

PATENT ASSIGNMENT COVER SHEET

Electronic Version v1.1
Stylesheet Version v1.2

EPAS ID: PAT6805874

SUBMISSION TYPE:	NEW ASSIGNMENT
NATURE OF CONVEYANCE:	ASSIGNMENT
CONVEYING PARTY DATA	
Name	Execution Date
DUKE UNIVERSITY	09/13/1996
RECEIVING PARTY DATA	
Name:	SYNPAC (NORTH CAROLINA), INC.
Street Address:	176 MINE LAKE COURT, SUITE 100
City:	RALEIGH
State/Country:	NORTH CAROLINA
Postal Code:	27615
PROPERTY NUMBERS Total: 8	
Property Type	Number
Patent Number:	7056712
Patent Number:	8679478
Patent Number:	8809282
Patent Number:	8900552
Patent Number:	9370556
Patent Number:	9907839
Patent Number:	10792341
Patent Number:	10869906
CORRESPONDENCE DATA	
Fax Number:	(650)849-6666
<i>Correspondence will be sent to the e-mail address first; if that is unsuccessful, it will be sent using a fax number, if provided; if that is unsuccessful, it will be sent via US Mail.</i>	
Phone:	6508496600
Email:	jordan.fraboni@finnegan.com
Correspondent Name:	FINNEGAN LLP
Address Line 1:	3300 HILLVIEW AVENUE
Address Line 4:	PALO ALTO, CALIFORNIA 94304
ATTORNEY DOCKET NUMBER:	15172.8051
NAME OF SUBMITTER:	YASUKO NAKAGAMI-SHER
SIGNATURE:	/Yasuko Nakagami-Sher/

DATE SIGNED:

07/09/2021

Total Attachments: 83

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TECHNOLOGY ASSIGNMENT AGREEMENT

THIS TECHNOLOGY ASSIGNMENT AGREEMENT made and entered into this 13th day of September, 1996, by and between DUKE UNIVERSITY, a North Carolina not-for-profit corporation having its principal office at Durham, North Carolina ("DUKE"), SYN PAC PHARMACEUTICALS (U.K.) LIMITED, a corporation of the United Kingdom having its principal office at Bedlington, Northumberland, England ("SYNPAC-UK"), and SYN PAC (NORTH CAROLINA), INC., a North Carolina corporation having its principal office at Durham, North Carolina ("SYNPAC-NC", and collectively with SYN PAC-UK, "SYNPAC").

W I T N E S S E T H:

WHEREAS, Dr. Y. T. Chen, a resident of North Carolina ("CHEN"), Dr. J. Van Hove, a resident of North Carolina ("VAN HOVE"), Helen W. Yang, a resident of North Carolina ("YANG"), and J-Y Wu, a resident of North Carolina ("WU"), are the authors and inventors of certain TECHNOLOGY and TECHNICAL INFORMATION as hereinafter defined; and

WHEREAS, DUKE has the right to assign the TECHNOLOGY and TECHNICAL INFORMATION and wishes to have the TECHNOLOGY and the TECHNICAL INFORMATION utilized in the public interest; and

WHEREAS, as herein set forth and subject to the terms hereof, SYN PAC desires to purchase all rights, title and interest in and to the TECHNOLOGY, the TECHNICAL INFORMATION, and any applications for orphan drug, investigational new drug, or new drug approval from DUKE, and DUKE desires to assign any and all of its rights, title and interest in and to the TECHNOLOGY, the TECHNICAL INFORMATION, and any applications for orphan drug, investigational new drug, or new drug approval to SYN PAC;

NOW, THEREFORE, for good and valuable consideration, which DUKE acknowledges having received from SYN PAC, and in further consideration of the mutual promises set forth herein, the parties agree as follows:

1. Definitions. As used herein the following defined terms shall have the following respective meanings:
 - a. "AFFILIATED COMPANY" means any company (i) in which SYN PAC now or hereafter owns or controls, directly or indirectly, fifty percent (50%) or more of the stock having the right to vote for directors thereof, or (ii) which owns or controls, directly or indirectly, fifty percent (50%) or more of SYN PAC's stock having the right to vote for directors.
 - b. "AGREEMENT" means this Technology Assignment Agreement.
 - c. "CLINICAL INFORMATION" means clinical data generated through the clinical trials for use within the SUBJECT AREA.
 - d. "DUKE PERSONNEL" means CHEN and VAN HOVE and any other doctor, scientist, employee, technician or student of DUKE who participates in the SUBJECT AREA research, development and trials.

- e. "EFFECTIVE DATE" means October 1, 1996.
- f. "FDA" means the United States Food and Drug Administration.
- g. "FIRST COMMERCIAL SALE" means the initial transfer, following PLA approval by the FDA, by SYN PAC of PRODUCTS in exchange for cash or some equivalent to which value can be assigned for the purpose of determining NET SALES.
- h. "FUNCTIONAL EQUIVALENT" for human acid alpha glucosidase shall mean any other protein (including glycoproteins and other substances which contain one or more polypeptide chains as constituent parts), protein fragment, subunit, or polypeptide, with enzymatic activity and substrate preferences sufficiently similar to those of human acid alpha glucosidase so as to allow said substance to be substituted for human acid alpha glucosidase in any method, device or substance within the scope of the SUBJECT AREA.
- i. "IND" means an Investigational New Drug application filed with the FDA arising from the TECHNOLOGY or any Invention, as defined in the SPONSORED RESEARCH AGREEMENT.
- j. "NDA" means a New Drug Application filed with the FDA or its component PLA and Equipment Licensing Agreement applications arising from the TECHNOLOGY or any Invention, as defined in the SPONSORED RESEARCH AGREEMENT.
- k. "NET SALES" means the gross sales of the PRODUCT by SYN PAC or any licensee of SYN PAC to independent third parties, less price adjustments, return goods, billing corrections, cash, trade and contract discounts, taxes arising from the sale of the PRODUCT, freight, and other special charges. If a PRODUCT is not sold independently, but rather is sold in combination with other material which is not a PRODUCT, then (i) the NET SALES of said PRODUCT shall be deemed to be the current equivalent NET SALES for the same quantity of said PRODUCT which is sold independently; or (ii) if there are not independent current sales of said PRODUCT, the NET SALES shall be deemed to be equal to one hundred fifty percent (150%) of the direct cost of producing said PRODUCT, determined in accordance with generally accepted accounting principles consistently applied.
- l. "ODA" means an Orphan Drug Application filed with the FDA arising from the TECHNOLOGY or any Invention, as defined in the SPONSORED RESEARCH AGREEMENT.
- m. "PATENTS" means all letters patents and patents rights (both U.S. and foreign), now or hereafter owned or controlled by DUKE which cover all or any part of the SUBJECT AREA, including but not limited to patents of importation, improvements patents, patents and certificates of addition, and utility models, as well as divisions, reissues, re-examinations, continuations, renewals, and extensions of any of the foregoing, and applications therefor (including patents which may issue on such applications) and patent application serial number 60/012,855 entitled "Tissue Specific Recombinant Human Lysosomal Acid α -Glucosidase" filed March 5, 1996 in the United States Patent and Trademark Office.
- n. "PLA" means Product Licensing Agreement.
- o. "PRODUCT(S)" means any product which is produced or sold by SYN PAC, any AFFILIATED COMPANY or any licensee of SYN PAC that utilizes the TECHNOLOGY, the TECHNICAL INFORMATION, or infringes one or more claims of the PATENTS.

p. "SPONSORED RESEARCH AGREEMENT" means that certain Sponsored Research Agreement of even date herewith by and between DUKE and SYN PAC, a copy of which is attached hereto as Exhibit B.

q. "SUBJECT AREA" means (i) the creation of cell lines which produce commercially significant quantities of human acid alpha glucosidase or its FUNCTIONAL EQUIVALENT, (ii) the isolation, purification, manufacture, production, and storage of human acid alpha glucosidase or its FUNCTIONAL EQUIVALENT, (iii) the delivery of human acid alpha glucosidase or its FUNCTIONAL EQUIVALENT to people to prevent or to treat Pompe's Disease or other human diseases, specifically including, without limitation, use in enzyme replacement therapy; (iv) the use of the proteins in (ii) for development and screening of drugs for the prevention and treatment of Pompe's Disease and other human diseases, including drug design and drug targeting; and (v) the use of the proteins of (ii) for analysis of glycogen.

r. "SYNPAC" means Synpac Pharmaceuticals (U.K.) Limited and any AFFILIATED COMPANY of Synpac Pharmaceuticals (U.K.) Limited.

s. "TECHNICAL INFORMATION" means all scientific or technical information, know-how, show-how, data, and test results, regardless of form or characteristics relating to the SUBJECT AREA developed, produced or generated by DUKE PERSONNEL.

t. "TECHNOLOGY" means the cell line set forth in Exhibit A, attached hereto and incorporated herein by reference, all progeny and derivatives of said cell line, and PATENTS.

2. *Assignment.*

a. DUKE hereby sells, assigns, grants and conveys to SYN PAC-UK, its successors, assigns, nominees, or legal representatives, DUKE's entire right, title and interest in and to the now-existing TECHNICAL INFORMATION, including all rights to make, use, sell, offer for sale, import and license the TECHNICAL INFORMATION. DUKE hereby sells, assigns, grants and conveys to SYN PAC-NC, its successors, assigns, nominees, or legal representatives, DUKE's entire right, title and interest in and to all of the TECHNOLOGY, including all rights to make, use, sell, offer for sale, import and license the TECHNOLOGY, any existing patent applications thereon and the right to file patent applications thereon throughout the world, all claims for damages and profits by reason of any past infringement pertaining to the TECHNOLOGY and the right to sue therefor, and all rights of priority consequent upon the filing of applications to patent the TECHNOLOGY, to the full end of the term or terms for which letters patent respectively may be granted, reissued, or extended.

b. Duke hereby agrees to execute and deliver to Synpac the Patent Assignment, attached hereto as Exhibit C and hereby incorporated into this AGREEMENT.

c. Within thirty (30) days following the execution of this AGREEMENT and upon reasonable notice during the term of this AGREEMENT, DUKE agrees to provide SYN PAC with a list of all existing TECHNICAL INFORMATION, PATENTS, CLINICAL INFORMATION and any information relating to the TECHNOLOGY. DUKE further agrees to provide SYN PAC with a copy of all such information requested by SYN PAC within a reasonable time after receipt of such request.

3. *ODA, IND, and NDA.* Duke agrees to prepare and submit for approval, at SYN PAC's expense, an ODA, IND and NDA with respect to any PRODUCTS and further grants SYN PAC an option

to acquire such applications without option fee other than the consideration of the Sponsored Research Agreement and the payment of all expenses incurred related to such applications. Such option with respect to each such application shall extend until ninety (90) days following notice to SYNPAAC of the approval of such application. If SYNPAAC does not exercise such option within the prescribed ninety (90) day option period, or notifies DUKE that it will not exercise such option, then SYNPAAC shall no longer own any rights in such application.

4. *Grantback of Non-exclusive, Royalty-free License.* Upon the assignment of the TECHNOLOGY under this AGREEMENT or any Invention, as defined in the Sponsored Research Agreement, SYNPAAC shall grant to DUKE a non-exclusive, royalty-free license to produce, make, or use the TECHNOLOGY or Invention solely for research, education, teaching and clinical purposes; provided, however, DUKE shall have no right to sublicense or assign the rights granted pursuant to this Section 4, and, after FDA approval of the PLA, DUKE will, at its sole discretion, use PRODUCTS when appropriate for clinical purposes.

5. *Consideration, Records and Reports.*

a. SYNPAAC shall pay to DUKE an assignment fee of Fifty Thousand Dollars (\$50,000) upon the execution of this AGREEMENT by all parties thereto. In addition, SYNPAAC shall pay to DUKE a milestone fee upon the achievement of certain milestones in the development of PRODUCTS as follows:

- i. One Hundred Thousand Dollars (\$100,000) upon the filing of the first NDA with the FDA or a similar regulatory agency in a foreign country; and
- ii. Two Hundred Thousand Dollars (\$200,000) upon approval of the first NDA with the FDA or a similar regulatory agency in a foreign country.

Such fees shall not be creditable to any royalty or other fee or payment due to DUKE under this AGREEMENT. The first Two Hundred Thousand Dollars (\$200,000) of such fees shall be paid by SYNPAAC-UK as consideration for the assignment of the TECHNICAL INFORMATION. The remaining One Hundred Fifty Thousand Dollars (\$150,000) of such fees, as well as all other compensation due Duke pursuant to this AGREEMENT, shall be paid by SYNPAAC-NC as consideration for the assignment of the TECHNOLOGY and all such other obligations owed by DUKE under this AGREEMENT.

b. Commencing with the FIRST COMMERCIAL SALE and at such times and in such manner set forth hereinafter, SYNPAAC shall pay to DUKE a royalty on NET SALES of PRODUCTS. Such royalty shall be at the rate of six percent (6%) of NET SALES.

If SYNPAAC demonstrates through written records (i) that it has been necessary to license additional technology from third parties or to take an assignment for additional technology from DUKE in order to commercialize the PRODUCTS ("NECESSARY TECHNOLOGY") and (ii) that such license or assignment for NECESSARY TECHNOLOGY obligates SYNPAAC to pay royalties on NET SALES of PRODUCTS, then SYNPAAC shall be permitted to reduce the royalty due DUKE under this AGREEMENT by one-half of any such additional royalties payable to third parties in respect of the PRODUCTS and by the full amount of such additional royalties payable to DUKE in respect of the PRODUCTS; provided, however, in no case shall the royalty rate payable to DUKE pursuant to this Section 5.b, when reduced by any royalties due third parties for NECESSARY TECHNOLOGY, be less than two percent (2%) of NET SALES, and in no case shall the royalty rate payable to DUKE pursuant to

this Section 5.b, when combined with any royalties due under additional assignment agreements with DUKE for NECESSARY TECHNOLOGY, be greater than six percent (6%) of NET SALES.

c. Commencing with the FIRST COMMERCIAL SALE and at such times and in such manner set forth hereinafter, SYN PAC shall render to DUKE prior to February 28th and August 31st of each year a written account of the NET SALES of PRODUCTS subject to royalty hereunder made during the prior six (6) month periods ending December 31st and June 30th, respectively, and shall simultaneously pay to DUKE the royalties due on such NET SALES in United States Dollars. Minimum annual royalties, if any, which are due DUKE for any calendar year, shall be paid by SYN PAC along with the written report due on February 28th of each year.

d. SYN PAC shall, at DUKE's option, either (a) reassign to DUKE all TECHNOLOGY and TECHNICAL INFORMATION assigned to SYN PAC under this AGREEMENT or (b) license to DUKE all TECHNOLOGY and TECHNICAL INFORMATION assigned to SYN PAC under this AGREEMENT under a royalty-free, exclusive license without other restrictions if (i) SYN PAC fails to make the FIRST COMMERCIAL SALE of the PRODUCT within two (2) years of the date the PLA for the PRODUCT is approved by the FDA or similar regulatory agency in any foreign country or (ii) royalties earned by DUKE pursuant to the sale of the first PRODUCT for therapeutic administration during the second year following FIRST COMMERCIAL SALE are less than One Thousand Dollars (\$1,000).

e. SYN PAC shall keep full, true and accurate books of accounts and other records containing all particulars which may be necessary to properly ascertain and verify the royalties payable by them hereunder. Upon DUKE's request, SYN PAC shall permit an independent Certified Public Accountant selected by DUKE (except one to whom SYN PAC has some reasonable objection) to have access during ordinary business hours to such of SYN PAC's records as may be necessary to determine, in respect of any quarter ending not more than two (2) years prior to the date of such request, the correctness of any report and/or payment made under this AGREEMENT.

f. Concurrently with the execution of this AGREEMENT, DUKE and SYN PAC shall execute the SPONSORED RESEARCH AGREEMENT.

g. SYN PAC agrees to contribute to a qualifying charitable organization two percent (2%) of SYN PAC's net profits, before tax and before charitable contributions, derived from the sale of PRODUCTS. A qualifying charitable organization shall be a not-for-profit organization qualifying under Section 501(c)(3) of the Internal Revenue Code of the United States of 1986, as amended, and which has as a principal purpose providing financial assistance for the treatment of patients with Pompe's Disease. SYN PAC shall have the right, but not the obligation, to designate any such gift solely for the purpose of patient care.

h. During the term of this AGREEMENT, representatives of the DUKE will meet with representatives of SYN PAC at times and places mutually agreed upon to discuss the progress and results, as well as the ongoing plans, with respect to the evaluation and development of the TECHNOLOGY and TECHNICAL INFORMATION assigned to SYN PAC; provided, however, that should DUKE's personnel be required by SYN PAC to consult with SYN PAC outside of Durham, North Carolina, SYN PAC will reimburse reasonable travel and living expenses incident thereto.

