IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF SOUTH CAROLINA
ANDERSON DIVISION

Poly-Med, Inc.,	)	
	)	
Plaintiff,	)	Civil Action No.: 8:15-cv-01964-JMC
	)	
v.	)	
	)	
Novus Scientific Pte. Ltd.,	)	
Novus Scientific, Inc., and	)	
Novus Scientific AB,	)	**ORDER AND OPINION**
	)	
Defendants.	)	
	)	

This matter is before the court pursuant to Plaintiff Poly-Med, Inc.'s Motion to Certify Order for Interlocutory Appeal and to Stay the Proceedings, or in the Alternative, to Certify a Question of State Law to the South Carolina Supreme Court and to Stay (ECF No. 257). Defendants Novus Scientific Pte. Ltd., Novus Scientific, Inc., and Novus Scientific AB (collectively "Defendants") filed a response in opposition (ECF No. 262). For the reasons set forth below, the court **DENIES** Poly-Med's Motion to Certify Order for Interlocutory Appeal and to Stay the Proceedings, or in the Alternative, to Certify a Question of State Law to the South Carolina Supreme Court and to Stay (ECF No. 257).

I. RELEVANT FACTUAL AND PROCEDURAL BACKGROUND

Founded by Dr. Shalaby W. Shalaby in 1993, Poly-Med is a South Carolina corporation with its principal place of business at 6309 Highway 187, Anderson, South Carolina 29625. (ECF Nos. 1 at 1 ¶ 1 & 104-1 at 1 ¶ 3.) "Poly-Med designs, develops, and manufactures products and materials [out of bio-absorbable and biodegradable polymers] for use in medical, pharmaceutical and biotechnology applications." (ECF No. 1 at 3 ¶¶ 8–9; *see also* ECF No. 104-1 at 1 ¶ 3.) "Poly-Med has numerous trademarks, more than one hundred thirty patents and

patent applications and has successfully licensed and manufactured technologies found in many commercially available medical applications." (ECF No. 104-1 at 2 ¶ 5.) "In addition to creating its own products and materials, Poly-Med offers manufacturing services and consulting, analytic and research and development services to a variety of firms in the medical, pharmaceutical and biotechnology industries." (*Id.* at ¶ 6.)

In December 2004, a Swedish company called Radi Medical Systems AB ("Radi") applied for a patent entitled "Mesh Implant for Use in Reconstruction of Soft Tissue Defects." (ECF No. 126-2 at 2 ¶ 4.) Radi's goal was "to commercialize the invention in order to reconstruct soft tissue defects to promote optimal healing and tissue restoration." (*Id.*) Even though Radi "possessed the background and know-how regarding degradable polymers, polymerization, and processing into final medical devices," it "did not have all of the physical equipment needed." (*Id.* at 2–3 ¶ 5.)

In early 2005, Poly-Med began negotiations with and eventually entered into a Sale of Materials and License Agreement (the "Agreement") with Radi on or about June 8, 2005. (ECF No. 104-1 at 2 ¶ 7–4 ¶ 15.) The Agreement required Poly-Med to "develop and manufacture at least six different types of Absorbable Composite Meshes[1] for sale to and use by Radi" in hernial repair products." (ECF No. 126-1 at 4 ¶ 2(a).) Additionally, the Agreement contained the

[1] The Agreement defined "Absorbable Composite Mesh" as "any special absorbable composite fibrous constructs absorbed by the human body for specific use in herniated tissues which (i) has not been previously sold or licensed to any other person or entity for product development or commercial application that conflicts with its use by RADI AB in its hernial mesh application; (ii) that falls within the scope of any valid claim of any POLY-MED patent or patent application; or (iii) is manufactured under or using a process that falls within the scope of any Valid Claim of any POLY-MED Patent or POLY-MED Patent Application; or (iv) comprises or makes use of POLY-MED Know-How; or (v) is manufactured under, or using a process constituting, POLY-MED Know-How." (ECF No. 126-1 at 3 ¶ 1(f).)

following provisions relevant to this action:

- This license shall include the right of RADI AB to arrange for manufacture of Select Absorbable Composite Hernial Meshes used in RADI Absorbable Composite Hernial Meshes with an independent manufacturing company at any location selected by RADI AB, at prices and on terms and conditions acceptable to RADI AB; provided however that (i) in no event may RADI AB manufacture, deliver or sell, or cause the manufacture for delivery and sale, of Select Absorbable Composite Meshes except for use in RADI Products for hernial repair; . . . .

