UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF FLORIDA
Ft. Lauderdale Division

CASE NO.: 0:12-cv-60739-CIV-SCOLA/OTAZO-REYES

BIOAXONE BIOSCIENCES, INC., a Florida corporation, as successor in interest to Bioaxone Therapeutique, Inc., a Canadian Business corporation,

Plaintiff,

vs.

NORDION INC., a Canadian corporation, formerly known as MDS INC., NORDION (CANADA) INC., a Canadian corporation, formerly known as MDS (CANADA) INC., NORDION (US), INC., a Delaware corporation, formerly known as MDS PHARMA SERVICES (US) INC.; a Nebraska corporation, and RICERCA BIOSCIENCES, LLC., a Delaware Limited Liability Company,

Defendants.
_____/

DEFENDANT NORDION (US), INC.'S STATEMENT OF UNDISPUTED MATERIAL FACTS WITH RESPECT TO ITS MOTION FOR SUMMARY JUDGMENT

Pursuant to Local Rule 56.1(a) of the United States District Court for the Southern District of Florida, Defendant Nordion (US), Inc. ("Nordion US") submits the following Statement of Material Facts as to which there is no genuine issue in dispute:

1. Plaintiff, Bioaxone Biosciences, Inc. ("Bioaxone"), is a Florida corporation, with its principal place of business in Ft. Lauderdale, Florida. Second Amended Complaint ("Complaint") [DE 63], ¶ 6. Bioaxone was incorporated on May 10, 2011 by Lisa McKerracher, Ph.D. ("Dr. McKerracher.") Deposition of Lisa McKerracher, Ph.D., taken on May 30, 2013 ("McKerracher Depo.") at 19, 41, attached as Exhibit A (without exhibits). From the time of incorporation through the present time, Dr. McKerracher has been an officer, director and

shareholder of Bioaxone. *Id.* at 24-27. Dr. McKerracher is the chief executive officer of Bioaxone. *Id.* at 26.

2. Defendant, Nordion (US), Inc. ("Nordion US"), is a Delaware corporation, authorized to do business in the State of Florida. Complaint, ¶ 12.

3. In its Second Amended Complaint, Bioaxone joined Nordion Inc. ("Nordion") and Nordion (Canada) Inc. ("Nordion Canada") in the case previously filed only against Nordion US. Bioaxone alleges that Nordion was the parent of Nordion Canada and Nordion US and that Nordion was in the business of providing "clinical and laboratory research services, including discovery and early stage/preclinical business to pharmaceutical companies…" and that Nordion provided such service through the employees of its subsidiaries, Nordion Canada and Nordion US, using a business unit name of MDS Pharma Services. Complaint, ¶ 15.

4. Bioaxone Therapeutique, Inc. ("Therapeutique") is a Canadian corporation which at all material times had its principal place of business in Quebec, Canada. Complaint, ¶ 6. Between 2000 and around 2010, Dr. McKerracher was a shareholder, officer and director of Therapeutique. McKerracher Depo. at 19, 41.

5. On or about April 15, 2003, Therapeutique's president, Pierre Caouette, signed a Protocol Order Form ("Protocol Order Form") with MDS Pharma Services for Assigned Study Number 0307301 for the preparation, qualification and storage of a master cell bank ("Master Cell Bank") to be used connection with Therapeutique's development of a new drug called "Cethrin" that Therapeutique was developing to treat acute spinal cord injuries. McKerracher Depo. at 74. Protocol Order Form, Exhibit B (Exhibit 3 to McKerracher Depo). The Protocol Order Form included the following language:

> MDS Pharma Services warrants that work performed pursuant to this order will be performed in accordance with the terms of the protocol in compliance with all applicable GLP [Good Laboratory Practice] or cGMP [(Current) Good Manufacturing Practice] guidelines. MDS Pharma Services makes no other expressed or implied warranties including merchantability or fitness for a particular purpose of any work performed or information or products supplied by it. **In no event shall MDS Pharma Services' liability, if any, for damages relating or arising out of this Study exceed the fees paid to MDS Pharma Services under this order.**

Protocol Order Form, Exhibit B (Emphasis added).[1]

6. Plaintiff alleges that Nordion agreed to prepare the Master Cell Bank using good manufacturing practice ("GMP"), which Plaintiff claims is mandatory in pharmaceutical and biopharmaceutical manufacturing and is enforced by the Food and Drug Administration ("FDA"). According to Plaintiff, GMP requires the use of animal-free raw materials in the manufacture of master cell banks. Complaint, ¶ 21, 22, 23, 24.