6. *Representations and Covenants by DUKE.*

a. DUKE represents that:

i. To the best of DUKE's knowledge, DUKE is the sole and exclusive owner of the entire right, title and interest in the TECHNOLOGY and TECHNICAL INFORMATION, unencumbered by any outstanding contracts, agreements or priority claims;

ii. With the exception of SYN PAC, DUKE did not utilize the resources of any other person or entity in the development of the TECHNOLOGY and TECHNICAL INFORMATION, other than as already disclosed to SYN PAC;

iii. DUKE has full right to enter into this AGREEMENT, make this assignment, and carry out the transactions contemplated hereby;

iv. DUKE has not executed any agreement in conflict with this AGREEMENT;

v. To the best of DUKE's knowledge and except as has been previously disclosed to SYN PAC, there has been no disclosure such as would invalidate the patentability of any component of the TECHNOLOGY or as would cause secret and substantial TECHNICAL INFORMATION to have fallen into the public domain; and

vi. DUKE is the party named in any and all patent applications based on the TECHNOLOGY, DUKE is the party who filed, or caused to be filed, all patent applications based on the TECHNOLOGY, and all patent applications are free of any and all liens, security interests, claims, or other encumbrances of any nature or kind, and no interest in any patents has been previously or simultaneously granted, transferred, assigned, licensed, or otherwise conveyed.

b. Duke covenants that:

i. During the term of this AGREEMENT and for such time thereafter as those obligations which survive the expiration or termination of this AGREEMENT shall apply, DUKE shall not enter into any agreement in conflict with this AGREEMENT or such surviving obligations; and

ii. DUKE shall take all reasonable care to protect, maintain, and keep secure the cell line set forth in Exhibit A and all progeny and derivatives of said cell line to the extent the same are in the sole possession of DUKE.

7. *SYN PAC's Due Diligence Requirements.*

a. SYN PAC shall use commercially reasonable efforts to bring the PRODUCTS to market through a thorough, vigorous and diligent program for exploitation of the TECHNOLOGY and TECHNICAL INFORMATION throughout the term of this AGREEMENT.

- b. In addition, SYN PAC shall adhere to the following commercialization milestones:
- i. deliver to DUKE on or before February 1, 1997, a business plan showing the amount of money, number and kind of personnel and time budgeted and planned for each research and scale-up phase of the development of the PRODUCTS.
 - ii. SYN PAC shall achieve the FIRST COMMERCIAL SALE of a PRODUCT on or before two years following PLA approval by the FDA of such PRODUCT, and shall promptly notify DUKE in writing of the details of such sale.
- c. SYN PAC agrees to use commercially reasonable efforts to develop a vigorous licensing program to effect commercialization of PRODUCTS in any field of use that SYN PAC decides not to exploit on its own.
- d. During the term of this AGREEMENT, SYN PAC will submit annual progress reports, including a financial report of moneys spent to date, to DUKE by August 31 of each year which discuss the progress and results, as well as ongoing plans, with respect to the TECHNOLOGY and TECHNICAL INFORMATION. DUKE shall have the right to request one meeting per year to discuss such information.
- e. SYN PAC shall, at DUKE's option, either (a) reassign to DUKE all TECHNOLOGY and TECHNICAL INFORMATION assigned to SYN PAC under this AGREEMENT or (b) license to DUKE all TECHNOLOGY and TECHNICAL INFORMATION assigned to SYN PAC under this AGREEMENT under a royalty-free, exclusive license without further restrictions if SYN PAC fails to meet any of the commercialization milestones set forth in subsection b. of this Section 7.

8. *Patents.*

a. Subsequent to the EFFECTIVE DATE of this AGREEMENT, SYN PAC shall have sole responsibility for the filing, prosecuting and maintaining of appropriate worldwide patents for the TECHNOLOGY, and all of the expenses of such protection shall be paid by SYN PAC. DUKE shall fully assist SYN PAC in the preparation of patent applications, and SYN PAC shall reimburse DUKE for all legal expenses which have been incurred to date or any expense which is incurred during the term of this AGREEMENT in the preparation, prosecution and maintenance of such patents. SYN PAC shall keep DUKE advised as to the prosecution of such applications by forwarding to DUKE copies of all official correspondence relating thereto. DUKE agrees to cooperate with SYN PAC in the prosecution of worldwide patent applications to insure that the applications reflect, to the best of DUKE's knowledge, all items of commercial and technical interest and importance.

b. Each party to this AGREEMENT (here, the "notifying party") shall give the other party to this AGREEMENT prompt notice of each claim or allegation received by the notifying party that the manufacture, use or sale of PRODUCTS constitutes a significant infringement of a third-party patent or patents. SYN PAC shall have the sole right and responsibility at its own expense to defend and control the defense of any such claim against SYN PAC, by counsel of SYN PAC's own choosing. The settlement of any such actions must be approved by DUKE, which approval may not be unreasonably withheld. DUKE agrees to cooperate with SYN PAC in any reasonable manner deemed by SYN PAC to be necessary

in defending or prosecuting such actions. SYNPAC shall reimburse DUKE for all expenses incurred in providing such assistance. Notwithstanding the foregoing, DUKE, shall, in its sole discretion and at its sole expense, be entitled to participate through counsel of its own choosing in any such action.

9. *Infringement by Third Parties.* Upon learning of the infringement of the TECHNOLOGY by a third party, the party learning of such infringement shall promptly inform the other party in writing of that fact along with any evidence available pertaining to the infringement. SYNPAC may at its own expense take whatever steps are necessary to stop the infringement and recover damages. In such case, SYNPAC will keep DUKE informed of the steps taken and the progress of any legal action taken. DUKE shall receive twelve and one-half percent (12.5%) of any damages received in excess of legal expenses incurred by SYNPAC in enforcing rights in the TECHNOLOGY.

10. *Ownership of Rights.*

a. The PATENTS shall be the sole and exclusive property of SYNPAC subject to the reversionary assignment and license rights granted to DUKE in this AGREEMENT. DUKE shall, upon demand, execute and deliver to SYNPAC such documents as may be reasonably considered necessary and advisable by counsel for SYNPAC for filing in the appropriate patent offices or equivalent to evidence the granting of the assignment granted under this AGREEMENT.

b. SYNPAC shall retain all right, title and interest to any improvement, modification and new discoveries pertaining to the PRODUCTS solely developed or invented by SYNPAC or by a third party on behalf of SYNPAC, including those discoveries, improvements, and designs for the manufacture and production of devices, processes, or equipment as developed or invented by SYNPAC, or by a third party on behalf of SYNPAC, for the manufacture or production of the PRODUCTS. If such discoveries, improvements, changes, modifications, or designs have been created in whole or in part as a result of collaborative efforts between DUKE and SYNPAC other than under the SPONSORED RESEARCH AGREEMENT, DUKE and SYNPAC shall share ownership of such discoveries, improvements, changes, modifications, or designs consistent with relevant patent or other intellectual property law.

11. *Government Clearance, Publication, Other Use, Export.*

a. SYNPAC agrees to use its reasonable efforts to have the TECHNOLOGY and TECHNICAL INFORMATION cleared for marketing in those countries in which SYNPAC intends to sell the PRODUCTS by the responsible government agencies requiring such clearance. To accomplish said clearances at the earliest possible date, SYNPAC agrees to file, according to the usual practice of SYNPAC, any necessary data with said government agencies. Should SYNPAC cancel its development efforts under this AGREEMENT, SYNPAC agrees to assign its full interest and title in such market clearance application, including all data relating thereto, to DUKE at no cost to DUKE.

b. DUKE shall be free to publish the results of its continued research on the TECHNOLOGY and TECHNICAL INFORMATION but agrees to submit to SYNPAC for its review and comment, a copy of any proposed publication resulting from the subject research at least thirty (30) days prior to the date submitted for publication, and if no response is received within thirty (30) days of the date submitted to SYNPAC, it will be conclusively presumed that the publication may proceed without delay. DUKE shall in good faith consider any comments provided by SYNPAC and shall consider the sensitive nature and timing of publication of unprotected intellectual property. If SYNPAC determines that the proposed publication contains proprietary subject matters which require protection, SYNPAC may request the delay for ninety (90) days from the date first submitted to SYNPAC in order to perfect such protection.

Duke agrees to consider requests by SYN PAC for additional reasonable delays in publication if such delays are required to protect proprietary subject matter necessary for the development of a cure for Pompe's Disease. Nothing in this Agreement shall be construed as giving SYN PAC editorial control over any publication. Nothing in this AGREEMENT shall be construed as prohibiting DUKE or SYN PAC from reporting on the results of such research to a governmental agency if so required by law. For purposes of this AGREEMENT, publication shall mean the disclosure of information to any person or entity who is not subject to the confidentiality provisions of Section 14 of this AGREEMENT.

c. Except SYN PAC's publication review rights set forth in Section 11.b of this AGREEMENT, nothing in this Section 11 shall be construed as to restrict DUKE's right to use the TECHNOLOGY, TECHNICAL INFORMATION and PATENTS for its own educational, teaching, research and clinical purposes as may be set forth elsewhere in this AGREEMENT; provided, after FDA approval of the PLA, DUKE will, at its sole discretion, use PRODUCTS when appropriate for clinical purposes.

d. This AGREEMENT is subject to all United States laws, rules, and regulations controlling the export of technical data, computer software, laboratory prototypes and other commodities and technology.

12. *Duration and Termination.*

a. This AGREEMENT shall become effective upon the EFFECTIVE DATE, and unless sooner terminated in accordance with any of the provisions of this AGREEMENT, shall remain in full force and effect until the last-to-expire of any PATENTS, but in no case less than seventeen (17) years from the EFFECTIVE DATE.

b. SYN PAC may terminate this AGREEMENT by giving DUKE written notice at least three (3) months prior to such termination. Upon such termination, SYN PAC shall, at DUKE's option, either (a) reassign to DUKE all TECHNOLOGY and TECHNICAL INFORMATION assigned to SYN PAC under this AGREEMENT or the SPONSORED RESEARCH AGREEMENT or (b) license to DUKE all TECHNOLOGY and TECHNICAL INFORMATION assigned to SYN PAC under this AGREEMENT OR THE SPONSORED RESEARCH AGREEMENT under a royalty-free, exclusive license without further restrictions. As of the effective date of termination, SYN PAC shall have no further obligation to DUKE under Section 5 of this AGREEMENT, except to pay such amounts as are due and payable prior to the effective date of termination.

c. Either party may immediately terminate this AGREEMENT for fraud, willful misconduct, or illegal conduct of the other party upon written notice of same to such other party. If either party fails to fulfill any of its obligations under this AGREEMENT, the non-breaching party may terminate this AGREEMENT upon written notice to the breaching party as provided in this subsection c. of Section 12. Such notice must contain a full description of the event or occurrence constituting a breach of the AGREEMENT. The party receiving notice of the breach will have the opportunity to cure the breach within thirty (30) days of receipt of such notice. If the breach is not cured within such thirty (30) day period, the termination will be effective as of the thirtieth (30th) day after receipt of notice.

d. If during the term of this AGREEMENT, SYN PAC shall be adjudicated a bankrupt or insolvent or if the business of SYN PAC shall be placed in the hands of a receiver or trustee, whether by the voluntary act of SYN PAC or otherwise, or if SYN PAC shall cease to exist as an active business, this AGREEMENT shall immediately terminate.

e. If this AGREEMENT is terminated by DUKE pursuant to any breach by SYN PAC pursuant to Section 12.c of this AGREEMENT or for any reason set forth in Section 12.d of this AGREEMENT, SYN PAC shall, at DUKE's option, either (a) reassign to DUKE all TECHNOLOGY and TECHNICAL INFORMATION assigned to SYN PAC under this AGREEMENT or (b) license to DUKE all TECHNOLOGY and TECHNICAL INFORMATION assigned to SYN PAC under this AGREEMENT under a royalty-free, exclusive license without further restrictions. As of the effective date of termination, SYN PAC shall have no further obligation to DUKE under Section 5 of this AGREEMENT, except to pay such amounts as are due and payable prior to the effective date of termination.

f. As security for its conditional obligation to assign the TECHNOLOGY and TECHNICAL INFORMATION pursuant to Sections 12.b and e. of this AGREEMENT, SYN PAC agrees to grant, execute and deliver to DUKE, concurrently with the execution of this AGREEMENT, a security interest in the TECHNOLOGY and TECHNICAL INFORMATION, including any PATENTS, in the form attached hereto as Exhibit D and incorporated herein.

g. Upon any reassignment or license of the TECHNOLOGY and TECHNICAL INFORMATION to DUKE pursuant to the provisions of this Section 12, SYN PAC agrees to negotiate a license to DUKE to make, use and sublicense any technology and technical information within the SUBJECT AREA then owned by SYN PAC, other than the TECHNOLOGY and TECHNICAL INFORMATION, which DUKE may require to further the development of a cure for Pompe's Disease.

13. *Force Majeure.*

a. Neither party shall be considered in breach of its obligations under this AGREEMENT nor liable for any costs or damages due to nonperformance under this AGREEMENT arising out of any cause or event not within the reasonable control of such party and without such party's fault or negligence, such causes or events being hereinafter referred to as "Events of Force Majeure."

b. Each party shall give the other party prompt notice of the occurrence of any Event of Force Majeure, including such information as is reasonably necessary to establish the Event of Force Majeure; thereupon, the obligations of the party giving notice, so far as they are affected by the Event of Force Majeure, shall be suspended during, but no longer than, the continuance of the Event of Force Majeure.

c. Events of Force Majeure shall only excuse delays in performance and only to the extent such delays are directly attributable to the Event of Force Majeure. No Event of Force Majeure shall be an excuse for permanent nonperformance.

d. Neither party shall be liable for any delay or failure in the performance of its obligations under this AGREEMENT that directly results from any failure of the other party to perform its obligations as set forth in this AGREEMENT.

14. *Confidentiality.*

a. "Confidential Information" means all information, including, but not limited to, the trade secrets and know-how of the respective parties which is clearly identified as "Confidential" or "Proprietary" by the disclosing party at the time of disclosure. If such transmittal occurs orally, the

disclosing party shall identify the oral disclosure as confidential at the time of disclosure and shall confirm in writing the confidential nature of such information within thirty (30) days of the disclosure. Confidential information shall not mean any information that:

- i. is known to the receiving party at the time of disclosure by the disclosing party;
- ii. is developed independently by the receiving party;
- iii. is within, or later falls within, the public domain without breach of this AGREEMENT by the receiving party;
- iv. is publicly disclosed with written approval of the disclosing party; or
- v. becomes lawfully known or available to the receiving party without restriction from a source having the lawful right to disclose the information without breach of this AGREEMENT by the receiving party.

Provided further, the receiving party shall have the burden of proof as to prior knowledge and absence of breach.

b. Confidential Information disclosed on a restricted basis pursuant to a judicial or other lawful government order shall remain Confidential Information as between the parties and shall only be disclosed under terms which provide for continued protection of the information, and, where possible, the disclosing party shall be a party to the negotiation of the terms for such protection. Notwithstanding any provision herein to the contrary, this AGREEMENT shall not be construed to limit the receiving party's obligation and ability to comply with any judicial or other lawful government order to disclose Confidential Information on a restricted basis.

c. The obligation of confidentiality under this AGREEMENT shall apply regardless of the form the Confidential Information takes.

d. Each party acknowledges that in the performance of this AGREEMENT it shall receive Confidential Information from the other party and that such Confidential Information is the exclusive property of the disclosing party. The receiving party agrees to hold the Confidential Information of the disclosing party in strict confidence in accordance with the provisions of this AGREEMENT. A receiving party:

- i. shall not permit or suffer its employees or agents to remove any proprietary or other legends or restrictive notices contained or included in any Confidential Information provided by the disclosing party;
- ii. shall not permit or suffer its employees or agents to copy any Confidential Information, except as provided in this AGREEMENT or consented to in writing by the disclosing party ;
- iii. shall not, except as may be provided in Section 11 of this AGREEMENT regarding publication, disclose any Confidential Information to a third party without the prior written consent of the disclosing party hereto;
- iv. shall exercise care to keep secure and maintain the Confidential Information of the disclosing party in a manner no less protective than that used to

maintain the confidentiality of the receiving party's own Confidential Information, but in any event not less than a reasonable degree of care; and

v. agrees to use the Confidential Information only to further the purposes set forth in this AGREEMENT.

e. A receiving party may disclose Confidential Information to officers, employees or agents under the control and direction of the receiving party only in the normal course of business and on a need-to-know basis within the purpose of this AGREEMENT. Provided, however, prior to any disclosure all such officers, employees or agents shall have entered into written agreements with the receiving party, or have in place binding policies covering the disclosure of such third-party Confidential Information and have on file signed acknowledgments of such binding policies from each officer, employee or agent to which Confidential Information is disclosed, requiring such officers, employees or agents to treat and use all such Confidential Information in a manner consistent with the terms and conditions of this AGREEMENT.

f. A receiving party's obligation to comply with the confidentiality provisions of this AGREEMENT with respect to Confidential Information disclosed by the disclosing party shall extend for a period of six (6) years from the date of disclosure of Confidential Information.

g. Upon thirty (30) days written notice from the disclosing party, the receiving party shall: (i) surrender and deliver all Confidential Information of the disclosing party, including all copies thereof; or (ii) with the written consent of the disclosing party, destroy the Confidential Information and all copies thereof and provide satisfactory evidence of such destruction to the disclosing party within one (1) month following said notice. Notwithstanding anything in this AGREEMENT to the contrary, (i) a receiving party may retain one copy of each item of Confidential Information disclosed by the disclosing party solely as evidence of compliance with this AGREEMENT and for no other purpose, and (ii) upon a request by SYN PAC to surrender and deliver all SYN PAC's Confidential Information, Duke shall be relieved of its obligation to continue any research dependent upon SYN PAC's Confidential Information.

