintained and regularly reviewed to ensure compliance in accordance with the terms of this Agreement and Applicable Laws.

6. Intellectual Property. Licensor (or its Affiliates) will own the entire right, title and interest in and to any and all inventions conceived solely by its employees and agents before, on or after the Effective Date relating to the Licensed Compound or any Licensed Product, including the Licensed Rights and any such inventions that constitute an adaptation of any manufacturing process or proprietary drug delivery or formulation technology of Licensor or its Affiliates for the production of the Licensed Compound or any Licensed Product, and any patents covering such invention (**Licensor Sole Inventions**), subject to the license granted to Sublicensor.

Manufacturing Process Results

a) To the extent Sublicensee accepts a Technical Transfer Package, or otherwise has access to any non-public proprietary information or confidential information of Licensor relating to the manufacturing process used by Licensor to manufacture Licensed Compound and Licensed Product (not including the specifications of the Licensed Compound or Licensed Product that are required for a Sublicensee to demonstrate that the Licensed Compound or Licensed Product manufactured by the Sublicensee using its process are pharmaceutically equivalent to the Licensed Compound or Licensed Product manufactured using Licensor's manufacturing process):
    i. Licensor shall own (and shall have the sole right to patent or not to patent) all inventions and results developed or generated by the Sublicensee related to the process to manufacture Licensed Compound or Licensed Product (**Process Results**) (whether or not patentable) that are specific to the Licensed Product and/or that incorporate any non-public proprietary information or confidential information or intellectual property of Licensor and Sublicensee will provide reasonable assistance to Licensor, as may be required, for such prosecution; and
    ii. Sublicensee shall own (and shall have the sole right to patent or not to patent) all Process Results (whether or not patentable) solely to the extent separable from the Licensed Product (i.e., that such can be used to manufacture products other than the Licensed Product) and that do not incorporate any non-public proprietary information or confidential information of Licensor.
b) If Sublicensee has not accepted a Technical Transfer Package, and has not had access to any non-public proprietary information or confidential information of Licensor relating to Licensor's manufacturing process (not including the specifications of the Licensed Compound or Licensed Product that are required for a Sublicensee to demonstrate that the Licensed Compound or Licensed Product manufactured by the Sublicensee using its process are pharmaceutically equivalent to the Licensed Compound or Licensed Product manufactured using Licensor's manufacturing process):
    i. Sublicensee shall own (and shall have the sole right to patent or not to patent) all Process Results (whether or not patentable) developed or generated by or for them that do not incorporate any non-public proprietary information or confidential information of Licensor.
c) The Process Results shall be considered confidential information of the party who owns the results, provided that each of Licensor, Sublicensor and Sublicensee shall have the right to access and use all Process Results in accordance with the licenses set forth in this Sublicense Agreement and the License Agreement.
d) Licensor shall have the sublicensable right to use all Process Results not owned by it for development, regulatory filings, manufacturing, commercialization or otherwise to enable or facilitate access to any product containing cefiderocol worldwide.

Development Activity Sublicense Results

a) With respect to any inventions, know-how or results (whether or not patentable) developed or generated by or for Sublicensor and/or Sublicensee in the performance of any Development activities conducted pursuant to this Sublicense Agreement other than Development activities relating to Manufacturing (the results of which are Process Results governed by the terms above) (**Development Results**):