(ECF No. 126-1 at 10 ¶ 6(c).)

- RADI AB shall neither acquire nor possess any right, title or interest in or to the POLY-MED Know-How or other POLY-MED Intellectual Property with respect to the specific fiber combinations used in construction, creation, manufacture or production of Absorbable Composite Hernial Meshes. POLY-MED may file patent applications in the United States with respect to any Absorbable Constructs at any time, will have all right, title and interest in and to any patent applications with respect thereto, and will own any and all patents on any Absorbable Composite Mesh developed pursuant to this Agreement.

(*Id.* at 11 ¶ 7(a).)

- If POLY-MED declines, after RADI AB's written request, to prepare and file or maintain a patent application with respect to a Select Absorbable Composite Hernial Mesh in a specified territory, including but not limited to the United States, RADI AB shall have the right (but not the obligation) to prepare and file or to maintain or prosecute a patent application in such territory in POLY-MED's name and on POLY-MED's behalf, at RADI AB's sole cost and expense, and shall have authority and power in POLY-MED'S name and on POLY-MED's behalf but at RADI AB's expense, to seek, file or execute (and pay the filing fees or other costs associated with) any continuations, continuations-in-part or divisionals thereof and any patents issuing thereon together with all reissues and extensions thereof; provided however that RADI AB shall in all such cases keep POLY-MED advised of the progress of any such applications, continuations, continuations-in-part or divisionals and first consult with POLY-MED about the desired course of action.

(*Id.* at 13 ¶ 8.)

- This Agreement shall be governed by and construed in all matters with respect to the validity, interpretation, legal effect and construction hereof in accordance with the laws of SWEDEN, and in all matters with respect to patent or trademark enforceability, validity, and infringement, in accordance with the patent or trademark laws of the relevant country.

(*Id*. at 27 ¶ 28.)

- [N]either party to this Agreement may assign its rights or delegate its duties without the prior written consent of the other party, which consent shall be in its sole and absolute discretion; . . .

(*Id.* at 28 ¶ 30(a).)

From the group of six proprietary, absorbable surgical meshes, Radi was to select one or two which it believed "hold the most promise for purposes of developing RADI Products . . . ." (*Id.* at 7 ¶ 4(a).) Radi would then "have the exclusive right to use any Select Absorbable Composite Mesh used by it in the development, manufacture, sale and distribution of its medical products . . . ." (*Id.* at 8 ¶ 5.) Per the terms of the Agreement, "Radi was to compensate Poly-Med for its development work, manufacturing and production of the mesh that took place exclusively in South Carolina." (ECF No. 35-2 at 2 ¶ 11.) In February 2007, Radi selected one prototype surgical mesh which was then developed into a medical device called TIGR®Matrix Surgical Mesh ("TIGR®Mesh"). (ECF No. 126-2 at 4–5 ¶ 14.) In December 2008, Radi transferred its rights under the Agreement to Novus Singapore.[2] (ECF No. 126-5 at 2 ¶ 4.)

Upon receipt of an application, the U.S. Food and Drug Administration ("FDA") issued 510(k)[3] clearance of TIGR®Mesh on January 25, 2010, "for surgical use in 'reinforcement of soft tissue where weakness exists.'" (ECF No. 126-2 at 5 ¶ 17.) Poly-Med helped Novus

[2] Poly-Med contends that it was told by Radi that the Agreement was assigned to Novus Singapore, but a "Transfer Agreement" provided to Poly-Med reveals that the Agreement transferred from Radi to Novus USA. (*See* ECF Nos. 35-2 at 3 ¶¶ 13, 15 & 35-3 at 1.)