15. *Notices.* All notices or other communication shall be in writing and shall be deemed duly given one (1) day after delivery by facsimile, provided that an original or copy of the notice is deposited in the international mail, postage pre-paid, and addressed as set forth below; or five (5) days after deposit thereof in the registered international mail, return receipt requested, postage pre-paid with copies to the other parties addressed as follows:

If to DUKE:

Office of Science and Technology
Attn: License Administrator
Duke University
Room 230, North Building
Box 90083
Durham, North Carolina 27708
Facsimile No.: (919) 681-7599

with a copy to:
Office of the University Counsel
Duke University
011 Allen Building
Durham, North Carolina 27708
Facsimile No.: (919) 684-8725

If to SYNPAAC:
Synpac (North Carolina), Inc.
Attn: Mr. Leslie Cheng Yun Koo
8th Floor No. 1
Lane 25 Shung-Chung Street
Taipei, Taiwan
Republic of China
Facsimile No.: 011-8862-586-2337

with a copy to:
Mark H. Webbink, Esq.
Moore & Van Allen, PLLC
P.O. Box 3843
Durham, North Carolina 27702-3843
Facsimile: (919) 286-8199

and to:
Synpac Pharmaceuticals (U.K.) Limited
Cambois
Bedlington, Northumberland NE22 7DB
United Kingdom
Attn: Peter Clark
Facsimile No.: 011-44-1670-850-571

with a copy to:
Simon Concannon, Esq.
Walker Morris
Kings Court
12 King Street
Leeds, LS1 2HL
UNITED KINGDOM
Facsimile: 011-44-113-245-9412

Any party may change its address for notice by giving notice to the other party of the change.

16. *Assignment.* Neither DUKE nor SYNPAAC may assign, delegate or otherwise transfer any of its rights or obligations under this AGREEMENT without the prior written consent of the other party; provided, however, SYNPAAC may assign its rights and obligations under this AGREEMENT to any AFFILIATED COMPANY of SYNPAAC or to any AFFILIATED COMPANY of such AFFILIATED COMPANY of SYNPAAC or to any surviving entity with which SYNPAAC merges or to which SYNPAAC sells substantially all of SYNPAAC's assets, provided SYNPAAC shall give DUKE prior written notice of such assignment.

17. *Binding Effect.* This AGREEMENT will be binding upon and will inure to the benefit of the parties and their respective successors and assigns.

18. *Indemnity, Insurance, Representations, Status.*

a. SYN PAC agrees to indemnify, hold harmless and defend DUKE, its trustees, officers, employees, and agents, against any and all claims, suits, losses, damages, costs, fees and expenses asserted by third parties, both government and non-government, resulting from or arising out of SYN PAC's development, production, manufacturing, exploitation, or marketing of the TECHNOLOGY or TECHNICAL INFORMATION. SYN PAC further agrees to indemnify and save DUKE harmless from and against any loss, damage, or expense suffered by DUKE as a result of SYN PAC's default under or breach of this AGREEMENT. DUKE agrees to indemnify and save SYN PAC harmless against any loss, damages, or expense suffered by SYN PAC as a result of DUKE's negligence, wrongful acts or default under or breach of this AGREEMENT.

b. SYN PAC shall maintain in force at its sole cost and expense, with reputable insurance companies, general liability insurance and products liability insurance coverage in an amount reasonably sufficient to protect against liability under subsection a of this Section 18. DUKE shall have the right to ascertain from time to time that such coverage exists, such right to be exercised in a reasonable manner.

c. NOTHING IN THIS AGREEMENT SHALL BE DEEMED TO BE A REPRESENTATION OR WARRANTY BY DUKE OF THE VALIDITY OF ANY OF THE PATENTS OR THE ACCURACY, SAFETY, EFFICACY, OR USEFULNESS, FOR ANY PURPOSE, OF THE TECHNOLOGY. DUKE SHALL HAVE NO OBLIGATION, EXPRESS OR IMPLIED, TO SUPERVISE, MONITOR, REVIEW OR OTHERWISE ASSUME RESPONSIBILITY FOR THE PRODUCTION, MANUFACTURE, TESTING, MARKETING OR SALE OF ANY PRODUCT, AND DUKE SHALL HAVE NO LIABILITY WHATSOEVER TO SYN PAC OR ANY THIRD PARTIES FOR OR ON ACCOUNT OF ANY INJURY, LOSS, OR DAMAGE, OF ANY KIND OR NATURE, SUSTAINED BY, OR ANY DAMAGE ASSESSED OR ASSERTED AGAINST, OR ANY OTHER LIABILITY INCURRED BY OR IMPOSED UPON SYN PAC OR ANY OTHER PERSON OR ENTITY, ARISING OUT OF OR IN CONNECTION WITH OR RESULTING FROM:

- i. the production, use, or sale of any PRODUCT;
- ii. the use of the TECHNOLOGY and TECHNICAL INFORMATION; or
- iii. any advertising or other promotional activities with respect to any of the foregoing.

d. The parties to this AGREEMENT recognize and agree that each is operating as an independent contractor and not as an agent of the other. This AGREEMENT shall not constitute a partnership or joint venture, and neither party may be bound by the other to any contract, arrangement or understanding except as specifically stated herein.

19. *Use of a Party's Name.* Neither party will, without the prior written consent of the other party:

a. use in advertising, publicity or otherwise, any trade-name, personal name, trademark, trade device, service mark, symbol, or any abbreviation, contraction or simulation thereof owned by the other party; or

b. represent, either directly or indirectly, that any product or service of the other party is a product or service of the representing party or that it is made in accordance with or utilizes the information or documents of the other party.

20. *General.*

a. *Severance.* Each clause of this AGREEMENT is a distinct and severable clause and if any clause is deemed illegal, void or unenforceable, the validity, legality or enforceability of any other clause or portion of this AGREEMENT will not be affected thereby so long as the principal intent of this AGREEMENT is unaffected.

b. *Waiver.* The failure of a party in any instance to insist upon the strict performance of the terms of this AGREEMENT will not be construed to be a waiver or relinquishment of any of the terms of this AGREEMENT, either at the time of the party's failure to insist upon strict performance or at any time in the future, and such terms will continue in full force and effect. No waiver of any obligation under this AGREEMENT shall be effective unless in writing and signed by the authorized representative of the party consenting to such waiver.

c. *Modification.* Any alteration, modification, or amendment of this AGREEMENT must be in writing and signed by the authorized representative of each party.

d. *Governing Law.* This AGREEMENT shall be construed and enforced in accordance with and governed by the substantive law of the State of North Carolina and the United States of America, including the patent laws of the United States of America.

e. *Construction.* All titles and section headings contained in this AGREEMENT are inserted only as a matter of convenience and reference. Such titles and headings shall not define, limit, extend or describe the scope of this AGREEMENT or any of its provisions.

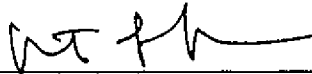
f. *Entire Understanding.* This AGREEMENT, along with the SPONSORED RESEARCH AGREEMENT between the parties of even date herewith, represents the entire understanding between the parties with respect to the subject matter contained therein and supersedes all other agreements, express or implied, between the parties with respect to the same.

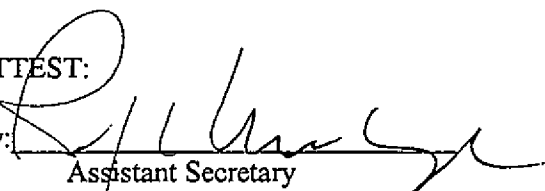
g. *Counterparts.* This AGREEMENT may be executed in any number of counterparts, each of which shall be deemed to be an original, but all of which together will constitute one and the same document.

h. All references to payments of monies under this AGREEMENT shall be deemed to be in U.S. dollars.

IN WITNESS WHEREOF, the authorized representatives of the parties have caused these presents to be executed under seal as of the date and year first above written.


DUKE UNIVERSITY

By: 
Name: Robert L. Taber, Ph.D.
Title: Associate Vice Chancellor

ATTEST:
By: 
Assistant Secretary

[CORPORATE SEAL]

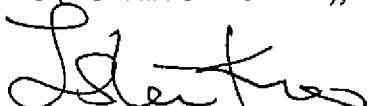
SYNPAC PHARMACEUTICALS (U.K.) LIMITED

By: 
Name: Peter Clark
Title: Director

ATTEST:
By: 
Secretary

[CORPORATE SEAL]

SYNPAC (NORTH CAROLINA), INC.

By: 
Name: LESLIE KUD
Title: PRESIDENT

ATTEST:
By: 
Secretary

[CORPORATE SEAL]

NORTH CAROLINA

DURHAM COUNTY

I, Jean O. Senter, a Notary Public of the aforesaid County and State, do hereby certify that Ralph McLaughan personally appeared before me this day and acknowledged that (s)he is the Assistant Secretary of DUKE UNIVERSITY, a North Carolina corporation, and that by authority duly given and as an act of the corporation, the foregoing instrument was signed in its name by its ~~President~~ President, and attested by herself/himself as Assistant Secretary, and sealed with its common corporate seal.

Witness my hand and notarial seal this 13 day of September, 1996.

Jean O. Senter
Notary Public

My Commission Expires:

Jan 12 1999

NORTH CAROLINA

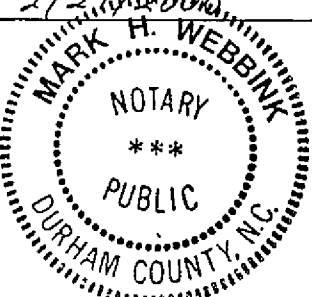
DURHAM COUNTY

I, MARK H. WEBBINK, a Notary Public of the aforesaid County and State, do hereby certify that Clive Goatman personally appeared before me this day and acknowledged that he is the Secretary of SYN PAC PHARMACEUTICALS (U.K.) LIMITED, a corporation of the United Kingdom, and that by authority duly given and as an act of the corporation, the foregoing instrument was signed in its name by its Director, and attested by himself as Secretary, and sealed with its common corporate seal.

Witness my hand and notarial seal this 13TH day of September, 1996.

Mark H. Webbink
Notary Public

My Commission Expires:

2/27/2000


NORTH CAROLINA

DURHAM COUNTY

I, Brenda V. Fulcher, a Notary Public of the aforesaid County and State, do hereby certify that Mark H. Webbink personally appeared before me this day and acknowledged that he is the Secretary of SYNPAAC (NORTH CAROLINA), INC., a North Carolina corporation, and that by authority duly given and as an act of the corporation, the foregoing instrument was signed in its name by its President, and attested by himself as Secretary, and sealed with its common corporate seal.

Witness my hand and notarial seal this 13th day of September, 1996.

Brenda V. Fulcher
Notary Public

My Commission Expires:

May 16, 1999

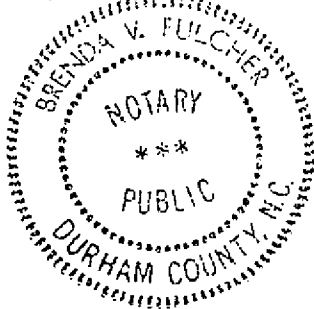


EXHIBIT A

THE TECHNOLOGY AND TECHNICAL INFORMATION

As defined in that certain Technology Assignment Agreement, dated September 13, 1996 by and among Duke University, Synpac Pharmaceuticals (U.K.) Limited, and Synpac (North Carolina), Inc., and to which this Exhibit A is attached and incorporated, the TECHNOLOGY and TECHNICAL INFORMATION includes that information disclosed to DUKE in Office and Science Technology File # 1180, all right, title and interest in and to which has been assigned to DUKE by CHEN, VAN HOVE, YANG, and WU.

The TECHNOLOGY also includes that certain cell line on deposit with the American Type Culture Collection and identified as CHO Cell Line, TCHO-pJW5'sGAA-5M25-5000-MTX-17.

The TECHNOLOGY also includes the invention disclosed in that certain provisional patent application serial number 60/012,855 titled "Tissue Specific Recombinant Human Lysosomal Acid α -Glucosidase filed March 5, 1996 on behalf of Yuan-Tsong Chen, Johan L.K. Van Hove, Helen Yang, and Jer-Yuarn Wu.

EXHIBIT B
SPONSORED RESEARCH AGREEMENT

EXHIBIT C

PATENT ASSIGNMENT

ASSIGNMENT OF LETTERS PATENT APPLICATION

Serial No. _____

Filed: _____

WHEREAS, DUKE UNIVERSITY, a North Carolina not-for-profit corporation ("Assignor"), is the assignee of [description of invention] _____ for which Duke executed an Application for Letters Patent of the United States, _____, _____, Application Serial No. _____; and,

WHEREAS, SYNPAC (NORTH CAROLINA), INC., a North Carolina corporation with a place of business at _____ ("Assignee"), is desirous of acquiring the entire right, title and interest in and to that application and the inventions therein disclosed and any letters patent that may issue thereon;

NOW, THEREFORE, in consideration of the sum of TEN DOLLARS (\$10.00) and other valuable consideration, the receipt of which is hereby acknowledged, and other good and valuable consideration, Assignor hereby sells, assigns and transfers unto the Assignee, its successors and assigns, the entire right, title and interest in and to any and all improvements which are disclosed in the invention entitled " _____", of which Assignor is the assignee and which is found in U.S. patent application _____ filed on _____, _____, and any legal equivalent thereof in a foreign country, including the right to claim priority and, in and to, all Letters Patent to be obtained for said invention by the above application or any continuation, division, renewal, or substitute thereof, and as to letters patent of any reissue or re-examination thereof.

Assignor hereby authorizes the Assignee, its successors and assigns, to file in its own name applications for patents in foreign countries in connection with the inventions hereby transferred, under the international convention claiming the priority of the U.S. application or otherwise, and to secure in its own name the patent or patents issued thereon.

Assignor hereby covenants that no assignment, sale, agreement or encumbrance has been or will be made or entered into which would conflict with this assignment.

In testimony whereof, Assignor has hereunto set his hand and seal this _____ day of _____, _____:

DUKE UNIVERSITY

By: _____
Name: _____
Title: _____

STATE OF NORTH CAROLINA

DURHAM COUNTY

I, _____, a Notary Public of the aforesaid County and State, do hereby certify that _____ personally appeared before me this day and acknowledged that (s)he is the _____ Secretary of DUKE UNIVERSITY, a North Carolina not-for-profit corporation, and that by authority duly given and as an act of the corporation, the foregoing instrument was signed in its name by its _____ President, and attested by herself/himself as _____ Secretary, and sealed with its common corporate seal.

Witness my hand and notarial seal this ____ day of _____, _____.

Notary Public

My Commission Expires:

Certificate Under 37 CFR 3.73(b)

Applicant: Duke University

Application No.: _____ Filed: _____

For: _____

Duke University, a corporation, certifies that it is the assignee of the entire right, title and interest in the patent application identified above by virtue of an assignment from the inventor of the patent application identified above for which a copy thereof is attached.

The undersigned has reviewed all the documents in the chain of title of the patent application identified above and, to the best of undersigned's knowledge and belief, title is in the assignee identified above.

The undersigned is empowered to sign this certificate on behalf of the assignee.

I hereby declare that all statements made herein of my own knowledge are true, and that all statements made on information and belief are believed to be true; and further, that these statements are made with the knowledge that willful false statements, and the like so made, are punishable by fine or imprisonment, or both, under Section 1001, Title 18 of the United States Code, and that such willful false statements may jeopardize the validity of the application of any patent issuing thereon.

Date: _____

Name: _____

Title: _____

Signature: _____

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re application of:

Serial No. _____

Group No.: _____

Filed: _____

Examiner: _____

For: Duke University, Durham, North Carolina

Title - _____

Assistant Commissioner for Patents
Washington, DC 20231

POWER OF ATTORNEY BY ASSIGNEE OF ENTIRE INTEREST
(REVOCATION OF PRIOR POWERS)

As assignee of record of the entire interest of the above identified application, which assignment is recorded herewith, all powers of attorney previously given are hereby revoked and the following attorney and/or agent is hereby appointed to prosecute and transact all business in the Patent and Trademark Office connected therewith:

_____, Esq. Reg. No. _____

Send all correspondence and direct all telephone calls to:

_____, Esq.

() _____

Attached to this power is a "CERTIFICATE UNDER 37 CFR 3.73(b)."

ASSIGNEE:

SYNPAC (NORTH CAROLINA), INC.

Date: _____

By: _____

Name: _____

Title: _____

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re application of: Duke University, Durham, North Carolina

Serial No.: _____ Group No.: _____
Filed: _____ Examiner: _____
For: _____

Assistant Commissioner for Patents
Washington, DC 20231

REQUEST FOR PATENT TO ISSUE TO ASSIGNEE (37 CFR 3.81(a))

Request is made that the above-identified application issue solely to the below-named assignee of the entire right, title and interest.

The name of the assignee is: SYNPAC (NORTH CAROLINA), INC.

Attached to this power is a "CERTIFICATE UNDER 37 CFR 3.73(b)."

ASSIGNEE:

SYNPAC (NORTH CAROLINA), INC.

Date: _____

By: _____

Name: _____

Title: _____

ATTORNEY:

Reg. No.: _____
Tel. No.: () _____

EXHIBIT D
SECURITY AGREEMENT

NORTH CAROLINA

CONDITIONAL ASSIGNMENT
AND SECURITY AGREEMENT

DURHAM COUNTY

THIS CONDITIONAL ASSIGNMENT AND SECURITY AGREEMENT (the "Security Agreement") is made as of September 13, 1996, by and among SYN PAC PHARMACEUTICALS (U.K.) LIMITED, a corporation of the United Kingdom and SYN PAC (NORTH CAROLINA), INC., a North Carolina corporation (collectively, the "Grantor"), and DUKE UNIVERSITY, a North Carolina not-for-profit corporation (the "Secured Party").