   i. Licensor shall own (and shall have the sole right to patent or not to patent) all Development Results that are specific to the Licensed Product and/or that incorporate any non-public proprietary information or confidential information or intellectual property of Licensor.
   ii. notwithstanding the above, Sublicensor shall own the clinical data associated with or arising from clinical studies conducted pursuant to this Sublicense Agreement (**Clinical Data**), but may use such Clinical Data only for the purposes consistent with this Sublicense Agreement and the License Agreement; and Licensor and Sublicensor shall have the right to access and use all such Clinical Data in accordance with the licenses set forth in this Sublicense Agreement and the License Agreement, and Sublicensor or Sublicensee, as applicable, shall provide at least one copy of the Clinical Data to Licensor upon completion of each applicable clinical study.
   iii. Each Party shall have the right to publish for scientific purposes Development Results developed or generated by or for such Party (subject if applicable to the rights of one or more other parties that may also have participated in the development or generation thereof), subject to, with respect to any such Development Results that relate to the Licensed Product or any proprietary or confidential information of Licensor, (i) Licensor's and Sublicensor's prior review of any such proposed publication, (ii) Licensor's right to remove its confidential information (but not of the Development Results themselves) from any such proposed publication, and (iii) Licensor's right to request a reasonable delay in publication for Licensor to file any related patent applications. Licensor shall have the right to oppose any such proposed publication for failure to comply with the foregoing requirements, or for any objection based on reasonable concerns relating to the accuracy and/or quality of the data referenced therein, and the publication may not proceed until Licensor's opposition based on the above has been resolved as set forth herein. Any disagreement regarding proposed publications contemplated by this Section shall be escalated for resolution to representatives of the Licensor, the Sublicensor and the Sublicensee.
   iv. Sublicensee shall have the right to use Clinical Data developed or generated by them only for regulatory filings, Commercialization, or otherwise to enable or facilitate access to Licensed Product, in the country(ies) in the Territory for which it has a license.
   v. Licensor shall have the sublicensable right to use all Development Results, including any and all Clinical Data, not owned by it for development, regulatory filings, manufacturing, commercialization or otherwise to enable or facilitate access to any product containing cefiderocol worldwide.

General Conditions Applicable to all Sublicense Results

a) Sublicensee grants Licensor a free, perpetual, nonexclusive, sublicensable license to use Sublicense Results owned by Sublicensee (including any intellectual property rights thereon) for the Development, Manufacture, and Commercialization of the Licensed Product worldwide.
b) Sublicensee grants Sublicensor a free, nonexclusive, sublicensable license to use Sublicense Results owned by Sublicensee (including any intellectual property rights thereon) for the Development, Manufacture, and Commercialization of the Licensed Product in the Territory pursuant to the License Agreement.
c) All Sublicense Results owned by Licensor (including any intellectual property rights thereon) shall be included in the License Rights licensed to Sublicensor pursuant to the License Agreement and sublicensed to Sublicensee pursuant to this Sublicense Agreement.

7. Recalls, Market Withdrawals or Corrective Action. In the event that any Regulatory Authority issues or requests a recall or takes a similar action in connection with the Licensed Product in the countries in the Territory covered by the Sublicense, or in the event Sublicensor, Licensor and/or Sublicensee reasonably determine that an adverse event, incident or circumstance has occurred that may result in the need for a recall or market withdrawal in the countries in the Territory covered by the Sublicense, the party notified of such recall or similar action, or the party(ies) that desire(s) such recall or similar action, must within twenty-four (24) hours, advise the other party(ies) by telephone (with written confirmation notice to follow) or by email to the address specified in Section [INSERT REFERENCE TO NOTICE SECTION]. The Parties will consult to decide whether to conduct any recall of Licensed Product in the Territory (except in the case of a Regulatory Authority mandated recall, in which case either Sublicensee or Sublicensor may act without such advance notice but, will notify the other Party and Licensor as soon as possible) and the manner in which any such recall will be conducted, it being understood that any one of Licensor, Sublicensor or Sublicensee may in any case require such a recall to be conducted. Sublicensee shall bear the sole expense of any recall of Licensed Product in the Territory.

8. Records. Sublicensee shall keep at its principal place of business true and accurate records of Net Sales, quantities of Licensed Product, and raw materials used to make Licensed Product, manufactured and/or sold pursuant to this Agreement (itemized by number of units of Licensed Product sold by strength and by country, together with current inventory reports), proper and comprehensive books of account including all information required to calculate the Cost Recoupment Fees and other moneys from time to time payable pursuant to this Sublicense Agreement this Agreement. Records must be maintained for at least ten (10) years.

