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U.S. Department of Commerce
Patent and Trademark Office

Our Ref.: 39-276

Commissioner of Patents and Trademarks
Box Assignment, Washington, D.C. 20231

To the Honorable Commissioner of Patents and Trademarks: Please record the attached original documents or copy thereof.

1. Name of conveying party(ies):

3.27.03

BTG INTERNATIONAL LIMITED
10 Fleet Place
Limeburner Lane
London EC4M 7SB
England

Additional name/s of conveying party/ies attached? ☐

3. Nature of conveyance:

☐ Assignment ☐ Merger
☐ Security Assignment ☐ Change of Name
☒ Other License Agreement

Execution Date: March 28, 2002

2. Name and address of receiving party(ies):

Name: RENOVO LIMITED
Internal Address:
Street Address: Manchester Incubator Building
Grafton Street
City: Manchester
State/Country: Lancashire, England
Zip: M13 9XX

Additional name/s & address/es attached? ☐ Yes ☒ No

4. Application number(s) or patent number(s):

If this document is being filed together with a new application, the execution date of the application is:

A. Patent Application No(s).
(1)
(2)
(3)

B. Patent No(s).
(1) 5,520,926
(2)
(3)

Additional numbers attached ☐ Yes ☒ No

5. Name and address of party to whom correspondence concerning document should be mailed:

Name: Mary J. Wilson

Internal Address:

Street Address: Nixon & Vanderhye P.C.
1100 North Glebe Road
8th Floor

City: Arlington State: VA Zip: 22201

6. Total number of applications & patents involved: 1

7. Total fee (37 CFR 3.41) $ 40.00
☒ Enclosed
☐ Authorized to be charged to deposit account #14-1140

8. The Commissioner is hereby authorized to charge any deficiency in the fee(s) filed, or asserted to be filed, or which should have been filed herewith (or with any paper thereafter filed in this application by this firm) to our **Account No. 14-1140.**

DO NOT USE THIS SPACE

9. Statements and signature.

To the best of my knowledge and belief, the foregoing information is true and correct and any attached copy is a true copy of the original document.

Mary J. Wilson
Name of Person Signing
Reg. No. 32,955

Mary J. Wilson
Signature

March 27, 2003
Date

Total number of pages including **original** cover sheet, attachments, and document: [18]

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28 March 2002

(1) BTG INTERNATIONAL LIMITED

- and -

(2) RENOVO LIMITED

LICENCE AGREEMENT

BTG International Limited
10 Fleet Place, Limeburner Lane, London EC4M 7SB
Tel. +44 20 7575 1000

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THIS AGREEMENT is made as a Deed on 28 March 2002

BETWEEN:

(1) **BTG INTERNATIONAL LIMITED** whose company registration number in England is 2664412 and whose registered office is at 10 Fleet Place, Limeburner Lane, London EC4M 7SB ("BTG"); and

(2) **RENOVO LIMITED** whose company registration number in England is 3622770 and whose registered office is at Manchester Incubator Building, Grafton Street, Manchester, Lancashire M13 9XX (the "Licensee").

RECITALS:

(A) BTG is the registered proprietor and/or is beneficially entitled to the patents and patent applications listed in Schedule 1 relating to the use of mannose-6-phosphate in wound-care.

(B) BTG owns or has licence rights to certain technical information and data that relates to the inventions which are the subject of those patents and patent applications.

(C) BTG is willing to grant the Licensee, and the Licensee is willing to accept, a licence under the Patents and the Know-How (as defined below) on the terms set out herein.

TERMS AGREED:

1 **Definitions**

In this Agreement the following terms shall have the following meanings:

"Accounting Date"	means 30 June and 31 December in each calendar year;

"Back Licence"	means a non-exclusive, world-wide licence with full rights to sub-license, under the Licensee Inventions and the Licensee Results;
"Chargeable Transaction"	means the manufacture, sale or other disposal of a Licensed Product by or on behalf of the Licensee or a Sub-licensee during the longer of the following periods, namely: (1) the period in a country where such manufacture, sale or other disposal would otherwise infringe the Valid Claims of Patents which is for the life of such Patents; or (2) in a country where there are no Valid Claims of Patents or such Valid Claims of Patents have expired, the period which runs for 10 years from First Commercial Sale of any Licensed Product; provided that where both the manufacture and the sale or other disposal of a Licensed Product would otherwise infringe the Valid Claims of Patents, the relevant Chargeable Transaction shall be the sale or other disposal; and where such sale or other disposal is made by or on behalf of the Licensee or Sub-licensee to another company within its Group for further sale or disposal then the Chargeable Transaction shall be the first sale or other disposal to a third party outside that Group, and provided always that if on the sale or disposal of Licensed Products by or on behalf of the Licensee, Sub-licensee or relevant Group company (as the case may be) the Licensed Product is not in Final Form

then the Chargeable Transaction shall be the first sale of Licensed Product which is in Final Form;