R E C I T A L S:

A. Pursuant to that certain Technology Assignment Agreement, of even date herewith among the parties hereto, Secured Party assigned to Grantor certain technology (hereinafter, the "Technology"), referred to in Schedule A attached hereto and incorporated herein.

B. Grantor has agreed to grant to the Secured Party a security interest in the Technology to secure Grantor's obligations, agreements, and covenants under the Technology Assignment Agreement.

NOW, THEREFORE, in consideration of the above Recitals and for other good and valuable consideration, the receipt and sufficiency of which are hereby acknowledged, Grantor hereby agrees as follows:

1. *Grant of Security Interest.* Grantor hereby grants to Secured Party a continuing security interest in the property described in Schedule A (collectively and severally, the "Collateral") to secure performance of the obligations of Grantor to Secured Party under the Technology Assignment Agreement.

2. *Ownership.* Grantor represents that, at the time of making of this Security Agreement, grantor is the sole owner of the Collateral, free and clear of all liens, encumbrances and security interests.

3. *Further Assurances.* Grantor shall execute and deliver to Secured Party, concurrently with the execution of this Security Agreement and at any time or times hereafter at the request of the Secured Party, financing statements, renewal financing statements, security agreements, affidavits, notices and such other agreements, instruments and documents that the Secured Party may reasonably request, in form satisfactory to the Secured Party, and shall take any and all other steps reasonably requested by Secured Party in order to perfect and maintain the security interests granted herein.

4. *Perfection.* The Grantor warrants and represents that: (a) the security interest granted to the Secured Party hereunder, when properly perfected by filing, shall constitute at all times a valid and perfected security interest in the Collateral.

5. *Subordination.* At Grantor's request, Secured Party agrees to subordinate the security interest granted under this Security Agreement to the security interests, liens or claims of any other person, firm or corporation from which Grantor may obtain funds for the development, manufacturing, marketing, or sale of the Collateral or any products derived from the Collateral.

6. *Taxes.* Grantor shall pay when due (or before overdue) all federal, state or local taxes of any kind or nature imposed upon the Collateral or which, if unpaid, could become a lien upon the Collateral. Upon the request of Secured Party, Grantor shall from time to time deliver to Secured Party evidence of payment of taxes.

7. *Location of Collateral.* Grantor represents and warrants that the principal offices of the Grantor are located at the addresses shown below and that all Collateral will be located at on of the addresses listed below or such other address as to which Grantor shall give Secured Party notice. Grantor will promptly notify Secured Party of any change in the name of Grantor or any change of the location of its principal offices or of any of the Collateral.

8. *Default and Remedies.* Subject to the terms and limitations of any subordination agreement to which Secured Party is a party and the subject matter of which is the Collateral, in the event that (i) Grantor terminates the Technology Assignment Agreement pursuant to Section 12.b of said agreement; or (ii) Secured Party terminates the Technology Assignment Agreement for fraud, willful misconduct, or illegal conduct of Grantor; or (iii) Grantor fails to fulfill any of its obligations under the Technology Assignment Agreement and Secured Party terminates the Technology Assignment Agreement upon written notice to Grantor as provided in this subsection c. of Section 12 of the Technology Assignment Agreement and Grantor fails to cure such breach within thirty (30) days of such notice; or (iv) if during the term of the Technology Assignment Agreement, Grantor is adjudicated a bankrupt or insolvent or if the business of Grantor is placed in the hands of a receiver or trustee, whether by the voluntary act of Grantor; or otherwise; or (v) if Grantor shall cease to exist as an active business; Grantor shall immediately convey and assign to Secured Party Grantor's entire right, title and interest in the Collateral subject only to such senior indebtedness as to which Secured Party's security interest is subordinate. Grantor agrees to execute and deliver all such instruments or documents as Secured Party may reasonably deem necessary so as to effect said assignment, and Grantor hereby appoints Secured Party as Grantor's attorney-in-fact for the purpose of executing and delivering any and all such instruments or documents.

9. *Cumulative Rights.* The rights, powers and remedies of Secured Party under this Security Agreement shall be in addition to all rights, powers and remedies given to Secured Party by virtue of any statute, rule of law, the Technology Assignment Agreement, or Sponsored Research Agreement, all of which rights, powers and remedies shall be cumulative and may be exercised successively or concurrently without impairing Secured Party's security interest in the Collateral.

10. *Notices.* All notices required to be given hereunder shall be in writing and addressed to the parties at the following addresses, or such other addresses as may from time to time be designated by written notice given as herein required:

To the Grantor:

Synpac (North Carolina), Inc.
c/o Moore & Van Allen, PLLC
2200 West Main Street, Suite 800
Durham, North Carolina 27705
Attn: Mark H. Webbink, Esq.
Facsimile No.: (919) 286-8199

and to:

Synpac Pharmaceuticals (U.K.) Limited
Attn: Peter Clark
Cambois
Bedlington, Northumberland NE22 7DB
United Kingdom
Facsimile No.: 011-44-1670-850-571

with a copy to:

c/o Walker Morris
Kings Court
12 King Street
Leeds, LS1 2HL
United Kingdom
Attn: Simon Concannon, Esq.
Facsimile No.: 011-44-113-245-9412

Additional Property Located At:

Synpac Pharmaceuticals (U.K.) Limited
Cambois
Bedlington, Northumberland NE22 7DB
United Kingdom

To the Secured Party:

Office of Science and Technology
Attn: Andrew E. Balber, Ph.D.
Duke University
Room 230, North Building
Box 90083
Durham, North Carolina 27708
Facsimile No.: (919) 684-8982

11. *Waiver.* Any forbearance, failure or delay by Secured Party in exercising any right, power or remedy shall not preclude the further exercise thereof, and every right, power or remedy of Secured Party shall continue in force and effect until such right, power or remedy is specifically waived in a writing executed by Secured Party. Grantor waives any right to require Secured Party to proceed against any person or to exhaust any Collateral or to pursue any remedy in Secured Party's power.

12. *Binding Upon Successors.* All rights of Secured Party under this Security Agreement shall inure to the benefit of its successors and assigns, and all obligations of Grantor under this Security Agreement shall bind its successors and assigns.

13. *Severability.* If any of the provisions of this Security Agreement shall be held invalid or unenforceable, the Agreement shall be construed as if not containing those provisions and the rights and obligations of the parties hereto shall be construed and enforced accordingly.

14. *Choice of Law.* This Security Agreement shall be construed in accordance with and governed by the substantive laws of the State of North Carolina.

IN WITNESS WHEREOF, the properly authorized representatives of the parties have executed and delivered this Security Agreement under seal the day and year first above written.

SECURED PARTY:

DUKE UNIVERSITY

By: [Signature]
Name: ROBERT L. TABER, Ph.D.
Title: ASSOCIATE VICE CHANCELLOR

ATTEST:
By: [Signature]
Assistant Secretary

[CORPORATE SEAL]

GRANTOR:

SYNPAC PHARMACEUTICALS (U.K.) LIMITED

By: [Signature]
Name: Peter Clark
Title: Director

ATTEST:
By: [Signature]
Secretary

[CORPORATE SEAL]

SYNPAC (NORTH CAROLINA), INC.

By: [Signature]
Name: LESLIE KOO
Title: PRESIDENT

ATTEST:
By: [Signature]
Secretary

[CORPORATE SEAL]

SCHEDULE A

(a) All Technology and Technical Information acquired from Secured Party under that certain Technology Assignment Agreement, by and among Grantor and Secured Party dated September 13, 1996 or that certain Sponsored Research Agreement, by and among Synpac Pharmaceuticals (U.K.) Limited and Secured Party dated September 13, 1996, which Grantor presently owns or hereafter acquires.

(b) All proceeds of the conversion, voluntary or involuntary, of any of the foregoing collateral.

FILED

NORTH CAROLINA
DURHAM COUNTY

2021 JUL 26 11 51 AM
IN THE GENERAL COURT OF JUSTICE
SUPERIOR COURT DIVISION

DURHAM CO., N.C. NO. 21-CVS-2647

Synpac (North Carolina), Inc. and
CSRC International Investment
Holdings Co., Ltd.,

CMA

Plaintiffs,

v.

Duke University,

Defendant.

COMPLAINT FOR
DAMAGES, INJUNCTIVE
RELIEF, AND SPECIFIC
PERFORMANCE
(Jury Trial Demanded)

NOW COME Synpac (North Carolina), Inc. ("Synpac NC") and CSRC International Investment Holdings Co., Ltd. ("CSRC"), (collectively, "Synpac"), for their Complaint against Duke University ("Duke"), and allege and say as follows:

NATURE OF THE ACTION

1. Synpac brings this action against Duke to recover damages resulting from Duke's breach of a 1996 Technology Assignment Agreement executed between Synpac and Duke (the "TAA"), to prohibit Duke from acting inconsistently with or otherwise interfering with Duke's assignment of patents and related patent applications to Synpac

under the TAA, and to compel Duke to execute assignment papers to formally assign Synpac patents and related patent applications assigned to and owned by Synpac under the TAA, but which Duke has wrongfully, as well as willfully or wantonly, arrogated to itself.

PARTIES

2. Synpac NC is a corporation incorporated under the laws of North Carolina and has its principal place of business in Durham, North Carolina.

3. CSRC, a corporation of the Republic of China having its principal office in Taipei, Taiwan, is a successor of all rights and obligations of SYN PAC PHARMACEUTICALS (U.K.) LIMITED ("SYNPAC-UK") under the TAA.

4. Synpac-UK was a corporation incorporated under the laws of the United Kingdom and had its principal place of business in Bedlington, Northumberland, England.

5. Duke is a North Carolina not-for-profit corporation located in Durham, North Carolina and operates as an institution of higher education.

JURISDICTION AND VENUE

6. This Court has subject matter jurisdiction over the causes of action asserted in this Complaint under the TAA and pursuant to N.C. Gen. Stat. §§ 7A-240 and 7A-243, and other constitutional, statutory, and common law.

7. This Court has jurisdiction over Duke pursuant to N.C. Gen. Stat. § 1-75.4, because Duke is a North Carolina corporation and engages in substantial activity within this State.

8. Venue is proper in Durham County pursuant to N.C. Gen. Stat. § 1-79 and other provisions of North Carolina law for the reasons, *inter alia*, that Duke has a registered office in and its principal place of business is in Durham County. The Superior Court Division is the proper division for this action pursuant to N.C. Gen. Stat. § 7A-243, because the amount in controversy exceeds \$25,000, and in particular, the value of the rights in controversy exceeds \$5,000,000.

FACTS

Synpac and Duke entered into the TAA relating to the treatment of diseases, including Pompe disease, with human acid alpha-glucosidase.

9. Pompe disease is a rare genetic disorder caused by insufficient activity of acid alpha-glucosidase, which is involved in the breakdown of complex sugars in the body. In those afflicted with Pompe disease, glycogen builds up in muscle tissue and results in tissue deterioration, particularly of the skeletal, heart, and lung muscle tissue. Pompe disease frequently occurs in children and can appear within a few months of birth. If untreated, it is fatal in approximately 98% of patients. Infantile Pompe disease generally carries a life expectancy of two years or less when left untreated.

10. As early as the 1960s, researchers began exploring the possibility of using enzyme replacement therapy to treat Pompe disease. At the time, treatments attempted to provide Pompe disease patients with the human acid alpha-glucosidase ("GAA") they lacked by creating that enzyme outside the human body (*i.e.*, "exogenous GAA") and administering it intravenously. Success with this treatment, however, proved elusive.

11. For more than three decades, doctors and scientists searched unsuccessfully for a source of exogenous GAA that could effectively process glycogen in Pompe disease patients. They attempted to extract enzymes from a variety of sources, including fungus, human liver tissue, and placentas, but all the treatments ultimately failed to provide a therapeutic benefit.

12. In the 1990s, a team of researchers at Duke, including Dr. Y. T. Chen, Dr. J. Van Hove, and others, began investigating treatments for Pompe disease based on recombinant human acid alpha-glucosidase ("rhGAA") generated in a Chinese hamster ovary ("CHO") cell line. The CHO cell line enabled production of rhGAA, which could be used for human enzyme replacement therapy.

13. Synpac, in response to Duke's request for funding its research, began collaborating with Duke in 1996.

14. To further their collaboration, Synpac and Duke entered into the TAA. Specifically, under the TAA:

DUKE hereby sells, assigns, grants and conveys . . . DUKE's entire right, title and interest in and to all of the TECHNOLOGY, including all rights to make, use, sell, offer for sale, import and license the TECHNOLOGY, any

existing patent applications thereon and the right to file patent applications thereon throughout the world, all claims for damages and profits by reason of any past infringement pertaining to the TECHNOLOGY and the right to sue therefor, and all rights of priority consequent upon the filing of applications to patent the TECHNOLOGY, to the full end of the term or terms for which letters patent respectively may be granted, reissued, or extended.

See TAA, attached as Exhibit A to this Complaint, § 2.a. (emphasis added).

15. The TAA specifically defines "TECHNOLOGY" as including "the cell line set forth in Exhibit A . . . all progeny and derivatives of said cell line, and PATENTS." See TAA, § 1.t. (emphasis added). Those "PATENTS" include "all letters patents and patents rights (both U.S. and foreign), now or hereafter owned or controlled by DUKE which cover all or any part of the SUBJECT AREA" See TAA, § 1.m. (emphasis added).

16. The parties defined "SUBJECT AREA" as:

(i) the creation of cell lines which produce commercially significant quantities of human acid alpha glucosidase or its FUNCTIONAL EQUIVALENT, (ii) the isolation, purification, manufacture, production, and storage of human acid alpha glucosidase or its

FUNCTIONAL EQUIVALENT, (iii) the delivery of human acid alpha glucosidase or its FUNCTIONAL EQUIVALENT to people to prevent or to treat Pompe's Disease or other human diseases, specifically including, without limitation, use in enzyme replacement therapy; (iv) the use of the proteins in (ii) for development and screening of drugs for the prevention and treatment of Pompe's Disease and other human diseases, including drug design and drug targeting; and (v) the use of the proteins of (ii) for analysis of glycogen.

See TAA, § 1.q. (emphasis added).

17. As reflected in the TAA, Synpac "desire[d] to purchase all rights, title and interest in and to [all scientific or technical information, know-how, show-how, data, and test results, regardless of form or characteristics relating to the SUBJECT AREA developed, produced or generated by] [Dr. Chen, Dr. Van Hove or 'any other doctor, scientist, employee, technician or student of DUKE who participated in SUBJECT AREA research, development and trials']." *Id.* at 1 (4th ¶), §§ 1.d., -s., -t.

18. Duke, for its part, expressed the complementary desire to assign to Synpac all of these rights, title and interest. *Id.* at 1 (4th ¶).

19. Accordingly, Synpac agreed to pay Duke an assignment fee and promised to pay future milestone fees and royalties in exchange for

Duke's agreement that "all letters patents and patents rights (both U.S. and foreign), now or hereafter owned or controlled by DUKE which cover all or any part of the SUBJECT AREA" (*id.* § 1.m.) "shall be the sole and exclusive property of SYN PAC subject to [certain] reversionary assignment and licenses rights granted to DUKE in this AGREEMENT" (*id.* § 10.a.).

20. Duke has received the consideration Synpac agreed to pay, which amounts to over \$100 million over time as a result of the TAA entered between Synpac and Duke.

21. Pursuant to the TAA, Duke has assigned to Synpac all patents and patent rights related to the SUBJECT AREA as defined under the TAA.

Synpac discovered Duke breached the TAA by refusing to acknowledge Synpac's rights in many SUBJECT AREA patents.

22. Synpac has paid all fees, royalties, and other considerations it agreed to pay and has otherwise performed all of its obligations under the TAA.

23. On or about August 2020, however, Synpac became aware that Duke purports to own over a dozen foreign and United States

patents and patent applications "relating to the SUBJECT AREA" of the TAA, and that such foreign and United States patents and patent applications falsely name Duke, rather than Synpac, as assignee in violation of the TAA's assignment of such foreign and United States patents and patent applications to Synpac.

24. Duke did not disclose to Synpac the inventions that were the subject of these foreign and United States patents and patent applications, and in so doing withheld the information and knowledge of them from Synpac. Duke's actions were wrongful, as well as willful or wanton.

25. In particular, such undisclosed patents and patent applications, among other things, fall expressly within the SUBJECT AREA of the TAA and have been assigned to and are exclusively owned by Synpac, as expressly provided in the TAA. *See* TAA, § 1.q.

26. The covered and assigned, but unacknowledged, patents and applications include at least the following U.S. Patents, together with their continuation or divisional patents and applications, their derivative and related patents and applications, and their foreign counterpart patents and applications:

U.S. Patent No. 8,679,478, which claims "A method of treating a patient having a lysosomal storage disease [**including Pompe disease**] characterized by reduced or deficient activity of a lysosomal enzyme comprising administering a β 2 agonist to the patient . . . wherein the lysosomal enzyme is **acid α -glucosidase.**"

U.S. Patent No. 8,809,282, which claims "A method of reducing titers of antibodies specific for a therapeutic agent, wherein said therapeutic agent is a proteinaceous replacement for **acid alpha-glucosidase (GAA), in a patient suffering from Pompe disease** treated with said therapeutic agent, said method comprising administering to said patient a proteosome inhibitor in an amount and under conditions such that said antibody titers are reduced."