9. Licensor's Right of Audit and Inspect. Sublicensee agrees at all reasonable times to permit Licensor's or Sublicensor's auditor to access, inspect and review the accounts, books and records referred to in Section 8. Such examination shall be conducted at Licensor's or Sublicensor's, as applicable, expense by an independent accountant, subject to execution of a customary confidentiality agreement with Sublicensee. The accountant may take copies of or extracts from the accounts, books and records, subject to the confidentiality agreement entered into by the accountant. Such audits may not be conducted more than once each calendar year and shall be conducted with reasonable prior notice and during normal office hours. Sublicensee agrees to give

Licensor's representatives reasonable assistance, access and facilities to enable them to verify such accounts, books and records and supply such other information as may be necessary or proper to enable Sublicensee's compliance with this Agreement to be verified. The auditor shall only report to Licensor and/or Sublicensor whether Sublicensee is in compliance with its obligations and/or such information as is reasonably necessary to demonstrate any deviation. If an audit conducted in accordance with this Section [9] identifies a deviation of more than ten percent (10%) from the amounts identified as payable in statements provided by Sublicensee pursuant to Section [INSERT REFERENCE TO RECOUPMENT OF COSTS SECTION] in any consecutive period of four quarters, the costs of the audit are to be reimbursed to Licensor by Sublicensee on demand. Licensor's and Sublicensor's rights under this Section [9] above apply during the Term and for four (4) years thereafter.

Sublicensee also agrees to permit appropriate representatives of Licensor and/or Sublicensor to inspect, at their cost, Sublicensee's manufacturing facilities and those of any permitted sub-contract manufacturers in order to verify Sublicensee's compliance with this Agreement. At least ten Business Days' advance notice of any such inspection will be given and such inspection shall be conducted with reasonable prior notice, during normal office hours and in a manner to minimize disruption of manufacturing operations. Sublicensee may require such representatives to sign a customary confidentiality agreement and may limit their access to facilities and documents that are reasonably necessary to verify that the manufacture of Licensed Compound and Licensed Product are compliant with the Sublicense Agreement.

10. Indemnification by Sublicensee of Licensor. Sublicensee hereby agrees to defend, hold harmless and indemnify Licensor and its Affiliates, and their respective officers, directors, employees, agents, licensors, and their respective successors, heirs and assigns, and representatives (**Licensor Indemnitees**), from and against any and all claims, threatened claims, damages, losses, suits, proceedings, liabilities, costs (including reasonable legal expenses, costs of litigation and reasonable attorney's fees) or judgments, whether for money or equitable relief, of any kind from a Third Party (**Losses and Claims**) arising out of or in connection with:

a) any activities conducted by Sublicensee or its Affiliates pursuant to this Sublicense Agreement;

b) any material breach by Sublicensee of any of the provisions of this Sublicense Agreement ;
c) any negligence or willful misconduct by or on behalf of Sublicensee;
d) Sublicensee's use and practice of the Licensed Rights and Licensed Manufacturing Know-How, including claims and threatened claims based on:
    i. any product liability, bodily injury, risk of bodily injury, death, or property damage;
    ii. infringement or misappropriation of Third-Party patents, copyrights, trademarks, or other intellectual property rights; or
    iii. the failure to comply with applicable laws related to the matters referred to in the foregoing with respect to the Licensed Compound and/or any Licensed Product.