"Connected Persons" has the meaning set out in section 839 of the Income and Corporation Taxes Act 1988;

"Deductions" means:

(a) normal trade discounts or credits actually given;

(b) provided they are separately charged on the relevant invoice, any costs of packaging, insurance, carriage, and freight;

(c) any value added (or similar) tax, any import duties or similar applicable government levies;

(d) amounts actually repaid or credited and allowances given by reason of chargebacks, retroactive price reductions or billing errors and rebates (including government-mandated rebates) and cash, credit or free goods allowances;

(e) amounts refunded or credited for Licensed Product which was rejected, spoiled, damaged, outdated or returned; and

(f) any amounts entitled to be deducted under Clause 10.1;

"Development Plan" the indicative plan contained in Schedule 4 relating to the development, registration, manufacture, commercial exploitation and marketing of Licensed Products by or on behalf of the Licensee (as such plan may be amended from

time to time by the Licensee) such plan to be in accordance with that adopted by and being undertaken by the Licensee, the expense of which is incorporated in the Licensee's financial budget as approved by the board of directors of the Licensee;

"Effective Date" means the date of this Agreement;

"Europe" the member states from time to time of the European Union;

"Field" the treatment of wounds, including the prevention of scarring, acceleration or promotion of healing and the treatment and/or prevention of fibrotic disorders at all body sites in humans and in animals;

"Final Form" means fully formulated, in final form packed for ultimate consumer use and suitable for purchase by a purchaser or distributor who is not undertaking substantial product support or marketing (e.g. a drug wholesaler, a pharmacist or a group of pharmacists, a chain of drug retailers or a hospital or central purchasing department for a group of hospitals);

"First Commercial Sale" (i) in respect of the United States of America, the first commercial sale by or on behalf of the Licensee or its Sub-licensees of Licensed Product in that country;

(ii) in respect of each of the countries from time to

time in Europe, the first commercial sale by or on behalf of the Licensee or its Sub-licensees of Licensed Product in any of the countries in Europe;

(iii) in respect of Japan, the later of the first commercial sale by or on behalf of the Licensee or its Sub-licensees of Licensed Product in: (a) United States of America; or (b) Europe; and

(iv) in respect of all remaining countries of the world (other than any country in Europe, the United States of America and Japan) taken together as one territory the first commercial sale by or on behalf of the Licensee or its Sub-licensees of Licensed Product in any country of that territory;

"Group" means in relation to either party or a Sub-licensee, and from time to time, any holding company or any subsidiary (as defined in sections 736 and 736A Companies Act 1985) of that party or Sub-licensee and any other subsidiary or holding company of that party's or Sub-licensee's holding company;

"Know-How" means the technical information and data specified in Schedule 2 and any other information and/or data disclosed to the Licensee by BTG pursuant to this Agreement;

"Licensed Product" means:

(a) mannose-6-phosphate; or

(b) any product made or sold or otherwise disposed of, in any country by, or on behalf of, the Licensee or a Sub-licensee, and which:

(i) falls within the scope of, or utilises any method or process which falls within the scope of Valid Claims of any of the Patents; or

(ii) embodies or utilises any of the Know-How;

"Licensee Inventions" means any and all discoveries and inventions which are owned or controlled by or licensed to the Licensee or any Sub-licensee and which relate to the inventions which are the subject of the Patents and which arise from any evaluation, trial, research and/or development, by or on behalf of the Licensee or Sub-licensee of Licensed Products;

"Licensee Results" means any and all technical data, know-how, software, notes, chemical compounds, biological material, reports, pre-clinical and clinical data, documentation relating to regulatory submissions and marketing authorisations, and all other material owned or controlled by or licensed to the Licensee or any Sub-licensee which arise from any

evaluation, trial, research and/or development by or on behalf of the Licensee or Sub-licensee of Licensed Products;

