

**IN THE UNITED STATES DISTRICT
COURT FOR THE SOUTHERN DISTRICT
OF TEXAS HOUSTON DIVISION**

CELLTEX THERAPEUTICS
CORPORATION,
Plaintiff,

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v.

R BIO CO. LTD. and HUMAN BIOSTAR,
INC.,
Defendants.

Case No. 4:18-CV-1901

**SPECIAL MASTER’S FINDINGS, RECOMMENDATIONS, AND PROPOSED ORDER
REGARDING DEFENDANTS’ MOTION TO INSPECT PREMISES**

Pursuant to FRCP Rule 53 the Special Master makes the following findings, recommendations and proposed order as follows:

1. On June 8th, 9th, 15th, 23rd and 30th the Master held hearings on a series of motions to compel filed by both parties. On June 15th, 23rd and 30th the Master heard Defendants’ motion to compel inspection of Plaintiff’s premises and procedures. The Master considered all the related responses, replies, sur-replies, rejoinders, exhibits, and arguments, such that the Master has now considered all filings and exhibits and heard all arguments relating to the documents described in footnote 1 below.¹

¹ The Master has now considered all filings which includes:

1. Defendants’ First Request for Permission to Enter Property Possessed or Controlled by Plaintiff (dated May 14, 2019);
2. Plaintiff’s Objection to and Denial of Defendants’ First Request to Enter Property (dated June 12, 2019);
3. Defendants’ Motion to Compel Inspection of Plaintiff’s Premises (dated November 11, 2019);
4. Plaintiff’s Response to Defendants’ Motion to Compel Inspection of Lab (dated December 10, 2019); and
5. Defendants’ Reply in Support of Motion to Compel Inspection (dated April 7, 2020).

R Bio's Motion to Compel Inspection

2. After reading the motion, response, and considering the arguments offered by counsel, the Master finds that an inspection is warranted and should be permitted. The Master finds that the inspection parameters contained in Exhibits A and B hereto are reasonable; and that R Bio is allowed to view any Celltex procedures it wishes but only as those procedures occur in the ordinary course of business and only at Celltex' convenience; and that only R Bio's expert Dr. Metzker is allowed into the "clean room", and then only under the supervision of a Celltex chaperone; and that while in the clean room Dr. Metzker may only ask such questions such as "What is that?", or "What is in it?", or "What is he/she doing now?". The Special Master accepts Celltex's invitation to be present during this inspection and intends to determine whether or not any questions Dr. Metzker poses during the inspection of the clean room are appropriate and, if not, to instruct that those questions not be answered and reserves the authority to shut down the inspection should he feel it necessary.

3. The Special Master further directs the parties to confer in good faith on the details, such as time of inspection, the number of necessary visits, and how the information in Exhibit A is to be provided during the inspection. All visitors, on the occasion of the inspection, must have a current negative Covid-19 test result before entering any part of the lab premises.

SIGNED this the 23RD day of July, 2020.

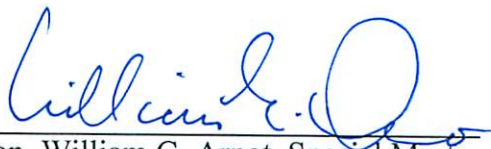

Hon. William G. Arnot, Special Master

Exhibit A: Site Inspection (in the ordinary course of business)

I. Creation of Media and Reagents

The creation of media and reagents is governed by Celltex MF-007, titled *Reagent and Media Preparation* (Celltex 002456-002459). This Standard Operating Procedure relates to the manufacturing of CTGM, CTSE, and CTcgs medias, as well as the reagent preparations (*i.e.*, stock solutions) for these medias. *See* Celltex 002457. MF-007 references eight documents, MF-007-1 through MF-007-8, some of which are described in more detail below.

A. MF-007-1: Preparation of Reagents for Media (CELLTEX 011081-011356). While in the “clean room” Dr. Metzker intends to witness the manufacturing and recording to prepare all stock reagents, such as Reagents 1-6, 8 listed below, as well as any other stock reagents or stock solutions used for media preparation:²

- Reagent 1: *N*-Acetyl-L-cysteine stock
- Reagent 2: Hydrocortisone stock
- Reagent 3: L-Ascorbic acid stock
- Reagent 4: Calcium chloride stock
- Reagent 5: Insulin stock
- Reagent 6: EGF stock
- Reagent 8: bFGF stock

B. MF-007-2: Sterilization and Aliquoting of Prepared Reagents (Ver 2.2: CELLTEX 011046-011047) and Reagent Filtration and Aliquot (Ver. 3.0: CELLTEX 011048). While in the “clean room” Dr. Metzker intends to witness the aliquoting and recording of all stock reagents, such as those reagents created in MF-007-1, the recording of which should include, but not be limited to, labeling each aliquot with name, lot number, QC request, and expiration date on form MF-007-2.³

C. MF-007-3: CTSE Media Preparation (CELLTEX 011059-011060). While in the “clean room” Dr. Metzker intends to witness the manufacturing, aliquoting, and recording of CTSE Media.⁴

² Each preparation of stock reagents or stock solutions should be performed according to its latest protocol version along with all chemicals used, all equipment used, and the steps conducted to prepare each stock reagent or stock solution.

³ The aliquoting of each stock reagents, stock solutions, or culture media should be performed according to its latest protocol version along with all chemicals used, all equipment used, and the steps conducted to prepare each stock reagent, stock solution, or culture media.

⁴ The preparation and aliquoting of CTSE media should be performed according to its latest protocol version along with all chemicals used, all equipment used, and the steps conducted to prepare and aliquot the CTSE media.