11. Indemnification Procedures. Each Party will promptly notify the other Party when it becomes aware of a Third Party claim for which indemnification may be sought hereunder (a **Claim**). To be eligible to be indemnified for a Claim, a Person seeking indemnification (the "Indemnified Party") shall (i) provide the Party required to indemnify such Person (the "Indemnifying Party") with prompt written notice of the Claim giving rise to the indemnification obligation under this Section [X], provided that, the failure to provide such prompt notice shall not relieve the Indemnifying Party of any of its obligations under this Section [X] except to the extent the Indemnifying Party is actually prejudiced thereby; (ii) provide the Indemnifying Party with the exclusive ability to defend (with the reasonable cooperation of the Indemnified Party) against the Claim; and (iii) not settle, admit or materially prejudice the Claim, without the Indemnifying Party's prior written consent. The Indemnified Party shall reasonably cooperate with the Indemnifying Party, at the Indemnifying Party's expense, in the defense of any Claim. Notwithstanding the foregoing, the Indemnified Party shall have the right to participate in and have its own counsel participate in any action or proceeding for which the Indemnified Party seeks to be indemnified by the Indemnifying Party. Such participation shall be at the Indemnified Party's expense, unless (i) the Indemnifying Party and the Indemnified Party shall have mutually agreed to the retention of such counsel or (ii) the named parties to any such proceeding (including any impleaded parties) include both the Indemnifying Party and the Indemnified Party and representation of both Parties by the same counsel would be inappropriate due to actual or potential differing interests between them. The Indemnifying Party's obligations under Section [X], as the case may be, shall not apply to the extent of the Indemnified Party's failure to take reasonable action to mitigate any Losses. The Indemnifying Party shall not settle or compromise, or consent to the entry of any judgment with respect to, any Claim, without the prior written consent of the Indemnified Party, which will not be unreasonably withheld or delayed.

12. Compliance with Laws. Sublicensee shall comply with all applicable laws and regulations in the Territory in exercising its rights and performing its obligations under this Agreement. Without limiting the foregoing, Sublicensee shall: (a) mark, and shall cause its sub-sublicensees to mark, all Licensed Product manufactured or sold under this Agreement with all notices relating to the Sublicensed Rights to the extent required by the marking laws of the countries in which Sublicensee (or its sub-sublicensees) commercialize Licensed Product under the Sublicense Agreement; (b) record this Agreement (or the relevant portions or summary hereof) with the applicable regulatory authority if required under applicable law; (c) comply with all applicable laws and regulations concerning the export of any Licensed Product, including any requirements for obtaining an export license or other required governmental approval; and (d) comply with any Sanctions legislation administered or enforced by the Sanctions Authorities or the national governments of the relevant country(ies) covered by the Sublicense Agreement.

13. Enforcement. Each Party shall promptly notify the other Party of any actual or suspected infringement of the Sublicensed Rights in the Territory to the extent relating to the Licensed Product. Sublicensee acknowledges that, in accordance with the License Agreement, Licensor has the right, in its discretion and at their expense, to bring any action or proceeding with respect to such infringement and to control its conduct (including any settlement).

14. Insurance.

14.1 Sublicensee and its Affiliates and sub-sublicensees, must take out and maintain the following insurances with a reputable insurer during the Term and, if the policy is on a claims-made basis, for five years thereafter:

a) a comprehensive commercial general liability and product liability policy to cover all sums which it may become legally liable to pay as compensation consequent upon:

   i. death of, or bodily injury (including disease or illness) to, any person in connection with the use or administration of Licensed Product; and
   ii. loss of, or damage to, property, happening in any country where Sublicensee is conducting any activities pursuant to the Sublicense Agreement and arising out of or in connection with this Sublicense Agreement.

   The limit of liability provided by this policy must be not less than [$10 million].

b) if they conduct any clinical trials of Licensed Product, clinical trial liability insurance in respect thereof; and
c) any other insurance required by law.

14.2 To the extent practicable, Sublicensor and Licensor shall be noted as an interested party on all policies required under Section [14.1(a) and 14.1(b)], and within ten (10) Business Days of a request from Sublicensor or Licensor, Sublicensee must produce evidence that the insurances required by this Section [14] are being maintained, including providing copies of policy documents. Sublicensee must notify Sublicensor and Licensor immediately of any cancellation or material change to a relevant insurance policy which would cause its coverage to no longer be compliant with the obligations of this Section 10.