7. Dr. McKerracher, designated as Bioaxone's corporate representative, testified that there was no agreement signed regarding the Master Cell Bank work. McKerracher Depo. at 192. The work was done based only on the Protocol Order Form. McKerracher Depo. at 192. The price listed on the Protocol Order Form for the Master Cell Bank was $45,791. Exhibit B. The Protocol Order Form does not include any provision which requires or specifies that the Master Cell Bank is to be created using animal-free raw materials. *Id.*

8. MDS Pharma Services' Protocol No. P-2003-04, pertaining to the Preparation of Bacterial Cell Banks, provided, in pertinent part, at Section 3.2 entitled: "Raw materials for cell cultures:"

> If the Sponsor wishes MDS to acquire the raw materials from a commercial source approved by the Sponsor, advise Client Services. The raw materials will be charged to the Sponsor at cost.

Protocol No. P-2003-04, Exhibit D (filed under seal).

9. Dowpharma, a division of the Dow Chemical Company ("DOW"), was the manufacturer of the drug substance for Therapeutique. McKerracher Depo. at 130-31. Prior to the time MDS Parma Services began creating the Master Cell Bank, Therapeutique discussed the cell bank and the raw materials to be used in the Master Cell Bank with DOW. *Id.* at 90. On March 04, 2003, Jon Benson ("Benson") of DOW sent an email to Dana Zbehlik Lasko ("Dr. Lasko"), Therapeutique's Director of Product Development, and Helen Paparis ("Ms. Paparis"),

[1] Because the language is clearer in the copy of a subsequent Protocol Order Form signed by Therapeutique using the same form, it is attached as Exhibit C (Exhibit 21 to McKerracher Depo.).

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Therapeutique's Director of Contract Manufacturing, discussing the raw materials to be used in the Master Cell Bank. Benson March 04, 2003 Email, Exhibit E. The three raw materials were LB Broth, Glycerin and kanamycin. *Id.* In the email, Benson listed the components to be used for the Master Cell Bank and Benson told Dr. Lasko and Ms. Paparis that:

> As per our discussion in last week's meeting (28 Feb), this bill of materials has been modified to use "animal free" products. It is Dow BCMS's position to move away from using animal derived components and substitute with non-animal derived due to issues surrounding BSE. **The LB Broth and the Glycerin are the components that have been changed to comply with this requirement.** To ensure that we understand your needs and that you understand our position, please respond to this email if you are in agreement.

At the end of the email, Benson listed the raw materials to be used as:

> APS-Select LB Broth Base- Becton Dickinson #292438-RMT-130
> **Kanamycin Solution- Sigma #K0254-RMT-124**
> Glycerin- JT Baker # 2143 - RMT-013

Exhibit E (Emphasis added).

10. On March 23, 2003, Dr. Lasko wrote back to Benson expressing Therapeutique's agreement. *Id.*

11. On May 6, 2003, Dr. Lasko sent an email to Rod Shivley ("Shivley"), Laboratory Supervisor for MDS Pharma Services in Bothell, Washington, providing MDS Pharma Services with instructions prepared by DOW for the creation of the Master Cell Bank. Lasko May 6, 2003 Email, Exhibit F (Exhibit 4 to McKerracher Depo.). The instructions listed the raw materials to be used as:

> LB vegetable based (such as: select APS LB Broth litrepak, cat # Becton Dickenson 292724)
> Glycerol: non-animal origin (Does MDS have a supplier?)
> Kanamycin

Exhibit F.

12. On May 8, 2003, Ms. Paparis sent an email to Shively instructing him to:

> [G]o ahead with ordering the …**kanamycin (from Sigma)**. It is much easier for us if you purchase the required raw materials as we are not equipped to send you GMP grade materials ourselves. So thank you for ordering the goodies on our

> behalf. We will obviously cover the costs of the raw materials you purchase on our behalf for our cell banking.

Paparis May 8, 2003 Email, Exhibit G (filed under seal) (Exhibit 5 to McKerracher Depo.).