U.S. Patent No. 10,869,906, which claims "A method for reducing titers of antibodies against a therapeutic protein in a patient treated with the therapeutic protein by administration of a nucleic acid comprising a nucleotide sequence encoding the therapeutic protein in expressible form, said administration able to elicit said antibodies . . . **wherein the patient suffers from Pompe disease and the therapeutic protein is acid alpha-glucosidase (GAA).**"

27. All of these covered and assigned, but unacknowledged, patents and patent applications are rightfully "the sole and exclusive property of" Synpac, because they "cover all or any part of" "the isolation, purification, manufacture, production, and storage of

human acid alpha glucosidase” or “the delivery of human acid alpha glucosidase to people to prevent or to treat Pompe's Disease or other human diseases.” *See* TAA, § 1.q. (emphasis added).

28. Synpac informed Duke of its breach of the TAA as early as September 2020, and requested corrective action in the form of Duke's formal execution of assignment papers confirming Synpac's existing and exclusive ownership, but Duke has refused to execute such papers.

29. Duke's breach has harmed Synpac and threatens to cause further harm at least because the covered patents and patent applications are exclusively owned by Synpac and belong in its patent portfolio, which Synpac exclusively licenses to a third party. Duke's breach threatens to deprive Synpac of its right to receive license royalties from its third-party licensee. Duke has been aware of Synpac's exclusive third-party license since 2000 and has received over \$100 million in royalties as a result of the TAA and Synpac's exclusive license.

30. All conditions precedent to the commencement of this action, the assertion of the claims herein, and the relief prayed herein have been satisfied, performed, or have occurred.

COUNT I
BREACH OF CONTRACT
FAILURE TO COMPLY WITH AND DISREGARD OF
ASSIGNMENT OF COVERED PATENTS

31. Synpac incorporates by reference each and every allegation set forth in paragraphs 1-30.

32. The TAA is a binding and enforceable contract between Synpac and Duke.

33. The TAA provides and requires that any patent application covering all or any part of the isolation, purification, manufacture, production, and storage of human acid alpha glucosidase or the delivery of human acid alpha glucosidase to people to prevent or to treat Pompe's Disease or other human diseases, and any patent issuing from those patent applications have been assigned to and are the exclusive property of Synpac.

34. Duke received good, valuable, and substantial consideration—more than \$100 million—for assigning to Synpac the rights to those patents and patent applications. Synpac has acquired and owns those rights under the TAA, and Synpac is entitled, whenever Synpac deems appropriate and necessary, to Duke's acknowledgement of

Synpac's acquisition and existing exclusive ownership of those rights under the TAA by, *inter alia*, Duke's execution of formal assignment papers concerning those patents and patent applications.

35. Duke has filed over a dozen applications, has obtained several patents from them, and has wrongfully recorded under Duke's name United States patents that cover all or any part of the isolation, purification, manufacture, production, and storage of human acid alpha glucosidase or the delivery of human acid alpha glucosidase to people to prevent or to treat Pompe's Disease or other human diseases.

36. Duke has failed and refused to execute assignment papers confirming Synpac's existing and exclusive ownership of those patents and applications, and Duke has continued to disregard Synpac's rights and interests under the TAA.

37. Duke's failure to acknowledge Synpac's existing exclusive ownership, its disregard of Synpac's rights, its refusal to execute assignment papers confirming Synpac's existing and exclusive ownership of these covered patents and patent applications, and its attempt to take for itself the benefits Synpac has acquired under the TAA and which

Synpac is entitled to enjoy, constitute material breaches of the TAA. Such breaches were wrongful as well as willful or wanton.

38. Duke's breaches were and still are direct and proximate causes of the harms Synpac suffered.

39. As a result of Duke's breaches, Synpac will continue to suffer substantial injury and damages.

40. Duke is liable for Synpac's injury and damages in an amount to be proven at trial.

41. Further, to the extent the foregoing allegations and discovery conducted in this action show that Duke's acts as alleged herein were wrongful and in conscious and intentional disregard of and indifference to Synpac's rights, which Duke knew or should have known was reasonably likely to result in injury, damage, or other harm to Synpac, thus constituting willful or wanton conduct, or to the extent the foregoing allegations and discovery conducted in this action show that other aggravating factors such as fraud or malice were present and related to Synpac's injury and damages, Synpac should be awarded punitive damages.

COUNT II
UNFAIR OR DECEPTIVE ACTS OR PRACTICES

42. Synpac incorporates by reference each and every allegation set forth in paragraphs 1-41.

43. Duke's acts as alleged herein were in or affecting commerce.

44. Duke's acts as alleged herein were unfair or deceptive within the meaning of N.C. Gen. Stat. §§ 75-1.1.

45. Duke's acts as alleged herein proximately caused injury and damage to Synpac in an amount to be proven at trial.

46. By reason of Duke's acts as alleged herein, which constitute unfair or deceptive acts or practices in or affecting commerce proximately causing injury and damage to Synpac, Synpac is entitled to recover treble damages pursuant to N.C. Gen. Stat. §§ 75-1.1 and 75-16.

47. Further, Duke's acts as alleged herein were willful, Duke has refused to fully resolve the matter which constitutes the basis of this suit, and Duke's refusal was unwarranted, in consequence of which Synpac should also be awarded its attorneys' fees pursuant to N. C. Gen. Stat. § 75-16.1(1).

**COUNT III
BREACH OF IMPLIED COVENANT OF GOOD FAITH
AND FAIR DEALING**

48. Synpac incorporates by reference each and every allegation set forth in paragraphs 1-47.

49. Duke's acts as alleged herein were not in good faith.

50. Duke did not make reasonable efforts to perform its obligations under the TAA.

51. Duke acts as alleged herein have wrongfully deprived Synpac of the benefits to which Synpac is entitled under the TAA.

52. Duke acts as alleged herein were for a wrongful or unconscionable purpose.

53. Duke's acts as alleged herein injured the rights of Synpac to receive the benefits of the TAA, and thus deprived Synpac of the fruits of the bargain represented by the TAA.

54. Duke's acts as alleged herein proximately caused injury and damage to Synpac in an amount to be proven at trial.

55. Further, to the extent the foregoing allegations and discovery conducted in this action show that Duke's acts as alleged herein were wrongful and in conscious and intentional disregard of and indifference

to Synpac's rights, which Duke knew or should have known was reasonably likely to result in injury, damage, or other harm to Synpac, thus constituting willful or wanton conduct, or to the extent that the foregoing allegations and discovery conducted in this action show that other aggravating factors such as fraud or malice were present and related to Synpac's injury and damages, Synpac should be awarded punitive damages.

COUNT IV INJUNCTIVE RELIEF

56. Synpac incorporates by reference each and every allegation set forth in paragraphs 1-55.

57. Duke's acts as alleged herein have undermined and interfered with Synpac's rights under the TAA.

58. In addition to refusing to acknowledge Synpac's existing exclusive ownership of the covered patents and patent applications and refusing to execute assignment papers confirming Synpac's existing and exclusive ownership of the covered patents and patent applications, Duke has further undermined and interfered with Synpac's rights under the TAA, by insisting on Synpac's performance of acts beyond the terms of

the TAA, by refusing to act without a third-party approval when none is required by the TAA, by disregarding Synpac's rights under the TAA, and by wrongly and unjustifiably denying and refusing to comply with Duke's obligations under the TAA.

59. Because Duke has violated the TAA as alleged herein and has undermined and interfered with Synpac's rights under the TAA as set forth herein, Synpac has been and will continue to be substantially and irreparably harmed if Duke is not enjoined from continuing or repeating such violations and conduct.

60. Synpac does not have an adequate remedy at law if Duke is not enjoined, preliminarily and permanently, from continuing or repeating such violations and conduct.

61. Accordingly, Duke should be preliminarily and permanently enjoined from continuing or repeating such violations.

62. In addition, Synpac is entitled to order and decree of specific performance, by which Duke must formally execute assignment papers concerning the patents and patent applications that fall under the TAA.

63. Therefore, Duke should be compelled to formally execute assignment papers for all patents and patent applications that have been

assigned to and are exclusively owned by Synpac under the TAA, but which Duke has wrongfully recorded under its own name, including but not limited to the patents identified in paragraphs 23-26, 35 and related patent applications, and all patents and patent applications identified in discovery conducted in this action that have been assigned to Synpac under the TAA.

PRAYER FOR RELIEF

WHEREFORE, Synpac prays for judgment and relief against Duke as follows:

a. for compensatory damages in an amount to be determined at trial for breach of contract, unfair or deceptive acts or practices, and/or breach of the implied covenant of good faith and fair dealing;

b. to the extent that the grounds for punitive damages are proven at trial, for an award of punitive damages in an amount to be determined at trial, or in the alternative and at Synpac's election before entry of judgment, that Synpac's compensatory damages be trebled for unfair or deceptive acts or practices by Duke;

c. for preliminary and permanent injunctive relief prohibiting Duke from continuing, repeating, or further breaching the TAA and from undermining and interfering with Synpac's rights under the TAA;

d. for an order of specific performance compelling Duke to execute assignments to formally assign to Synpac all patents and patent applications assigned to Synpac under the TAA, including but not limited to the patents identified in paragraphs 23-26, 35 and related patent applications, and all patents and patent applications identified in discovery conducted in this action that are assigned to Synpac under the TAA;

e. for the costs of this action;

f. for prejudgment and post judgment interest as allowed by law;

g. for an award of Synpac's reasonable attorneys' fees;

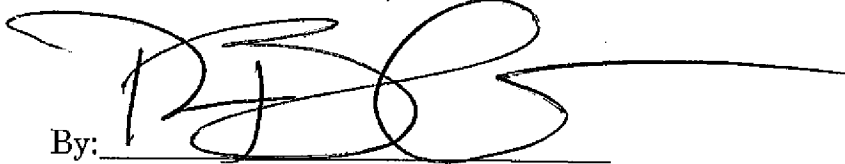
h. for a trial by jury; and

i. for such other and further relief as the Court may deem just and proper.

Dated: July 6, 2021

Respectfully submitted,

WILSON RATLEDGE, PLLC



By:

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*Attorneys for Synpac (North Carolina),
Inc. and CSRC International Investment
Holdings Co., Ltd.*

* *Pro hac vice* motion to be filed.

Synpac (North Carolina), Inc. and CSRC International Investment Holdings Co., Ltd. vs. Duke University, Durham County Superior Court

EXHIBIT A

TO

COMPLAINT FOR DAMAGES, INJUNCTIVE RELIEF,
AND SPECIFIC PERFORMANCE

TECHNOLOGY ASSIGNMENT AGREEMENT

THIS TECHNOLOGY ASSIGNMENT AGREEMENT made and entered into this 13th day of September, 1996, by and between DUKE UNIVERSITY, a North Carolina not-for-profit corporation having its principal office at Durham, North Carolina ("DUKE"), SYNPAK PHARMACEUTICALS (U.K.) LIMITED, a corporation of the United Kingdom having its principal office at Bedlington, Northumberland, England ("SYNPAC-UK"), and SYNPAK (NORTH CAROLINA), INC., a North Carolina corporation having its principal office at Durham, North Carolina ("SYNPAC-NC", and collectively with SYNPAK-UK, "SYNPAC").

WITNESSETH:

WHEREAS, Dr. Y. T. Chen, a resident of North Carolina ("CHEN"), Dr. J. Van Hove, a resident of North Carolina ("VAN HOVE"), Helen W. Yang, a resident of North Carolina ("YANG"), and J-Y Wu, a resident of North Carolina ("WU"), are the authors and inventors of certain TECHNOLOGY and TECHNICAL INFORMATION as hereinafter defined; and

WHEREAS, DUKE has the right to assign the TECHNOLOGY and TECHNICAL INFORMATION and wishes to have the TECHNOLOGY and the TECHNICAL INFORMATION utilized in the public interest; and

WHEREAS, as herein set forth and subject to the terms hereof, SYNPAK desires to purchase all rights, title and interest in and to the TECHNOLOGY, the TECHNICAL INFORMATION, and any applications for orphan drug, investigational new drug, or new drug approval from DUKE, and DUKE desires to assign any and all of its rights, title and interest in and to the TECHNOLOGY, the TECHNICAL INFORMATION, and any applications for orphan drug, investigational new drug, or new drug approval to SYNPAK;

NOW, THEREFORE, for good and valuable consideration, which DUKE acknowledges having received from SYNPAK, and in further consideration of the mutual promises set forth herein, the parties agree as follows:

1. Definitions. As used herein the following defined terms shall have the following respective meanings:

a. "AFFILIATED COMPANY" means any company (i) in which SYNPAK now or hereafter owns or controls, directly or indirectly, fifty percent (50%) or more of the stock having the right to vote for directors thereof, or (ii) which owns or controls, directly or indirectly, fifty percent (50%) or more of SYNPAK's stock having the right to vote for directors.

b. "AGREEMENT" means this Technology Assignment Agreement.

c. "CLINICAL INFORMATION" means clinical data generated through the clinical trials for use within the SUBJECT AREA.

d. "DUKE PERSONNEL" means CHEN and VAN HOVE and any other doctor, scientist, employee, technician or student of DUKE who participates in the SUBJECT AREA research, development and trials.

- e. "EFFECTIVE DATE" means October 1, 1996.
- f. "FDA" means the United States Food and Drug Administration.
- g. "FIRST COMMERCIAL SALE" means the initial transfer, following PLA approval by the FDA, by SYN PAC of PRODUCTS in exchange for cash or some equivalent to which value can be assigned for the purpose of determining NET SALES.
- h. "FUNCTIONAL EQUIVALENT" for human acid alpha glucosidase shall mean any other protein (including glycoproteins and other substances which contain one or more polypeptide chains as constituent parts), protein fragment, subunit, or polypeptide, with enzymatic activity and substrate preferences sufficiently similar to those of human acid alpha glucosidase so as to allow said substance to be substituted for human acid alpha glucosidase in any method, device or substance within the scope of the SUBJECT AREA.
- i. "IND" means an Investigational New Drug application filed with the FDA arising from the TECHNOLOGY or any Invention, as defined in the SPONSORED RESEARCH AGREEMENT.
- j. "NDA" means a New Drug Application filed with the FDA or its component PLA and Equipment Licensing Agreement applications arising from the TECHNOLOGY or any Invention, as defined in the SPONSORED RESEARCH AGREEMENT.
- k. "NET SALES" means the gross sales of the PRODUCT by SYN PAC or any licensee of SYN PAC to independent third parties, less price adjustments, return goods, billing corrections, cash, trade and contract discounts, taxes arising from the sale of the PRODUCT, freight, and other special charges. If a PRODUCT is not sold independently, but rather is sold in combination with other material which is not a PRODUCT, then (i) the NET SALES of said PRODUCT shall be deemed to be the current equivalent NET SALES for the same quantity of said PRODUCT which is sold independently; or (ii) if there are not independent current sales of said PRODUCT, the NET SALES shall be deemed to be equal to one hundred fifty percent (150%) of the direct cost of producing said PRODUCT, determined in accordance with generally accepted accounting principles consistently applied.
- l. "ODA" means an Orphan Drug Application filed with the FDA arising from the TECHNOLOGY or any Invention, as defined in the SPONSORED RESEARCH AGREEMENT.
- m. "PATENTS" means all letters patents and patents rights (both U.S. and foreign), now or hereafter owned or controlled by DUKE which cover all or any part of the SUBJECT AREA, including but not limited to patents of importation, improvements patents, patents and certificates of addition, and utility models, as well as divisions, reissues, re-examinations, continuations, renewals, and extensions of any of the foregoing, and applications therefor (including patents which may issue on such applications) and patent application serial number 60/012,855 entitled "Tissue Specific Recombinant Human Lysosomal Acid α -Glucosidase" filed March 5, 1996 in the United States Patent and Trademark Office.
- n. "PLA" means Product Licensing Agreement.
- o. "PRODUCT(S)" means any product which is produced or sold by SYN PAC, any AFFILIATED COMPANY or any licensee of SYN PAC that utilizes the TECHNOLOGY, the TECHNICAL INFORMATION, or infringes one or more claims of the PATENTS.

p. "SPONSORED RESEARCH AGREEMENT" means that certain Sponsored Research Agreement of even date herewith by and between DUKE and SYN PAC, a copy of which is attached hereto as Exhibit B.

q. "SUBJECT AREA" means (i) the creation of cell lines which produce commercially significant quantities of human acid alpha glucosidase or its FUNCTIONAL EQUIVALENT, (ii) the isolation, purification, manufacture, production, and storage of human acid alpha glucosidase or its FUNCTIONAL EQUIVALENT, (iii) the delivery of human acid alpha glucosidase or its FUNCTIONAL EQUIVALENT to people to prevent or to treat Pompe's Disease or other human diseases, specifically including, without limitation, use in enzyme replacement therapy; (iv) the use of the proteins in (ii) for development and screening of drugs for the prevention and treatment of Pompe's Disease and other human diseases, including drug design and drug targeting; and (v) the use of the proteins of (ii) for analysis of glycogen.

r. "SYNPAC" means Synpac Pharmaceuticals (U.K.) Limited and any AFFILIATED COMPANY of Synpac Pharmaceuticals (U.K.) Limited.

s. "TECHNICAL INFORMATION" means all scientific or technical information, know-how, show-how, data, and test results, regardless of form or characteristics relating to the SUBJECT AREA developed, produced or generated by DUKE PERSONNEL.

t. "TECHNOLOGY" means the cell line set forth in Exhibit A, attached hereto and incorporated herein by reference, all progeny and derivatives of said cell line, and PATENTS.