14.3 If any event occurs which may give rise to a claim involving Sublicensor or Licensor under any policy of insurance to be taken out by Sublicensee under this Section [14], then Sublicensee must:

a) notify Sublicensor and/or Licensor as soon as reasonably practicable but in any event within ten (10) Business Days of the occurrence of that event; and

b) ensure that Sublicensor and/or Licensor is kept fully informed of any subsequent actions and developments concerning the relevant claim.

15. Non-Diversion.

15.1 Sublicensee acknowledges that the sublicense to Licensed Rights granted under Section [X] is granted solely under and with respect to the Licensed Rights and Licensed Manufacturing Know-How for the purposes of Manufacturing Licensed Product for and supplying Licensed Product in the Field in the Territory.

15.2 Sublicensee acknowledges and agrees nothing in this Agreement will be construed as granting Sublicensee any rights under any patents, know-how, or otherwise to use, make,

have made, sell, or have sold the Licensed Compound or any Licensed Product for ultimate use outside of the Field and/or outside of the Territory.

15.3 Subject to any applicable competition law, Sublicensee acknowledges and agrees the Licensed Product intended for distribution in the Territory is strictly prohibited from being diverted outside the Territory.

16. Licensed Product Trademarks. Subject to any limitations set forth herein, Sublicensee shall own all right, title, and interest to the Licensed Product Trademarks in the Territory, and shall be responsible for the registration, prosecution, and maintenance thereof. All costs and expenses of registering, prosecuting, and maintaining the Licensed Product Trademarks shall be borne solely by Sublicensee. Notwithstanding the foregoing, (i) each Licensed Product Trademark must have color, markings and other presentation to be distinctive from the Licensor's Licensed Product; and (ii) Sublicensee must obtain Licensor's prior written approval (such approval not to be unreasonably withheld) for Sublicensee' proposed Licensed Product Trademarks, trade dress or product markings. Licensor shall provide its feedback for any proposed trademark or trade dress promptly following its receipt of all information requested in order to fully evaluate such request. If Licensor reasonably objects to such request within the foregoing time-period, the Parties shall discuss in good faith Licensor's concerns, and Sublicensee will agree to make such modifications to Sublicensee's proposed trademark, trade dress or product markings as are necessary to address Licensor's concerns. For the purposes of this Agreement, "**Licensed Product Trademarks**" means the trademark(s) to be used by Sublicensee or its Affiliates for the Commercialization of the Licensed Product in the countries covered by the Sublicense and any registrations thereof or any pending applications relating thereto in such countries (excluding, in any event, any trademarks that include any corporate name or logo of the Parties or their Affiliates, including Licensor's corporate names).

17. Confidentiality and Non-Disclosure.

17.1 **Confidentiality Obligations**. At all times during the Term and for a period of ten (10) years following termination or expiration of this Sublicense Agreement, or indefinitely with respect to all Confidential Information that constitutes trade secrets (including, without limitation, any Licensed Manufacturing Know-How, including the content of the Technical Transfer Package, and the content of the Licensor's European Union and United States cefiderocol regulatory filings received or accessed by Sublicensee, and any other trade secrets of the Licensor, including all Confidential Information that is of a technical nature, is identifiable and substantial, and has commercial value because it is not publicly available), for so long as the relevant trade secrets do not become publicly available other than as a result of a fault attributable to the receiving Party or its agents or sublicensees, each Party shall, and shall cause its Affiliates and their respective officers, directors, employees and agents to, keep completely confidential and not publish or otherwise disclose to a Third Party and not to use, directly or indirectly, for any purpose, any Confidential Information furnished or otherwise made known to it, directly or indirectly, by the other Party, except to the extent such disclosure or use is expressly permitted by the terms of this Agreement or such use is reasonably necessary for the performance of its