- D. MF-007-4: CTGM Media Preparation (CELLTEX 011067-011068).** While in the “clean room” Dr. Metzker intends to witness the manufacturing, aliquoting, and recording of CTGM Media.⁵
- E. MF-007-5: CTcgs Media Preparation (CELLTEX 011071-011072).** While in the “clean room” Dr. Metzker intends to witness the manufacturing, aliquoting, and recording of CTcgs Media.⁶
- F. MF-007-6: CTFZ Media Preparation (CELLTEX 011079).** While in the “clean room” Dr. Metzker intends to witness the manufacturing, aliquoting, and recording of CTFZ Media.⁷

II. Culturing

Culturing is governed by MF-006, titled *Mesenchymal Stem Cells (MSCs): Isolation, Culturing, and Cryopreservation (Banking to Final Product Formulation)*. See CELLTEX 002048-002062, section 9.0 – Cell expansion and cryopreservation, such as MBR-001 (Fat to P2 [banking]), MBR-002 (P2 [thawing] to P4 [outgoing]), MBR-003 (P1 [thawing] to P2 [banking]), MBR-004 (P3 [thawing] to P4 [outgoing]), MBR-017 (P0 [thawing] to P2 [banking]).

A. MBR-001: Human mesenchymal stem cell recovery from adipose tissue: Fat to P2 (banking). See CELLTEX 011410-011429. While in the “clean room” Dr. Metzker intends to witness the isolation/culturing and recording of one Celltex client’s human mesenchymal stem cells (“MSCs”) from step 1-1 through step 3-12.⁸

B. MBR-002, steps 1-1 to 1-11: Human adipose tissue derived mesenchymal stem cell recovery, growth, and packaging: P1/P2 (Thawing) to P3/P4 (Outgoing). See CELLTEX011430-011458. While in the “clean room” Dr. Metzker intends to witness the thawing/culturing and recording of one Celltex client’s human mesenchymal stem cells (“MSCs”) from step 1-1 to step 1-11.⁹

⁵ The preparation and aliquoting of CTGM media should be performed according to its latest protocol version along with all chemicals used, all equipment used, and the steps conducted to prepare and aliquot the CTGM media.

⁶ The preparation and aliquoting of CTcgs media should be performed according to its latest protocol version along with all chemicals used, all equipment used, and the steps conducted to prepare and aliquot the CTcgs media.

⁷ The preparation and aliquoting of CTFZ media should be performed according to its latest protocol version along with all chemicals used, all equipment used, and the steps conducted to prepare and aliquot the CTFZ media.

⁸ The isolation/culturing of the Celltex client’s MSCs should be performed according to the latest MBR-001 protocol version along with all chemicals used, all equipment used, and the steps conducted to isolate and culture such MSCs. For step 2-4, Dr. Metzker or other R Bio representatives do not need to be present for every two-day media change, just the last media change prior to starting step 3-1.

⁹ The thawing/culturing of the Celltex client’s MSCs should be performed according to the latest MBR-002 protocol version along with all chemicals used, all equipment used, and the steps conducted to thaw and culture such MSCs.

C. MBR-002, steps 5-1 to 5-29: Human adipose tissue derived mesenchymal stem cell recovery, growth, and packaging: P1/P2 (Thawing) to P3/P4 (Outgoing). See CELLTEX011430-

011458. While in the "clean room" Dr. Metzker intends to witness the Process Method of one Celltex client's human mesenchymal stem cells ("MSCs") from step 5-1 to step 5-29 for IV and/or IN routes of administration.¹⁰

D. MF-006, see section 11.0: bank-to final product formulation phase (CELLTEX 002054). See also MF-005 titled, *Shipping Finished Product to Clinical Sites* (CELLTEX011357-011369). While in the "clean room" Dr. Metzker intends to witness the packaging and recording of one Celltex client's human mesenchymal stem cells ("MSCs") for therapy at clinical sites.¹¹

Exhibit B: Schedule

1. Dr. Metzker must have a current negative Covid-19 test before he can enter the clean room.
2. The Celltex lab manager will chaperone Dr. Metzker while in the clean room.
3. Regarding the following steps from Exhibit A above:
 - a. I.A – Counsel for R Bio will be notified as to a convenient time when Celltex will perform this step.
 - b. I.B - This is performed after 1.A has been done. Both I.A and I.B happen on the same day.
 - c. I.C and I.E are based on the number of tissues that are expected on a weekly basis. Counsel for R Bio will be notified when Celltex is ready to schedule the performance of these steps.
 - d. I.D and I.F: Celltex will perform these steps when Dr. Metzker comes over for inspection.
 - e. II.A - Section 1- This is performed when tissue is extracted, tested by QC and released for manufacturing.
 - f. Section 2- This is performed the following day of performing Section 1.
 - g. Section 3 - This will depend on when the cells get confluent. Will be a few days after Section 1 is performed.
 - h. II. B: This is usually performed Tuesday to Thursday based on the outgoing schedule.
 - i. II. C - Outgoing is usually performed Monday to Thursday.
 - j. I. D - This is also performed for outgoing.

¹⁰ The Process Method of the Celltex client's MSCs should be performed according to the latest MBR-002 protocol version along with all chemicals used, all equipment used, and the steps conducted to perform the final formulation of such MSCs.

¹¹ The Shipping to Clinical Sites of the Celltex client's MSCs should be performed according to the latest MF-005 protocol version along with all chemicals used, all equipment used, and the steps conducted to perform the shipment of such MSCs to clinical sites.

Note: If this is scheduled a week in advance, Dr. Metzker can observe II.B, II.C and II.D in the morning. Then after lunch, he can observe I.D and I.F, and, *possibly*, II.A with advance notice.