2. *Assignment.*

a. DUKE hereby sells, assigns, grants and conveys to SYN PAC-UK, its successors, assigns, nominees, or legal representatives, DUKE's entire right, title and interest in and to the now-existing TECHNICAL INFORMATION, including all rights to make, use, sell, offer for sale, import and license the TECHNICAL INFORMATION. DUKE hereby sells, assigns, grants and conveys to SYN PAC-NC, its successors, assigns, nominees, or legal representatives, DUKE's entire right, title and interest in and to all of the TECHNOLOGY, including all rights to make, use, sell, offer for sale, import and license the TECHNOLOGY, any existing patent applications thereon and the right to file patent applications thereon throughout the world, all claims for damages and profits by reason of any past infringement pertaining to the TECHNOLOGY and the right to sue therefor, and all rights of priority consequent upon the filing of applications to patent the TECHNOLOGY, to the full end of the term or terms for which letters patent respectively may be granted, reissued, or extended.

b. Duke hereby agrees to execute and deliver to Synpac the Patent Assignment, attached hereto as Exhibit C and hereby incorporated into this AGREEMENT.

c. Within thirty (30) days following the execution of this AGREEMENT and upon reasonable notice during the term of this AGREEMENT, DUKE agrees to provide SYN PAC with a list of all existing TECHNICAL INFORMATION, PATENTS, CLINICAL INFORMATION and any information relating to the TECHNOLOGY. DUKE further agrees to provide SYN PAC with a copy of all such information requested by SYN PAC within a reasonable time after receipt of such request.

3. *ODA, IND, and NDA.* Duke agrees to prepare and submit for approval, at SYN PAC's expense, an ODA, IND and NDA with respect to any PRODUCTS and further grants SYN PAC an option

to acquire such applications without option fee other than the consideration of the Sponsored Research Agreement and the payment of all expenses incurred related to such applications. Such option with respect to each such application shall extend until ninety (90) days following notice to SYNPAAC of the approval of such application. If SYNPAAC does not exercise such option within the prescribed ninety (90) day option period, or notifies DUKE that it will not exercise such option, then SYNPAAC shall no longer own any rights in such application.

4. *Grantback of Non-exclusive, Royalty-free License.* Upon the assignment of the TECHNOLOGY under this AGREEMENT or any Invention, as defined in the Sponsored Research Agreement, SYNPAAC shall grant to DUKE a non-exclusive, royalty-free license to produce, make, or use the TECHNOLOGY or Invention solely for research, education, teaching and clinical purposes; provided, however, DUKE shall have no right to sublicense or assign the rights granted pursuant to this Section 4, and, after FDA approval of the PLA, DUKE will, at its sole discretion, use PRODUCTS when appropriate for clinical purposes.

5. *Consideration, Records and Reports.*

a. SYNPAAC shall pay to DUKE an assignment fee of Fifty Thousand Dollars (\$50,000) upon the execution of this AGREEMENT by all parties thereto. In addition, SYNPAAC shall pay to DUKE a milestone fee upon the achievement of certain milestones in the development of PRODUCTS as follows:

- i. One Hundred Thousand Dollars (\$100,000) upon the filing of the first NDA with the FDA or a similar regulatory agency in a foreign country; and
- ii. Two Hundred Thousand Dollars (\$200,000) upon approval of the first NDA with the FDA or a similar regulatory agency in a foreign country.

Such fees shall not be creditable to any royalty or other fee or payment due to DUKE under this AGREEMENT. The first Two Hundred Thousand Dollars (\$200,000) of such fees shall be paid by SYNPAAC-UK as consideration for the assignment of the TECHNICAL INFORMATION. The remaining One Hundred Fifty Thousand Dollars (\$150,000) of such fees, as well as all other compensation due Duke pursuant to this AGREEMENT, shall be paid by SYNPAAC-NC as consideration for the assignment of the TECHNOLOGY and all such other obligations owed by DUKE under this AGREEMENT.

b. Commencing with the FIRST COMMERCIAL SALE and at such times and in such manner set forth hereinafter, SYNPAAC shall pay to DUKE a royalty on NET SALES of PRODUCTS. Such royalty shall be at the rate of six percent (6%) of NET SALES.

If SYNPAAC demonstrates through written records (i) that it has been necessary to license additional technology from third parties or to take an assignment for additional technology from DUKE in order to commercialize the PRODUCTS ("NECESSARY TECHNOLOGY") and (ii) that such license or assignment for NECESSARY TECHNOLOGY obligates SYNPAAC to pay royalties on NET SALES of PRODUCTS, then SYNPAAC shall be permitted to reduce the royalty due DUKE under this AGREEMENT by one-half of any such additional royalties payable to third parties in respect of the PRODUCTS and by the full amount of such additional royalties payable to DUKE in respect of the PRODUCTS; provided, however, in no case shall the royalty rate payable to DUKE pursuant to this Section 5.b, when reduced by any royalties due third parties for NECESSARY TECHNOLOGY, be less than two percent (2%) of NET SALES, and in no case shall the royalty rate payable to DUKE pursuant to

this Section 5.b, when combined with any royalties due under additional assignment agreements with DUKE for NECESSARY TECHNOLOGY, be greater than six percent (6%) of NET SALES.

c. Commencing with the FIRST COMMERCIAL SALE and at such times and in such manner set forth hereinafter, SYN PAC shall render to DUKE prior to February 28th and August 31st of each year a written account of the NET SALES of PRODUCTS subject to royalty hereunder made during the prior six (6) month periods ending December 31st and June 30th, respectively, and shall simultaneously pay to DUKE the royalties due on such NET SALES in United States Dollars. Minimum annual royalties, if any, which are due DUKE for any calendar year, shall be paid by SYN PAC along with the written report due on February 28th of each year.

d. SYN PAC shall, at DUKE's option, either (a) reassign to DUKE all TECHNOLOGY and TECHNICAL INFORMATION assigned to SYN PAC under this AGREEMENT or (b) license to DUKE all TECHNOLOGY and TECHNICAL INFORMATION assigned to SYN PAC under this AGREEMENT under a royalty-free, exclusive license without other restrictions if (i) SYN PAC fails to make the FIRST COMMERCIAL SALE of the PRODUCT within two (2) years of the date the PLA for the PRODUCT is approved by the FDA or similar regulatory agency in any foreign country or (ii) royalties earned by DUKE pursuant to the sale of the first PRODUCT for therapeutic administration during the second year following FIRST COMMERCIAL SALE are less than One Thousand Dollars (\$1,000).

e. SYN PAC shall keep full, true and accurate books of accounts and other records containing all particulars which may be necessary to properly ascertain and verify the royalties payable by them hereunder. Upon DUKE's request, SYN PAC shall permit an independent Certified Public Accountant selected by DUKE (except one to whom SYN PAC has some reasonable objection) to have access during ordinary business hours to such of SYN PAC's records as may be necessary to determine, in respect of any quarter ending not more than two (2) years prior to the date of such request, the correctness of any report and/or payment made under this AGREEMENT.

f. Concurrently with the execution of this AGREEMENT, DUKE and SYN PAC shall execute the SPONSORED RESEARCH AGREEMENT.

g. SYN PAC agrees to contribute to a qualifying charitable organization two percent (2%) of SYN PAC's net profits, before tax and before charitable contributions, derived from the sale of PRODUCTS. A qualifying charitable organization shall be a not-for-profit organization qualifying under Section 501(c)(3) of the Internal Revenue Code of the United States of 1986, as amended, and which has as a principal purpose providing financial assistance for the treatment of patients with Pompe's Disease. SYN PAC shall have the right, but not the obligation, to designate any such gift solely for the purpose of patient care.

h. During the term of this AGREEMENT, representatives of the DUKE will meet with representatives of SYN PAC at times and places mutually agreed upon to discuss the progress and results, as well as the ongoing plans, with respect to the evaluation and development of the TECHNOLOGY and TECHNICAL INFORMATION assigned to SYN PAC; provided, however, that should DUKE's personnel be required by SYN PAC to consult with SYN PAC outside of Durham, North Carolina, SYN PAC will reimburse reasonable travel and living expenses incident thereto.

6. *Representations and Covenants by DUKE.*

a. DUKE represents that:

i. To the best of DUKE's knowledge, DUKE is the sole and exclusive owner of the entire right, title and interest in the TECHNOLOGY and TECHNICAL INFORMATION, unencumbered by any outstanding contracts, agreements or priority claims;

ii. With the exception of SYN PAC, DUKE did not utilize the resources of any other person or entity in the development of the TECHNOLOGY and TECHNICAL INFORMATION, other than as already disclosed to SYN PAC;

iii. DUKE has full right to enter into this AGREEMENT, make this assignment, and carry out the transactions contemplated hereby;

iv. DUKE has not executed any agreement in conflict with this AGREEMENT;

v. To the best of DUKE's knowledge and except as has been previously disclosed to SYN PAC, there has been no disclosure such as would invalidate the patentability of any component of the TECHNOLOGY or as would cause secret and substantial TECHNICAL INFORMATION to have fallen into the public domain; and

vi. DUKE is the party named in any and all patent applications based on the TECHNOLOGY, DUKE is the party who filed, or caused to be filed, all patent applications based on the TECHNOLOGY, and all patent applications are free of any and all liens, security interests, claims, or other encumbrances of any nature or kind, and no interest in any patents has been previously or simultaneously granted, transferred, assigned, licensed, or otherwise conveyed.

b. Duke covenants that:

i. During the term of this AGREEMENT and for such time thereafter as those obligations which survive the expiration or termination of this AGREEMENT shall apply, DUKE shall not enter into any agreement in conflict with this AGREEMENT or such surviving obligations; and

ii. DUKE shall take all reasonable care to protect, maintain, and keep secure the cell line set forth in Exhibit A and all progeny and derivatives of said cell line to the extent the same are in the sole possession of DUKE.

7. *SYN PAC's Due Diligence Requirements.*

a. SYN PAC shall use commercially reasonable efforts to bring the PRODUCTS to market through a thorough, vigorous and diligent program for exploitation of the TECHNOLOGY and TECHNICAL INFORMATION throughout the term of this AGREEMENT.

b. In addition, SYN PAC shall adhere to the following commercialization milestones:

i. deliver to DUKE on or before February 1, 1997, a business plan showing the amount of money, number and kind of personnel and time budgeted and planned for each research and scale-up phase of the development of the PRODUCTS.

ii. SYN PAC shall achieve the FIRST COMMERCIAL SALE of a PRODUCT on or before two years following PLA approval by the FDA of such PRODUCT, and shall promptly notify DUKE in writing of the details of such sale.

c. SYN PAC agrees to use commercially reasonable efforts to develop a vigorous licensing program to effect commercialization of PRODUCTS in any field of use that SYN PAC decides not to exploit on its own.

d. During the term of this AGREEMENT, SYN PAC will submit annual progress reports, including a financial report of moneys spent to date, to DUKE by August 31 of each year which discuss the progress and results, as well as ongoing plans, with respect to the TECHNOLOGY and TECHNICAL INFORMATION. DUKE shall have the right to request one meeting per year to discuss such information.

e. SYN PAC shall, at DUKE's option, either (a) reassign to DUKE all TECHNOLOGY and TECHNICAL INFORMATION assigned to SYN PAC under this AGREEMENT or (b) license to DUKE all TECHNOLOGY and TECHNICAL INFORMATION assigned to SYN PAC under this AGREEMENT under a royalty-free, exclusive license without further restrictions if SYN PAC fails to meet any of the commercialization milestones set forth in subsection b. of this Section 7.

8. *Patents.*

a. Subsequent to the EFFECTIVE DATE of this AGREEMENT, SYN PAC shall have sole responsibility for the filing, prosecuting and maintaining of appropriate worldwide patents for the TECHNOLOGY, and all of the expenses of such protection shall be paid by SYN PAC. DUKE shall fully assist SYN PAC in the preparation of patent applications, and SYN PAC shall reimburse DUKE for all legal expenses which have been incurred to date or any expense which is incurred during the term of this AGREEMENT in the preparation, prosecution and maintenance of such patents. SYN PAC shall keep DUKE advised as to the prosecution of such applications by forwarding to DUKE copies of all official correspondence relating thereto. DUKE agrees to cooperate with SYN PAC in the prosecution of worldwide patent applications to insure that the applications reflect, to the best of DUKE's knowledge, all items of commercial and technical interest and importance.

b. Each party to this AGREEMENT (here, the "notifying party") shall give the other party to this AGREEMENT prompt notice of each claim or allegation received by the notifying party that the manufacture, use or sale of PRODUCTS constitutes a significant infringement of a third-party patent or patents. SYN PAC shall have the sole right and responsibility at its own expense to defend and control the defense of any such claim against SYN PAC, by counsel of SYN PAC's own choosing. The settlement of any such actions must be approved by DUKE, which approval may not be unreasonably withheld. DUKE agrees to cooperate with SYN PAC in any reasonable manner deemed by SYN PAC to be necessary

in defending or prosecuting such actions. SYN PAC shall reimburse DUKE for all expenses incurred in providing such assistance. Notwithstanding the foregoing, DUKE, shall, in its sole discretion and at its sole expense, be entitled to participate through counsel of its own choosing in any such action.

9. *Infringement by Third Parties.* Upon learning of the infringement of the TECHNOLOGY by a third party, the party learning of such infringement shall promptly inform the other party in writing of that fact along with any evidence available pertaining to the infringement. SYN PAC may at its own expense take whatever steps are necessary to stop the infringement and recover damages. In such case, SYN PAC will keep DUKE informed of the steps taken and the progress of any legal action taken. DUKE shall receive twelve and one-half percent (12.5%) of any damages received in excess of legal expenses incurred by SYN PAC in enforcing rights in the TECHNOLOGY.

10. *Ownership of Rights.*

a. The PATENTS shall be the sole and exclusive property of SYN PAC subject to the reversionary assignment and license rights granted to DUKE in this AGREEMENT. DUKE shall, upon demand, execute and deliver to SYN PAC such documents as may be reasonably considered necessary and advisable by counsel for SYN PAC for filing in the appropriate patent offices or equivalent to evidence the granting of the assignment granted under this AGREEMENT.

b. SYN PAC shall retain all right, title and interest to any improvement, modification and new discoveries pertaining to the PRODUCTS solely developed or invented by SYN PAC or by a third party on behalf of SYN PAC, including those discoveries, improvements, and designs for the manufacture and production of devices, processes, or equipment as developed or invented by SYN PAC, or by a third party on behalf of SYN PAC, for the manufacture or production of the PRODUCTS. If such discoveries, improvements, changes, modifications, or designs have been created in whole or in part as a result of collaborative efforts between DUKE and SYN PAC other than under the SPONSORED RESEARCH AGREEMENT, DUKE and SYN PAC shall share ownership of such discoveries, improvements, changes, modifications, or designs consistent with relevant patent or other intellectual property law.

11. *Government Clearance, Publication, Other Use, Export.*

a. SYN PAC agrees to use its reasonable efforts to have the TECHNOLOGY and TECHNICAL INFORMATION cleared for marketing in those countries in which SYN PAC intends to sell the PRODUCTS by the responsible government agencies requiring such clearance. To accomplish said clearances at the earliest possible date, SYN PAC agrees to file, according to the usual practice of SYN PAC, any necessary data with said government agencies. Should SYN PAC cancel its development efforts under this AGREEMENT, SYN PAC agrees to assign its full interest and title in such market clearance application, including all data relating thereto, to DUKE at no cost to DUKE.

b. DUKE shall be free to publish the results of its continued research on the TECHNOLOGY and TECHNICAL INFORMATION but agrees to submit to SYN PAC for its review and comment, a copy of any proposed publication resulting from the subject research at least thirty (30) days prior to the date submitted for publication, and if no response is received within thirty (30) days of the date submitted to SYN PAC, it will be conclusively presumed that the publication may proceed without delay. DUKE shall in good faith consider any comments provided by SYN PAC and shall consider the sensitive nature and timing of publication of unprotected intellectual property. If SYN PAC determines that the proposed publication contains proprietary subject matters which require protection, SYN PAC may request the delay for ninety (90) days from the date first submitted to SYN PAC in order to perfect such protection.

Duke agrees to consider requests by SYN PAC for additional reasonable delays in publication if such delays are required to protect proprietary subject matter necessary for the development of a cure for Pompe's Disease. Nothing in this Agreement shall be construed as giving SYN PAC editorial control over any publication. Nothing in this AGREEMENT shall be construed as prohibiting DUKE or SYN PAC from reporting on the results of such research to a governmental agency if so required by law. For purposes of this AGREEMENT, publication shall mean the disclosure of information to any person or entity who is not subject to the confidentiality provisions of Section 14 of this AGREEMENT.

c. Except SYN PAC's publication review rights set forth in Section 11.b of this AGREEMENT, nothing in this Section 11 shall be construed as to restrict DUKE's right to use the TECHNOLOGY, TECHNICAL INFORMATION and PATENTS for its own educational, teaching, research and clinical purposes as may be set forth elsewhere in this AGREEMENT; provided, after FDA approval of the PLA, DUKE will, at its sole discretion, use PRODUCTS when appropriate for clinical purposes.

d. This AGREEMENT is subject to all United States laws, rules, and regulations controlling the export of technical data, computer software, laboratory prototypes and other commodities and technology.