obligations or the exercise of its rights under this Agreement. "**Confidential Information**" means any information provided by one Party (the "**Disclosing Party**") to the other Party (the "**Receiving Party**") under or in connection with this Agreement, including the terms of this Agreement or any information relating to the Licensed Product (including the regulatory documentation and market approvals and any information or data contained therein), any information relating to any exploitation of the Licensed Product in the Territory or the scientific, regulatory or business affairs or other activities of either Party. For the purposes hereof, the Licensed Rights [(including the Licensed Manufacturing Know-How) – IF APPLICABLE], shall be deemed to be Confidential Information of GARDP, and the terms of this Sublicense Agreement shall be deemed Confidential Information of both Parties. The obligations under Section 17.1 will not apply with respect to any portion of the Confidential Information that the Receiving Party can show by written evidence:

Specific aspects or details of Confidential Information shall not be deemed to be within the public domain or in the possession of the Receiving Party merely because the Confidential Information is embraced by more general information in the public domain or in the possession of the Receiving Party. Further, any combination of Confidential Information shall not be considered in the public domain or in the possession of the Receiving Party merely because individual elements of such Confidential Information are in the public domain or in the possession of the Receiving Party unless the combination and its principles are in the public domain or in the possession of the Receiving Party.

17.2 **Authorized Disclosures**. Each Receiving Party may disclose Confidential Information disclosed to it by the Disclosing Party to the extent (and only to the extent) that such disclosure by the Receiving Party is reasonably necessary in the following instances:

i. regulatory filings;
ii. prosecuting or defending litigation;
iii. complying with applicable governmental laws and regulations (including the rules and regulations of the Securities and Exchange Commission or any national securities exchange or laws and regulations) and with judicial process, if in the reasonable opinion of the Receiving Party's counsel, such disclosure is necessary for such compliance; and
iv. disclosure, in connection the receiving Party's performance of its obligations or exercise of its rights under this Agreement and solely on a "need-to-know basis", to Affiliates, potential sub-sublicensees and sub-sublicensees, potential donors and donors, research collaborators, employees, consultants, contractors or agents, each of whom prior to disclosure must be bound by obligations of confidentiality and non-use substantially equivalent in scope to those set forth in this Section 17 (the duration of such obligations being at least for the duration of the agreement with such other Person and a period of ten (10) years thereafter, or indefinitely with respect to all Confidential Information that constitutes trade secrets (including, without limitation, any Licensed Manufacturing Know-How, including the content of the Technical Transfer Package, and the content of Licensor's European Union and United States cefiderocol regulatory filings received or accessed by

Sublicensee, and any other trade secrets of the Licensor, including all Confidential Information that is of a technical nature, is identifiable and substantial, and has commercial value because it is not publicly available), for so long as the relevant trade secrets do not become publicly available other than as a result of a fault attributable to the receiving Party or to such other Person; provided, however, that the Receiving Party will remain responsible for any failure by any such Person who receives Confidential Information to treat such Confidential Information as required under this Section 17.

f) If and whenever any Confidential Information is disclosed in accordance with this Section 17.2, such disclosure will not cause any such information to cease to be Confidential Information except to the extent that such disclosure results in a public disclosure of such information (otherwise than by breach of this Agreement). Where reasonably possible, the receiving Party will notify the disclosing Party of the receiving Party's intent to make such disclosure pursuant to this Section 17.2 sufficiently prior to making such disclosure so as to allow the disclosing Party adequate time to take whatever action it may deem appropriate to protect the confidentiality of the information.