13. After receiving the DOW instructions and Therapeutique's directions as to raw materials, MDS Pharma Services prepared the form for the Master Batch Record. Master Batch Record, Exhibit H (Exhibit 7 to McKerracher Depo.). The Master Batch Record is the road map setting out in advance all aspects of creating the Master Cell Bank. McKerracher Depo. at 119-120, 121-22. It is a 20-page document that set out in detail every step to be taken and the raw materials to be used. Exhibit H. MDS Pharma Services prepared Master Batch Record with blank spaces next to each line item so that each person who completed each step could sign in the designated space to show that the task had been completed. McKerracher Depo. at 120. The form included an additional space at each line item for the supervisor to sign after every event was completed. Exhibit H. The first page of the blank Master Batch Record form listed the raw materials to be used in the Master Cell Bank. *Id.* The Master Batch Record form included not only the name of the raw materials but also the name of the manufacturer and the catalog number for each raw material. *Id.* When MDS Pharma Services created the form it listed the raw materials as follows:

Item	Source	Catalog Number	RM Number	Exp. Date	Quantity	Initial/Date
LB Broth, Animal Free, Vegetable Base	Remel	112439 Custom Manufacture)			1000 mL.	
Kanamycin, Sterile	Sigma	K0254			20 mL.	
Glycerol, Animal Free Sterile					200 mL.	

Exhibit H.

14. The front page of the Master Batch Record included places for both the Director of Product Development and the Quality Assurance officer of the sponsor, in this case Therapeutique, to sign to confirm that it approved of the plan of action and raw materials set out in the Master Batch Record form. Next to the signature lines were the words "Approved By." *Id.*

15. Before the work began, MDS Pharma Services sent the blank Master Batch Record form to Therapeutique so that Therapeutique could review and approve every step of the process and the raw materials to be used in the Master Cell Bank in advance of any of the work being performed. McKerracher Depo. at 120.

16. Two Therapeutique representatives signed the Master Batch Record indicating their approval on behalf of the Director of Product Development and the Quality Assurance officer and returned it to MDS Pharma Services to proceed with creating the Master Cell Bank in accordance with the Master Batch Record. Exhibit H. McKerracher Depo. at 123.

17. The kanamycin listed on page one of the Master Batch Record and approved by the two Therapeutique representatives was the precise kanamycin (1) specified by DOW in Benson's March 04, 2003 email (manufacturer and catalog number), Exhibit E; (2) listed on the Master Batch Record and approved by two Therapeutique employees (manufacturer and catalog number) Exhibit H; and (3) which Therapeutique instructed MDS Pharma Services to purchase (manufacturer name) in Ms. Paparis' May 8, 2003 email. Exhibit G. McKerracher Depo. at 124.

18. The work on the Master Cell Bank was undertaken at MDS Pharma Services' laboratory in Bothell, Washington. *Id.* at 71. The creation of the Master Cell Bank was completed no later than October 3, 2003, when MDS Pharma Services sent Therapeutique its final report. *Id.* at 132-33. Final Report, Exhibit I (filed under seal) (Exhibit 10 to McKerracher Depo.).

19. On June 23, 2003, Nordion Canada (when it was still called MDS (Canada) Inc.) entered into a Drug Development Program Agreement ("Agreement") with Therapeutique. McKerracher Depo. at 107-108. Agreement, Exhibit J (Exhibit 6 to McKerracher Depo.). MDS (Canada) Inc. maintained an office in Quebec, Canada. Complaint, ¶ 9; Defendants, Nordion, Inc. and Nordion (Canada) Inc.'s Answer and Affirmative Defenses. [DE 81], ¶ 9.

20. The Agreement, which MDS (Canada) Inc. entered into on behalf of itself and "its affiliates operating under the Business name MDS Pharma Services," was designed

> to provide the terms and conditions under which [Therapeutique] hereby engages MDSPS to provide services for a project to develop their lead large molecule therapeutic through preclinical and early clinical testing with the ultimate goal of

> conducting an assessment of preliminary evidence for safety and efficacy in treating of acute spinal cord injury, commonly known as the 'clinical proof of concept' study.