12. *Duration and Termination.*

a. This AGREEMENT shall become effective upon the EFFECTIVE DATE, and unless sooner terminated in accordance with any of the provisions of this AGREEMENT, shall remain in full force and effect until the last-to-expire of any PATENTS, but in no case less than seventeen (17) years from the EFFECTIVE DATE.

b. SYN PAC may terminate this AGREEMENT by giving DUKE written notice at least three (3) months prior to such termination. Upon such termination, SYN PAC shall, at DUKE's option, either (a) reassign to DUKE all TECHNOLOGY and TECHNICAL INFORMATION assigned to SYN PAC under this AGREEMENT or the SPONSORED RESEARCH AGREEMENT or (b) license to DUKE all TECHNOLOGY and TECHNICAL INFORMATION assigned to SYN PAC under this AGREEMENT OR THE SPONSORED RESEARCH AGREEMENT under a royalty-free, exclusive license without further restrictions. As of the effective date of termination, SYN PAC shall have no further obligation to DUKE under Section 5 of this AGREEMENT, except to pay such amounts as are due and payable prior to the effective date of termination.

c. Either party may immediately terminate this AGREEMENT for fraud, willful misconduct, or illegal conduct of the other party upon written notice of same to such other party. If either party fails to fulfill any of its obligations under this AGREEMENT, the non-breaching party may terminate this AGREEMENT upon written notice to the breaching party as provided in this subsection c. of Section 12. Such notice must contain a full description of the event or occurrence constituting a breach of the AGREEMENT. The party receiving notice of the breach will have the opportunity to cure the breach within thirty (30) days of receipt of such notice. If the breach is not cured within such thirty (30) day period, the termination will be effective as of the thirtieth (30th) day after receipt of notice.

d. If during the term of this AGREEMENT, SYN PAC shall be adjudicated a bankrupt or insolvent or if the business of SYN PAC shall be placed in the hands of a receiver or trustee, whether by the voluntary act of SYN PAC or otherwise, or if SYN PAC shall cease to exist as an active business, this AGREEMENT shall immediately terminate.

e. If this AGREEMENT is terminated by DUKE pursuant to any breach by SYN PAC pursuant to Section 12.c of this AGREEMENT or for any reason set forth in Section 12.d of this AGREEMENT, SYN PAC shall, at DUKE's option, either (a) reassign to DUKE all TECHNOLOGY and TECHNICAL INFORMATION assigned to SYN PAC under this AGREEMENT or (b) license to DUKE all TECHNOLOGY and TECHNICAL INFORMATION assigned to SYN PAC under this AGREEMENT under a royalty-free, exclusive license without further restrictions. As of the effective date of termination, SYN PAC shall have no further obligation to DUKE under Section 5 of this AGREEMENT, except to pay such amounts as are due and payable prior to the effective date of termination.

f. As security for its conditional obligation to assign the TECHNOLOGY and TECHNICAL INFORMATION pursuant to Sections 12.b and e. of this AGREEMENT, SYN PAC agrees to grant, execute and deliver to DUKE, concurrently with the execution of this AGREEMENT, a security interest in the TECHNOLOGY and TECHNICAL INFORMATION, including any PATENTS, in the form attached hereto as Exhibit D and incorporated herein.

g. Upon any reassignment or license of the TECHNOLOGY and TECHNICAL INFORMATION to DUKE pursuant to the provisions of this Section 12, SYN PAC agrees to negotiate a license to DUKE to make, use and sublicense any technology and technical information within the SUBJECT AREA then owned by SYN PAC, other than the TECHNOLOGY and TECHNICAL INFORMATION, which DUKE may require to further the development of a cure for Pompe's Disease.

13. *Force Majeure.*

a. Neither party shall be considered in breach of its obligations under this AGREEMENT nor liable for any costs or damages due to nonperformance under this AGREEMENT arising out of any cause or event not within the reasonable control of such party and without such party's fault or negligence, such causes or events being hereinafter referred to as "Events of Force Majeure."

b. Each party shall give the other party prompt notice of the occurrence of any Event of Force Majeure, including such information as is reasonably necessary to establish the Event of Force Majeure; thereupon, the obligations of the party giving notice, so far as they are affected by the Event of Force Majeure, shall be suspended during, but no longer than, the continuance of the Event of Force Majeure.

c. Events of Force Majeure shall only excuse delays in performance and only to the extent such delays are directly attributable to the Event of Force Majeure. No Event of Force Majeure shall be an excuse for permanent nonperformance.

d. Neither party shall be liable for any delay or failure in the performance of its obligations under this AGREEMENT that directly results from any failure of the other party to perform its obligations as set forth in this AGREEMENT.

14. *Confidentiality.*

a. "Confidential Information" means all information, including, but not limited to, the trade secrets and know-how of the respective parties which is clearly identified as "Confidential" or "Proprietary" by the disclosing party at the time of disclosure. If such transmittal occurs orally, the

disclosing party shall identify the oral disclosure as confidential at the time of disclosure and shall confirm in writing the confidential nature of such information within thirty (30) days of the disclosure. Confidential information shall not mean any information that:

- i. is known to the receiving party at the time of disclosure by the disclosing party;
- ii. is developed independently by the receiving party;
- iii. is within, or later falls within, the public domain without breach of this AGREEMENT by the receiving party;
- iv. is publicly disclosed with written approval of the disclosing party; or
- v. becomes lawfully known or available to the receiving party without restriction from a source having the lawful right to disclose the information without breach of this AGREEMENT by the receiving party.

Provided further, the receiving party shall have the burden of proof as to prior knowledge and absence of breach.

b. Confidential Information disclosed on a restricted basis pursuant to a judicial or other lawful government order shall remain Confidential Information as between the parties and shall only be disclosed under terms which provide for continued protection of the information, and, where possible, the disclosing party shall be a party to the negotiation of the terms for such protection. Notwithstanding any provision herein to the contrary, this AGREEMENT shall not be construed to limit the receiving party's obligation and ability to comply with any judicial or other lawful government order to disclose Confidential Information on a restricted basis.

c. The obligation of confidentiality under this AGREEMENT shall apply regardless of the form the Confidential Information takes.

d. Each party acknowledges that in the performance of this AGREEMENT it shall receive Confidential Information from the other party and that such Confidential Information is the exclusive property of the disclosing party. The receiving party agrees to hold the Confidential Information of the disclosing party in strict confidence in accordance with the provisions of this AGREEMENT. A receiving party:

- i. shall not permit or suffer its employees or agents to remove any proprietary or other legends or restrictive notices contained or included in any Confidential Information provided by the disclosing party;
- ii. shall not permit or suffer its employees or agents to copy any Confidential Information, except as provided in this AGREEMENT or consented to in writing by the disclosing party ;
- iii. shall not, except as may be provided in Section 11 of this AGREEMENT regarding publication, disclose any Confidential Information to a third party without the prior written consent of the disclosing party hereto;
- iv. shall exercise care to keep secure and maintain the Confidential Information of the disclosing party in a manner no less protective than that used to

maintain the confidentiality of the receiving party's own Confidential Information, but in any event not less than a reasonable degree of care; and

v. agrees to use the Confidential Information only to further the purposes set forth in this AGREEMENT.

e. A receiving party may disclose Confidential Information to officers, employees or agents under the control and direction of the receiving party only in the normal course of business and on a need-to-know basis within the purpose of this AGREEMENT. Provided, however, prior to any disclosure all such officers, employees or agents shall have entered into written agreements with the receiving party, or have in place binding policies covering the disclosure of such third-party Confidential Information and have on file signed acknowledgments of such binding policies from each officer, employee or agent to which Confidential Information is disclosed, requiring such officers, employees or agents to treat and use all such Confidential Information in a manner consistent with the terms and conditions of this AGREEMENT.

f. A receiving party's obligation to comply with the confidentiality provisions of this AGREEMENT with respect to Confidential Information disclosed by the disclosing party shall extend for a period of six (6) years from the date of disclosure of Confidential Information.

g. Upon thirty (30) days written notice from the disclosing party, the receiving party shall: (i) surrender and deliver all Confidential Information of the disclosing party, including all copies thereof; or (ii) with the written consent of the disclosing party, destroy the Confidential Information and all copies thereof and provide satisfactory evidence of such destruction to the disclosing party within one (1) month following said notice. Notwithstanding anything in this AGREEMENT to the contrary, (i) a receiving party may retain one copy of each item of Confidential Information disclosed by the disclosing party solely as evidence of compliance with this AGREEMENT and for no other purpose, and (ii) upon a request by SYNPAC to surrender and deliver all SYNPAC's Confidential Information, Duke shall be relieved of its obligation to continue any research dependent upon SYNPAC's Confidential Information.

15. *Notices.* All notices or other communication shall be in writing and shall be deemed duly given one (1) day after delivery by facsimile, provided that an original or copy of the notice is deposited in the international mail, postage pre-paid, and addressed as set forth below; or five (5) days after deposit thereof in the registered international mail, return receipt requested, postage pre-paid with copies to the other parties addressed as follows:

If to DUKE:

Office of Science and Technology
Attn: License Administrator
Duke University
Room 230, North Building
Box 90083
Durham, North Carolina 27708
Facsimile No.: (919) 681-7599

with a copy to:

Office of the University Counsel
Duke University
011 Allen Building
Durham, North Carolina 27708
Facsimile No.: (919) 684-8725

If to SYNPAAC:

Synpac (North Carolina), Inc.
Attn: Mr. Leslie Cheng Yun Koo
8th Floor No. 1
Lane 25 Shung-Chung Street
Taipei, Taiwan
Republic of China
Facsimile No.: 011-8862-586-2337

with a copy to:

Mark H. Webbink, Esq.
Moore & Van Allen, PLLC
P.O. Box 3843
Durham, North Carolina 27702-3843
Facsimile: (919) 286-8199

and to:

Synpac Pharmaceuticals (U.K.) Limited
Cambois
Bedlington, Northumberland NE22 7DB
United Kingdom
Attn: Peter Clark
Facsimile No.: 011-44-1670-850-571

with a copy to:

Simon Concannon, Esq.
Walker Morris
Kings Court
12 King Street
Leeds, LS1 2HL
UNITED KINGDOM
Facsimile: 011-44-113-245-9412

Any party may change its address for notice by giving notice to the other party of the change.

16. *Assignment.* Neither DUKE nor SYNPAAC may assign, delegate or otherwise transfer any of its rights or obligations under this AGREEMENT without the prior written consent of the other party; provided, however, SYNPAAC may assign its rights and obligations under this AGREEMENT to any AFFILIATED COMPANY of SYNPAAC or to any AFFILIATED COMPANY of such AFFILIATED COMPANY of SYNPAAC or to any surviving entity with which SYNPAAC merges or to which SYNPAAC sells substantially all of SYNPAAC's assets, provided SYNPAAC shall give DUKE prior written notice of such assignment.

17. *Binding Effect.* This AGREEMENT will be binding upon and will inure to the benefit of the parties and their respective successors and assigns.

18. *Indemnity, Insurance, Representations, Status.*

a. SYN PAC agrees to indemnify, hold harmless and defend DUKE, its trustees, officers, employees, and agents, against any and all claims, suits, losses, damages, costs, fees and expenses asserted by third parties, both government and non-government, resulting from or arising out of SYN PAC's development, production, manufacturing, exploitation, or marketing of the TECHNOLOGY or TECHNICAL INFORMATION. SYN PAC further agrees to indemnify and save DUKE harmless from and against any loss, damage, or expense suffered by DUKE as a result of SYN PAC's default under or breach of this AGREEMENT. DUKE agrees to indemnify and save SYN PAC harmless against any loss, damages, or expense suffered by SYN PAC as a result of DUKE's negligence, wrongful acts or default under or breach of this AGREEMENT.

b. SYN PAC shall maintain in force at its sole cost and expense, with reputable insurance companies, general liability insurance and products liability insurance coverage in an amount reasonably sufficient to protect against liability under subsection a of this Section 18. DUKE shall have the right to ascertain from time to time that such coverage exists, such right to be exercised in a reasonable manner.

c. NOTHING IN THIS AGREEMENT SHALL BE DEEMED TO BE A REPRESENTATION OR WARRANTY BY DUKE OF THE VALIDITY OF ANY OF THE PATENTS OR THE ACCURACY, SAFETY, EFFICACY, OR USEFULNESS, FOR ANY PURPOSE, OF THE TECHNOLOGY. DUKE SHALL HAVE NO OBLIGATION, EXPRESS OR IMPLIED, TO SUPERVISE, MONITOR, REVIEW OR OTHERWISE ASSUME RESPONSIBILITY FOR THE PRODUCTION, MANUFACTURE, TESTING, MARKETING OR SALE OF ANY PRODUCT, AND DUKE SHALL HAVE NO LIABILITY WHATSOEVER TO SYN PAC OR ANY THIRD PARTIES FOR OR ON ACCOUNT OF ANY INJURY, LOSS, OR DAMAGE, OF ANY KIND OR NATURE, SUSTAINED BY, OR ANY DAMAGE ASSESSED OR ASSERTED AGAINST, OR ANY OTHER LIABILITY INCURRED BY OR IMPOSED UPON SYN PAC OR ANY OTHER PERSON OR ENTITY, ARISING OUT OF OR IN CONNECTION WITH OR RESULTING FROM:

- i. the production, use, or sale of any PRODUCT;
- ii. the use of the TECHNOLOGY and TECHNICAL INFORMATION; or
- iii. any advertising or other promotional activities with respect to any of the foregoing.

d. The parties to this AGREEMENT recognize and agree that each is operating as an independent contractor and not as an agent of the other. This AGREEMENT shall not constitute a partnership or joint venture, and neither party may be bound by the other to any contract, arrangement or understanding except as specifically stated herein.

19. *Use of a Party's Name.* Neither party will, without the prior written consent of the other party:

a. use in advertising, publicity or otherwise, any trade-name, personal name, trademark, trade device, service mark, symbol, or any abbreviation, contraction or simulation thereof owned by the other party; or

b. represent, either directly or indirectly, that any product or service of the other party is a product or service of the representing party or that it is made in accordance with or utilizes the information or documents of the other party.

20. *General.*

a. *Severance.* Each clause of this AGREEMENT is a distinct and severable clause and if any clause is deemed illegal, void or unenforceable, the validity, legality or enforceability of any other clause or portion of this AGREEMENT will not be affected thereby so long as the principal intent of this AGREEMENT is unaffected.

b. *Waiver.* The failure of a party in any instance to insist upon the strict performance of the terms of this AGREEMENT will not be construed to be a waiver or relinquishment of any of the terms of this AGREEMENT, either at the time of the party's failure to insist upon strict performance or at any time in the future, and such terms will continue in full force and effect. No waiver of any obligation under this AGREEMENT shall be effective unless in writing and signed by the authorized representative of the party consenting to such waiver.

c. *Modification.* Any alteration, modification, or amendment of this AGREEMENT must be in writing and signed by the authorized representative of each party.

d. *Governing Law.* This AGREEMENT shall be construed and enforced in accordance with and governed by the substantive law of the State of North Carolina and the United States of America, including the patent laws of the United States of America.

e. *Construction.* All titles and section headings contained in this AGREEMENT are inserted only as a matter of convenience and reference. Such titles and headings shall not define, limit, extend or describe the scope of this AGREEMENT or any of its provisions.


f. *Entire Understanding.* This AGREEMENT, along with the SPONSORED RESEARCH AGREEMENT between the parties of even date herewith, represents the entire understanding between the parties with respect to the subject matter contained therein and supersedes all other agreements, express or implied, between the parties with respect to the same.

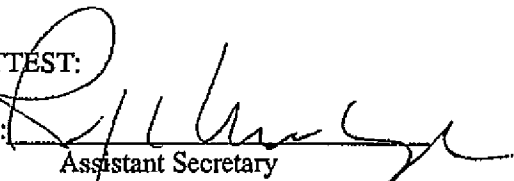
g. *Counterparts.* This AGREEMENT may be executed in any number of counterparts, each of which shall be deemed to be an original, but all of which together will constitute one and the same document.

h. All references to payments of monies under this AGREEMENT shall be deemed to be in U.S. dollars.

IN WITNESS WHEREOF, the authorized representatives of the parties have caused these presents to be executed under seal as of the date and year first above written.


DUKE UNIVERSITY

By: 
Name: Robert L. Taber, Ph.D.
Title: Associate Vice Chancellor

ATTEST:
By: 
Assistant Secretary

[CORPORATE SEAL]

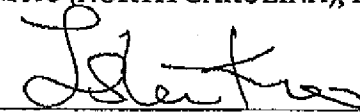
SYNPAC PHARMACEUTICALS (U.K.) LIMITED

By: 
Name: Peter Clark
Title: Director

ATTEST:
By: 
Secretary

[CORPORATE SEAL]

SYNPAC (NORTH CAROLINA), INC.