"Major Territory" means any of the United States of America, Spain, Italy, France, Germany or the United Kingdom;

"Marketing Authorisation" means regulatory approval granted to a Related Company from the body or bodies having responsibility for the regulation of medicinal products in a particular market for Licensed Products to be marketed and sold;

"Net Selling Price" means the aggregate of the price of:

(a) Licensed Products; and

(b) any plaster, bandage, adsorbent pad, dressing, or other supporting material or carrier or diluting material or liquid only where Licensed Products are incorporated into or contained in or on the same,

which are the subject of a Chargeable Transaction calculated as follows:

(i) in the case of an arm's length sale or other disposal, the gross price as charged or invoiced, less any Deductions;

(ii) in the case of a sale or other disposal

which is not at an open market price or which is for non-cash consideration the open market price in the country where the transaction was effected less any Deductions;

(iii) in the case of combination products where the Licensed Product is sold together with another active medicinal or pharmaceutical product which is not itself a Licensed Product (and does not comprise supporting or other materials referred to in (b) above), and the Licensee or Sub-licensee receives royalties or other sums without distinction as to the amount deriving from Licensed Products, then the Net Selling Price shall be calculated in accordance with the following formula:

$$A \times \frac{B}{B + C}$$

where:

A means the amount received by the Licensee or Sub-licensee in respect of the combination package; and

B means the amount that would have been received by the Licensee or Sub-licensee in respect of the Licensed Products (as calculated in (a) and (b) above) if sold separately at the open market price in the country where the

transaction was effected; and

C means the amount that would have been received by the Licensee or Sub-licensee in respect of the other product(s) or materials if sold separately at the open market price in the country where the transaction was effected,

less Deductions equal to:

$$D \times \frac{B}{B + C}$$

where D is the total Deductions recorded by the Licensee or Sub-licensee in respect of the combination product and B and C are as defined above;

save that if for the purposes of sub-paragraph (iii) the open market price is not determinable then it shall be determined by agreement between the Parties (acting in good faith) or failing such agreement, as determined by a reputable independent auditor appointed by agreement between the Parties (or failing which the President of the Institute of Chartered Accountants of England and Wales for the time being) with such auditor acting as an expert not an arbitrator.

In such circumstances the cost of appointment of the auditor shall be borne equally between the parties;

"Phase III Clinical Trial" an investigation or a series of investigations to assess the efficacy and safety of a Licensed Product as a medicinal product, such investigation being carried out on a significantly large group of patients with the objective of obtaining Marketing Authorisation;

"Patents"

(i) the patents and applications for patents specified in Schedule 1 and any patent which may be granted pursuant to any of such applications; and

(ii) any patents and applications corresponding to such patents and applications which may be granted to or made by BTG in other countries; and

(iii) any reissues or extensions of such patents, any supplementary protection certificates relating to such patents which are granted to BTG, and any divisions and continuations of such applications;

"Patent Territories" means the territories covered by subsisting Patents;

"Related Company" means the Licensee; any Sub-licensee; any Connected Person of the Licensee or any Sub-

licensee; each member of each Group including the Licensee or any Sub-licensee; and each company acting on behalf of any of the above;

"Sub-licensee" the recipient of a sub-license of any of the licenses granted to the Licensee by BTG hereunder; and

"Valid Claims" shall mean either:

(a) a claim of an issued and unexpired patent included within the Patents, which has not been permanently revoked, unenforceable or held invalid by a decision of a court or other governmental agency of competent jurisdiction, whose decision is unappealable or un-appealed within the time allowed for appeal, and which has not been admitted to be invalid or unenforceable through reissue or disclaimer or otherwise; or

(b) a claim of pending patent application included within the Patents which claim was filed and is being prosecuted in good faith and has not been abandoned or finally disallowed without the possibility of appeal or refiling of the application.

2 Grant of Licences

2.1 *Licences*

BTG grants to the Licensee, subject to the provisions of this Agreement:

2.1.1 exclusive licences under the Patents to manufacture, have manufactured, use, import, market, have marketed, sell, have sold, or otherwise dispose of Licensed Products in the Field in the Patent Territories; and

2.1.2 a non-exclusive worldwide licence for the purposes set out in clause 2.1.1 to use the Know-How and the copyright in the Know-How in the Field.