17.3 **Destruction of Confidential Information**. Within sixty (60) Business Days after termination or expiration of this Agreement, each Party shall at the other Party's request: (A) return to the other Party or destroy all documents and tangible materials (and any copies) containing Confidential Information of the other Party; and (B) certify to the other Party in writing that it has complied with the requirements of this Section 17.3; provided that: (i) the Receiving Party may retain one archival copy of the Confidential Information of the other Party, but not any Confidential Information that constitutes trade secrets of the other Party (including, without limitation, the Licensed Manufacturing Know-How, including the content of the Technical Transfer Package, and the content of Licensor's European Union and United States cefiderocol regulatory filings received or accessed by Sublicensee, and any other trade secrets of the Licensor, including all Confidential Information that is of a technical nature, is identifiable and substantial, and has commercial value because it is not publicly available, except for any of such that has become publicly available other than as a result of a fault attributable to GARDP and/or a Sublicensee) in a limited access file (meaning only accessible by such Party's Information Technology (IT) department or by such Party's legal personnel) to the extent that the receiving Party requires such Confidential Information for the purpose of performing any obligations or exercising any rights under this Agreement that may survive such expiration or termination, subject in any case to continued compliance by such Party of its confidentiality obligations as set out in Section 17 above; (ii) the receiving Party may retain Confidential Information of the other Party to the extent that the receiving Party is required to retain such information for compliance purposes under applicable laws and regulations; and (iii) the above obligations shall not require either Party to delete any automatic electronic backup files maintained in accordance with its standard policies and to which access is limited and only accessible by such Party's IT department. Notwithstanding any of the foregoing, Sublicensees are prohibited from retaining any Confidential Information received by the Sublicensee that constitutes trade secrets, including, without limitation, the Licensed Manufacturing Know-How, including the content of the Technical Transfer Package, and the content of Licensor's European Union and United States cefiderocol regulatory filings

received or accessed by Sublicensee, and any other trade secrets of the Licensor, including all Confidential Information that is of a technical nature, is identifiable and substantial, and has commercial value because it is not publicly available, except for any of such that has become publicly available other than as a result of a fault attributable to Sublicensee or its agents or sublicensees and except as may be required for compliance purposes under applicable laws and regulations, and subject in any case to continued compliance by such Party of its confidentiality obligations as set out in Section 17 above.

18. Assignment. Sublicensee may not assign or transfer any of its rights or delegate any of its obligations hereunder, in each case whether voluntarily, involuntarily, by operation of law or otherwise, without the prior written consent of Sublicensor. No delegation or other transfer will relieve Sublicensee of any of its obligations or performance under this Agreement. Any purported assignment, delegation, or transfer in violation of this Section is void ab initio. This Agreement is binding upon and inures to the benefit of the Parties and their respective permitted successors and assigns. For clarity, Sublicensee's use of contractors for which it remains entirely responsible to perform its obligations under this Sublicense Agreement shall not be considered an assignment or delegation of its obligations under the Sublicense Agreement.

19. Choice of Law. This Agreement will be governed, and will be construed in accordance with the laws of _____, without regard to its conflicts of law provisions.

20. Additional Waiver (Disclaimer of Warranty). SUBLICENSEE AGREES THAT: (A) THE LICENSED RIGHTS ARE LICENSED "AS IS," "WITH ALL FAULTS," AND "WITH ALL DEFECTS," AND SUBLICENSEE EXPRESSLY WAIVES ALL RIGHTS TO MAKE ANY CLAIM WHATSOEVER AGAINST LICENSOR OR SUBLICENSOR FOR MISREPRESENTATION OR FOR BREACH OF PROMISE, GUARANTEE OR WARRANTY OF ANY KIND RELATING TO THE LICENSED RIGHTS; (B) SUBLICENSEE AGREES THAT LICENSOR AND SUBLICENSOR WILL HAVE NO LIABILITY TO SUBLICENSEE FOR ANY ACT OR OMISSION IN THE PREPARATION, FILING, PROSECUTION, MAINTENANCE, ENFORCEMENT, DEFENSE OR OTHER HANDLING OF THE LICENSED RIGHTS; AND (C) SUBLICENSEE IS SOLELY RESPONSIBLE FOR DETERMINING WHETHER THE LICENSED RIGHTS HAVE APPLICABILITY OR UTILITY IN SUBLICENSEE'S CONTEMPLATED EXPLOITATION OF THE LICENSED PRODUCT, AND SUBLICENSEE ASSUMES ALL RISK AND LIABILITY IN CONNECTION WITH SUCH DETERMINATION.