Agreement, 1; Exhibit J. The Agreement included a choice of laws clause which provided:

> This Agreement shall be construed, governed, interpreted, and applied in accordance with the laws of the Province of Quebec, applicable to contracts to be performed fully within the Province of Quebec exclusive of its conflicts of laws provisions.

Agreement, ¶ 12.9; Exhibit J.

21. MDS Pharma Services continued to store vials of the Master Cell Bank for Therapeutique until October 31, 2006, when MDS Pharma Services ceased its Biopharmaceuticals operations. McKerracher Depo. at 203. September 7, 2006 Letter, Exhibit K (Exhibit 18 to McKerracher Depo.). On September 7, 2006, MDS Pharma Services advised Therapeutique that it was closing its Biopharmaceuticals unit. *Id.*

22. In or around December 28, 2006, Therapeutique entered into a licensing agreement with a pharmaceutical company called Alseres Pharmaceuticals, Inc. ("Alseres") related to the development and marketing of Cethrin which was still in the development phase. Exhibit L (Exhibit 14 to McKerracher Depo., Bates-Stamp Number Bioaxone 00285). During the course of working with Cethrin, Alseres allegedly requested the certificate of origin of the kanamycin used in the Master Cell Bank from Sigma-Aldrich and after receiving it learned that the Master Cell Bank was created using kanamycin that was not animal-free. McKerracher Depo. at 150-51.

23. In October 2008, Alseres informally advised Therapeutique that it had discovered that the Master Cell Bank created by MDS Pharma Services was not animal-free and on October 23, 2008, Alseres issued a formal report entitled "BA-210 Master Cell Bank (Lot # 0307301-00-01) Discovery of Contamination with Bovine Material, Evidence for non-compliance with cGMP, and Subsequent Actions taken by Alseres." ("Alseres Report"). Alseres Report, at 5. Exhibit L. Complaint, ¶ 37.

24. In paragraph 37 of the Second Amended Complaint, Plaintiff alleges:

> In or about October, 2008, Plaintiff informally became aware for the first time of the contamination and was subsequently provided with a formal status report dated October 15, 2008 informing BIOAXONE that the Master Cell Bank was not GMP compliant.

25. On May 31, 2011, Therapeutique and Plaintiff Bioaxone entered into an Asset Purchase Agreement ("Asset Purchase Agreement") whereby Therapeutique transferred certain assets to Bioaxone. McKerracher Depo. at 46-47; Asset Purchase Agreement, Exhibit M (Exhibit 2 to McKerracher Depo.). At the time Therapeutique and Bioaxone executed the Asset Purchase Agreement, both Therapeutique and Bioaxone were aware of the alleged issues with the Master Cell Bank. McKerracher Depo. at 51. Although the Asset Purchase Agreement expressly enumerates the assets sold to Plaintiff Bioaxone, there is no mention in the Asset Purchase Agreement of the claim brought in this case as having been one of the assets transferred to Plaintiff. Exhibit M, at § 1. The Asset Purchase Agreement included all of the assets transferred by Therapeutique to Bioaxone; the Asset Purchase Agreement was never modified and Therapeutique and Bioaxone never entered into any other agreement transferring assets. McKerracher Depo. at 48, 52.

26. Plaintiff Bioaxone did not file this case until April 26, 2012. [DE 1]. On May 13, 2013, Plaintiff Bioaxone filed the Second Amended Complaint joining Nordion and Nordion Canada as Defendants. [DE 63]. The original Compliant and the Second Amended Complaint include a single claim against "NORDION" (which term Plaintiff defines as collectively referring to Nordion, Nordion Canada and Nordion US) for negligence in connection with the creation of the Master Cell Bank. Complaint, ¶¶ 58-69. Bioaxone claims that "NORDION negligently prepared the Master Cell Bank using kanamycin they purchased that was made in China and that contained beef broth and avian products" and "negligently certified to BIOAXONE the quality assurance and GMP compliance of all raw materials used in preparing the Master Cell Bank." Complaint, ¶¶ 1, 35.

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CERTIFICATE OF SERVICE

We hereby certify that on July 17, 2013 we electronically filed the foregoing with the Clerk of the Court by using the CM/ECF System which will send the foregoing to: ALL COUNSEL and/or INTERESTED PERSONS/CORPORATIONS ON THE ATTACHED SERVICE LIST.

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