By: 
Name: LESLIE KOO
Title: PRESIDENT

ATTEST:
By: 
Secretary

[CORPORATE SEAL]

NORTH CAROLINA

DURHAM COUNTY

I, Jean D. Senter, a Notary Public of the aforesaid County and State, do hereby certify that Ralph McLaughlin personally appeared before me this day and acknowledged that (s)he is the Assistant Secretary of DUKE UNIVERSITY, a North Carolina corporation, and that by authority duly given and as an act of the corporation, the foregoing instrument was signed in its name by its ~~President~~ President, and attested by herself/himself as Assistant Secretary, and sealed with its common corporate seal.

Witness my hand and notarial seal this 13 day of September, 1996.

Jean D. Senter
Notary Public

My Commission Expires:

Jan 12 1999

NORTH CAROLINA

DURHAM COUNTY

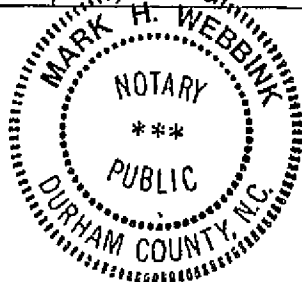
I, MARK H. WEBBINK, a Notary Public of the aforesaid County and State, do hereby certify that Clive Goatman personally appeared before me this day and acknowledged that he is the Secretary of SYN PAC PHARMACEUTICALS (U.K.) LIMITED, a corporation of the United Kingdom, and that by authority duly given and as an act of the corporation, the foregoing instrument was signed in its name by its Director, and attested by himself as Secretary, and sealed with its common corporate seal.

Witness my hand and notarial seal this 13TH day of September, 1996.

Mark H. Webbink
Notary Public

My Commission Expires:

2/27/2000



NORTH CAROLINA

DURHAM COUNTY

I, Brenda V. Fulcher, a Notary Public of the aforesaid County and State, do hereby certify that Mark H. Webbink personally appeared before me this day and acknowledged that he is the Secretary of SYNPAAC (NORTH CAROLINA), INC., a North Carolina corporation, and that by authority duly given and as an act of the corporation, the foregoing instrument was signed in its name by its President, and attested by himself as Secretary, and sealed with its common corporate seal.

Witness my hand and notarial seal this 13th day of September, 1996.

Brenda V. Fulcher
Notary Public

My Commission Expires:

May 16, 1999

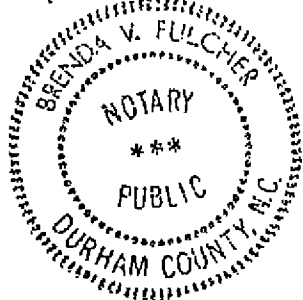


EXHIBIT A

THE TECHNOLOGY AND TECHNICAL INFORMATION

As defined in that certain Technology Assignment Agreement, dated September 13, 1996 by and among Duke University, Synpac Pharmaceuticals (U.K.) Limited, and Synpac (North Carolina), Inc., and to which this Exhibit A is attached and incorporated, the TECHNOLOGY and TECHNICAL INFORMATION includes that information disclosed to DUKE in Office and Science Technology File # 1180, all right, title and interest in and to which has been assigned to DUKE by CHEN, VAN HOVE, YANG, and WU.

The TECHNOLOGY also includes that certain cell line on deposit with the American Type Culture Collection and identified as CHO Cell Line, TCHO-pJW5'sGAA-5M25-5000-MTX-17.

The TECHNOLOGY also includes the invention disclosed in that certain provisional patent application serial number 60/012,855 titled "Tissue Specific Recombinant Human Lysosomal Acid α -Glucosidase filed March 5, 1996 on behalf of Yuan-Tsong Chen, Johan L.K. Van Hove, Helen Yang, and Jer-Yuarn Wu.

EXHIBIT B
SPONSORED RESEARCH AGREEMENT

F:\DOCS\MHW\INTELLEC\138390_3.DOC

PATENT
REEL: 056816 FRAME: 0598

EXHIBIT C

PATENT ASSIGNMENT

ASSIGNMENT OF LETTERS PATENT APPLICATION

Serial No. _____

Filed: _____

WHEREAS, DUKE UNIVERSITY, a North Carolina not-for-profit corporation ("Assignor"), is the assignee of [description of invention] _____ for which Duke executed an Application for Letters Patent of the United States, _____, _____, Application Serial No. _____; and,

WHEREAS, SYN PAC (NORTH CAROLINA), INC., a North Carolina corporation with a place of business at _____ ("Assignee"), is desirous of acquiring the entire right, title and interest in and to that application and the inventions therein disclosed and any letters patent that may issue thereon;

NOW, THEREFORE, in consideration of the sum of TEN DOLLARS (\$10.00) and other valuable consideration, the receipt of which is hereby acknowledged, and other good and valuable consideration, Assignor hereby sells, assigns and transfers unto the Assignee, its successors and assigns, the entire right, title and interest in and to any and all improvements which are disclosed in the invention entitled " _____", of which Assignor is the assignee and which is found in U.S. patent application _____ filed on _____, _____, and any legal equivalent thereof in a foreign country, including the right to claim priority and, in and to, all Letters Patent to be obtained for said invention by the above application or any continuation, division, renewal, or substitute thereof, and as to letters patent of any reissue or re-examination thereof.

Assignor hereby authorizes the Assignee, its successors and assigns, to file in its own name applications for patents in foreign countries in connection with the inventions hereby transferred, under the international convention claiming the priority of the U.S. application or otherwise, and to secure in its own name the patent or patents issued thereon.

Assignor hereby covenants that no assignment, sale, agreement or encumbrance has been or will be made or entered into which would conflict with this assignment.

In testimony whereof, Assignor has hereunto set his hand and seal this _____ day of _____, _____.

DUKE UNIVERSITY

By: _____
Name: _____
Title: _____

STATE OF NORTH CAROLINA

DURHAM COUNTY

I, _____, a Notary Public of the aforesaid County and State, do hereby certify that _____ personally appeared before me this day and acknowledged that (s)he is the _____ Secretary of DUKE UNIVERSITY, a North Carolina not-for-profit corporation, and that by authority duly given and as an act of the corporation, the foregoing instrument was signed in its name by its _____ President, and attested by herself/himself as _____ Secretary, and sealed with its common corporate seal.

Witness my hand and notarial seal this ____ day of _____, _____.

Notary Public

My Commission Expires:

Certificate Under 37 CFR 3.73(b)

Applicant: Duke University

Application No.: _____ Filed: _____

For: _____

Duke University, a corporation, certifies that it is the assignee of the entire right, title and interest in the patent application identified above by virtue of an assignment from the inventor of the patent application identified above for which a copy thereof is attached.

The undersigned has reviewed all the documents in the chain of title of the patent application identified above and, to the best of undersigned's knowledge and belief, title is in the assignee identified above.

The undersigned is empowered to sign this certificate on behalf of the assignee.

I hereby declare that all statements made herein of my own knowledge are true, and that all statements made on information and belief are believed to be true; and further, that these statements are made with the knowledge that willful false statements, and the like so made, are punishable by fine or imprisonment, or both, under Section 1001, Title 18 of the United States Code, and that such willful false statements may jeopardize the validity of the application of any patent issuing thereon.

Date: _____

Name: _____

Title: _____

Signature: _____

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re application of:

Serial No. _____

Group No.: _____

Filed: _____

Examiner: _____

For: Duke University, Durham, North Carolina

Title - _____

Assistant Commissioner for Patents
Washington, DC 20231

POWER OF ATTORNEY BY ASSIGNEE OF ENTIRE INTEREST
(REVOCATION OF PRIOR POWERS)

As assignee of record of the entire interest of the above identified application, which assignment is recorded herewith, all powers of attorney previously given are hereby revoked and the following attorney and/or agent is hereby appointed to prosecute and transact all business in the Patent and Trademark Office connected therewith:

_____, Esq. Reg. No. _____

Send all correspondence and direct all telephone calls to:

_____, Esq.

() _____

Attached to this power is a "CERTIFICATE UNDER 37 CFR 3.73(b)."

ASSIGNEE:

SYNPAC (NORTH CAROLINA), INC.

Date: _____

By: _____

Name: _____

Title: _____

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re application of: Duke University, Durham, North Carolina

Serial No.: _____ Group No.: _____
Filed: _____ Examiner: _____
For: _____

Assistant Commissioner for Patents
Washington, DC 20231

REQUEST FOR PATENT TO ISSUE TO ASSIGNEE (37 CFR 3.81(a))

Request is made that the above-identified application issue solely to the below-named assignee of the entire right, title and interest.

The name of the assignee is: SYNPAC (NORTH CAROLINA), INC.

Attached to this power is a "CERTIFICATE UNDER 37 CFR 3.73(b)."

ASSIGNEE:

SYNPAC (NORTH CAROLINA), INC.

Date: _____

By: _____

Name: _____

Title: _____

ATTORNEY:

Reg. No.: _____
Tel. No.: () _____

EXHIBIT D

SECURITY AGREEMENT

NORTH CAROLINA

CONDITIONAL ASSIGNMENT
AND SECURITY AGREEMENT

DURHAM COUNTY

THIS CONDITIONAL ASSIGNMENT AND SECURITY AGREEMENT (the "Security Agreement") is made as of September 13, 1996, by and among SYNPAK PHARMACEUTICALS (U.K.) LIMITED, a corporation of the United Kingdom and SYNPAK (NORTH CAROLINA), INC., a North Carolina corporation (collectively, the "Grantor"), and DUKE UNIVERSITY, a North Carolina not-for-profit corporation (the "Secured Party").

RECITALS:

A. Pursuant to that certain Technology Assignment Agreement, of even date herewith among the parties hereto, Secured Party assigned to Grantor certain technology (hereinafter, the "Technology"), referred to in Schedule A attached hereto and incorporated herein.

B. Grantor has agreed to grant to the Secured Party a security interest in the Technology to secure Grantor's obligations, agreements, and covenants under the Technology Assignment Agreement.

NOW, THEREFORE, in consideration of the above Recitals and for other good and valuable consideration, the receipt and sufficiency of which are hereby acknowledged, Grantor hereby agrees as follows:

1. *Grant of Security Interest.* Grantor hereby grants to Secured Party a continuing security interest in the property described in Schedule A (collectively and severally, the "Collateral") to secure performance of the obligations of Grantor to Secured Party under the Technology Assignment Agreement.

2. *Ownership.* Grantor represents that, at the time of making of this Security Agreement, grantor is the sole owner of the Collateral, free and clear of all liens, encumbrances and security interests.

3. *Further Assurances.* Grantor shall execute and deliver to Secured Party, concurrently with the execution of this Security Agreement and at any time or times hereafter at the request of the Secured Party, financing statements, renewal financing statements, security agreements, affidavits, notices and such other agreements, instruments and documents that the Secured Party may reasonably request, in form satisfactory to the Secured Party, and shall take any and all other steps reasonably requested by Secured Party in order to perfect and maintain the security interests granted herein.

4. *Perfection.* The Grantor warrants and represents that: (a) the security interest granted to the Secured Party hereunder, when properly perfected by filing, shall constitute at all times a valid and perfected security interest in the Collateral.

5. *Subordination.* At Grantor's request, Secured Party agrees to subordinate the security interest granted under this Security Agreement to the security interests, liens or claims of any other person, firm or corporation from which Grantor may obtain funds for the development, manufacturing, marketing, or sale of the Collateral or any products derived from the Collateral.

6. *Taxes.* Grantor shall pay when due (or before overdue) all federal, state or local taxes of any kind or nature imposed upon the Collateral or which, if unpaid, could become a lien upon the Collateral. Upon the request of Secured Party, Grantor shall from time to time deliver to Secured Party evidence of payment of taxes.

7. *Location of Collateral.* Grantor represents and warrants that the principal offices of the Grantor are located at the addresses shown below and that all Collateral will be located at one of the addresses listed below or such other address as to which Grantor shall give Secured Party notice. Grantor will promptly notify Secured Party of any change in the name of Grantor or any change of the location of its principal offices or of any of the Collateral.

8. *Default and Remedies.* Subject to the terms and limitations of any subordination agreement to which Secured Party is a party and the subject matter of which is the Collateral, in the event that (i) Grantor terminates the Technology Assignment Agreement pursuant to Section 12.b of said agreement; or (ii) Secured Party terminates the Technology Assignment Agreement for fraud, willful misconduct, or illegal conduct of Grantor; or (iii) Grantor fails to fulfill any of its obligations under the Technology Assignment Agreement and Secured Party terminates the Technology Assignment Agreement upon written notice to Grantor as provided in this subsection c. of Section 12 of the Technology Assignment Agreement and Grantor fails to cure such breach within thirty (30) days of such notice; or (iv) if during the term of the Technology Assignment Agreement, Grantor is adjudicated a bankrupt or insolvent or if the business of Grantor is placed in the hands of a receiver or trustee, whether by the voluntary act of Grantor; or otherwise; or (v) if Grantor shall cease to exist as an active business; Grantor shall immediately convey and assign to Secured Party Grantor's entire right, title and interest in the Collateral subject only to such senior indebtedness as to which Secured Party's security interest is subordinate. Grantor agrees to execute and deliver all such instruments or documents as Secured Party may reasonably deem necessary so as to effect said assignment, and Grantor hereby appoints Secured Party as Grantor's attorney-in-fact for the purpose of executing and delivering any and all such instruments or documents.

9. *Cumulative Rights.* The rights, powers and remedies of Secured Party under this Security Agreement shall be in addition to all rights, powers and remedies given to Secured Party by virtue of any statute, rule of law, the Technology Assignment Agreement, or Sponsored Research Agreement, all of which rights, powers and remedies shall be cumulative and may be exercised successively or concurrently without impairing Secured Party's security interest in the Collateral.

10. *Notices.* All notices required to be given hereunder shall be in writing and addressed to the parties at the following addresses, or such other addresses as may from time to time be designated by written notice given as herein required:

To the Grantor:

Synpac (North Carolina), Inc.
c/o Moore & Van Allen, PLLC
2200 West Main Street, Suite 800
Durham, North Carolina 27705
Attn: Mark H. Webbink, Esq.
Facsimile No.: (919) 286-8199

and to:

Synpac Pharmaceuticals (U.K.) Limited
Attn: Peter Clark
Cambois
Bedlington, Northumberland NE22 7DB
United Kingdom
Facsimile No.: 011-44-1670-850-571

with a copy to:

c/o Walker Morris
Kings Court
12 King Street
Leeds, LS1 2HL
United Kingdom
Attn: Simon Concannon, Esq.
Facsimile No.: 011-44-113-245-9412

Additional Property Located At:

Synpac Pharmaceuticals (U.K.) Limited
Cambois
Bedlington, Northumberland NE22 7DB
United Kingdom

To the Secured Party:

Office of Science and Technology
Attn: Andrew E. Balber, Ph.D.
Duke University
Room 230, North Building
Box 90083
Durham, North Carolina 27708
Facsimile No.: (919) 684-8982

11. *Waiver.* Any forbearance, failure or delay by Secured Party in exercising any right, power or remedy shall not preclude the further exercise thereof, and every right, power or remedy of Secured Party shall continue in force and effect until such right, power or remedy is specifically waived in a writing executed by Secured Party. Grantor waives any right to require Secured Party to proceed against any person or to exhaust any Collateral or to pursue any remedy in Secured Party's power.

12. *Binding Upon Successors.* All rights of Secured Party under this Security Agreement shall inure to the benefit of its successors and assigns, and all obligations of Grantor under this Security Agreement shall bind its successors and assigns.


13. *Severability.* If any of the provisions of this Security Agreement shall be held invalid or unenforceable, the Agreement shall be construed as if not containing those provisions and the rights and obligations of the parties hereto shall be construed and enforced accordingly.

14. *Choice of Law.* This Security Agreement shall be construed in accordance with and governed by the substantive laws of the State of North Carolina.

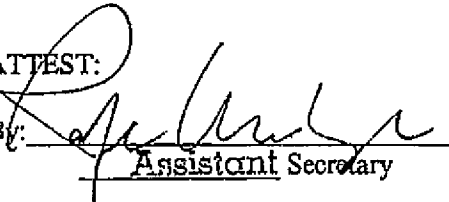
IN WITNESS WHEREOF, the properly authorized representatives of the parties have executed and delivered this Security Agreement under seal the day and year first above written.

SECURED PARTY:

DUKE UNIVERSITY

By: 
Name: ROBERT L. TABER, Ph.D.
Title: ASSOCIATE VICE CHANCELLOR


ATTEST:

By: 
Assistant Secretary

[CORPORATE SEAL]

GRANTOR:

SYNPAC PHARMACEUTICALS (U.K.) LIMITED

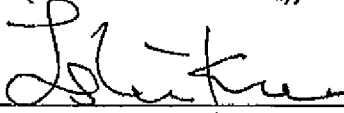
By: 
Name: Peter Clark
Title: Director

ATTEST:


By: 
Secretary

[CORPORATE SEAL]

SYNPAC (NORTH CAROLINA), INC.

By: 
Name: LESLIE KOO
Title: PRESIDENT

ATTEST:

By: 
Secretary

[CORPORATE SEAL]

SCHEDULE A

(a) All Technology and Technical Information acquired from Secured Party under that certain Technology Assignment Agreement, by and among Grantor and Secured Party dated September 13, 1996 or that certain Sponsored Research Agreement, by and among Synpac Pharmaceuticals (U.K.) Limited and Secured Party dated September 13, 1996, which Grantor presently owns or hereafter acquires.

(b) All proceeds of the conversion, voluntary or involuntary, of any of the foregoing collateral.