2.2 *Scope of Licences*

2.2.1 The licences in clause 2.1 are granted only for the purposes of manufacturing, having manufactured, using, importing, marketing, having marketed, selling, having sold or otherwise disposing of Licensed Products during the life of this Agreement.

2.2.2 BTG shall not grant rights to use the Know-how to any third party during the period from the Effective Date to the date falling ten years after the date when a Licensed Product is first put on the market within Europe by or on behalf of the Licensee or any Sub-licensee.

2.3 *Formal Licences*

BTG shall, at the request of the Licensee, execute any further formal document that may be necessary to give effect to this Agreement in any country. Until such licence shall be granted formally, this Agreement shall take effect as such licence.

2.4 *Sub-Licensing*

The Licensee shall be entitled to grant sub-licences of its rights under this Agreement to any person provided that the Licensee shall comply with and the sub-licence shall be granted on the terms and conditions set out in Schedule 3 to this Agreement.

SCHEDULE 1

The Patents

Title: Scar Prevention

Granted Patents **Country**	**Granted Patent Number**	**Date of Grant**	**Expiry Date**
United Kingdom	2,265,310	25 September 1996	16 March 2013
United Kingdom	2,299,025	27 November 1996	16 March 2013
Australia	667887	30 July 1996	16 March 2013
Austria	EP0728006	11 October 2000	16 March 2013
Belgium	EP0728006	11 October 2000	16 March 2013
Denmark	EP0728006	11 October 2000	16 March 2013
France	EP0728006	11 October 2000	16 March 2013
Germany	EP0728006	11 October 2000	16 March 2013
Greece	EP0728006	11 October 2000	16 March 2013
Ireland	EP0728006	11 October 2000	16 March 2013
Israel	105079	16 September 1998	16 March 2013
Italy	EP0728006	11 October 2000	16 March 2013
Korea, South	0249136	22 December 1999	16 March 2013
Luxembourg	EP0728006	11 October 2000	16 March 2013
Monaco	EP0728006	11 October 2000	16 March 2013
Netherlands	EP0728006	11 October 2000	16 March 2013
New Zealand	249915	10 December 1996	16 March 2013
Norway	306808	27 December 1999	16 March 2013
Portugal	EP0728006	11 October 2000	16 March 2013
Singapore	9608660-8	04 January 2002	16 March 2013
South Africa	93/1869	30 November 1994	16 March 2013
Spain	EP0728006	11 October 2000	16 March 2013
Sweden	EP0728006	11 October 2000	16 March 2013
Switzerland	EP0728006	11 October 2000	16 March 2013
USA	5,520,926	28 May 1996	28 May 2013
Patent Application **Country**	**Application Number**	**Application Date**	**Expiry Date**
Canada 2130805	93/516357	16 March 1993	16 March 2013
Japan	~~9608660-8~~	16 September 1994	16 March 2013

Granted Patents **Country**	**Granted Patent Number**	**Date of Grant**	**Expiry Date**
United Kingdom	2,316,002	23 September 1998	31 July 2017
Australia	721224	12 October 2000	31 July 2017
South Africa	97/7151	28 April 1999	11 August 2017
USA	6093388	25 July 2000	31 July 2017
Patent Applications **Country**	**Application Number**	**Application Date**	**Expiry Date**
United Kingdom	97934624.4	31 July 1997	31 July 2017
Austria	97934624.4	31 July 1997	31 July 2017
Belgium	97934624.4	31 July 1997	31 July 2017
Canada	2261988	31 July 1997	31 July 2017
Denmark	97934624.4	31 July 1997	31 July 2017
Finland	97934624.4	31 July 1997	31 July 2017
France	97934624.4	31 July 1997	31 July 2017
Germany	97934624.4	31 July 1997	31 July 2017
Greece	97934624.4	31 July 1997	31 July 2017
Ireland	97934624.4	31 July 1997	31 July 2017
Italy	97934624.4	31 July 1997	31 July 2017
Japan	98/509472	31 July 1997	31 July 2017
Luxembourg	97934624.4	31 July 1997	31 July 2017
Monaco	97934624.4	31 July 1997	31 July 2017
Netherlands	97934624.4	31 July 1997	31 July 2017
Portugal	97934624.4	31 July 1997	31 July 2017
Spain	97934624.4	31 July 1997	31 July 2017
Sweden	97934624.4	31 July 1997	31 July 2017
Switzerland	97934624.4	31 July 1997	31 July 2017