[3] "A 510(k) is a premarket submission made to FDA to demonstrate that the device to be marketed is at least as safe and effective, that is, substantially equivalent, to a legally marketed device (21 CFR 807.92(a)(3)) that is not subject to PMA." FDA Premarket Notification 510(k), http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/HowtoMarketYourDevice/PremarketSubmissions/PremarketNotification510k/default.htm (last visited Dec. 5, 2016). "Submitters must compare their device to one or more similar legally marketed devices and make and support their substantial equivalency claims." *Id.*

Defendants obtain FDA approval of the TIGR®Mesh by (1) maintaining their Device Master Record[4] ("DMR") in South Carolina and (2) allowing them to use "confidential and proprietary information located in South Carolina and substantial consultation, testing and assistance." (ECF No. 38-3 at 4 ¶¶ 19, 25.) After receiving 510(k) clearance, Novus Singapore began marketing and selling TIGR®Mesh. (ECF No. 126-5 at 2 ¶ 5.)

On September 27, 2010, Waleed Shalaby, Poly-Med's Chief Science Officer ("CSF"), sent an e-mail to its then President, David Shalaby,[5] in which the CSF observed that a lawyer needed to be contacted because Novus "Defendants were making, selling, and/or using the Medical Device for TRAM flap/breast reconstruction surgery[6]—. . . an application other than hernia repair." (ECF No. 209 at 7 (referencing ECF No. 209-1 at 1).) In response to this information, Poly-Med told Novus Defendants that "it objected to commercialization of the TIGR®Mesh as a 'surgical' mesh rather than a 'hernia' mesh" and allegedly demanded "firm commitments by Novus defendants on further orders for production at substantially increased prices." (ECF No. 104-1 at 16 ¶ 62; *see also* ECF No. 126-5 at 2 ¶ 7.) Then, on September 30, 2010, Poly-Med was informed by a consultant that "it could be inferred from the Novus website that the company is indicating its use for 'soft tissue repair'" and that "if Novus is indeed promoting its use beyond hernia repair, it could be argued that they have violated the terms of the

[4] "A Device Master Record is a compilation of all the instructions, drawings and other records that must be used to produce a product." (ECF No. 38-3 at 4 ¶ 25.) "The term is used in Quality Management Systems that cover product design and production." (*Id.*) "Under FDA regulations, a DMR must be maintained by the manufacturer of any medical device for use in humans." (*Id.* at 4–5 ¶ 25.)

[5] In August 2010, David Shalaby replaced his father as President of Poly-Med. (ECF No. 104-1 at 16 ¶ 61.)

[6] In a TRAM flap procedure (or abdominal wall reconstruction surgery), a section of the abdomen wall is removed and used in breast reconstruction and the mesh is used to repair the hole in the abdomen wall." (ECF No. 104-1 at 16 ¶ 62.)

license agreement and it could thus be terminated." (ECF No. 209 at 8 (quoting ECF No. 209-2 at 6 & 7).) On December 22, 2010, Poly-Med sent a letter to Novus Defendants containing the following language:

> Novus has commercialized the TIGR hernia mesh as a 'surgical mesh' when our agreement clearly identifies product licensure by Novus as a 'hernia' mesh only. We believe this to be a serious issue that needs to be addressed by Novus immediately.

(ECF No. 209-3 at 5.)

On or about February 27, 2013, Novus Singapore transferred its interest in the Agreement to its Swedish sister company, Novus Sweden. (ECF No. 126-8 at 1 ¶ 2.) "Since August 2014, using its own manufacturing procedures, Novus Sweden has manufactured TIGR®Matrix Surgical Mesh in its own production facilities, and has continued to sell TIGR® Matrix Surgical Mesh in accordance with the 510(k) clearance and CE registration." (*Id.* at ¶ 3.) "Novus Sweden has paid and continues to pay royalties to Poly-Med regardless of the end use of TIGR®Matrix Surgical Mesh . . . and regardless of whether Poly-Med or Novus Sweden manufactured the TIGR®Matrix Surgical Mesh." (*Id.* at 2 ¶ 5.) "Poly-Med has accepted royalty payments arising from all end uses." (*Id.*)

On May 8, 2015, Poly-Med filed a Complaint against Novus Defendants alleging four causes of action: breach of contract, tortious interference with contract, violation of the South Carolina Trade Secrets Act ("SCTSA"), S.C. CODE ANN. §§ 39-8-10 to -130 (2016), and violation of the South Carolina Unfair Trade Practices Act ("SCUTPA"), S.C. CODE ANN. §§ 39- 5-10 to -560 (2016). (ECF No. 1 at 13–25.) After Novus Defendants answered the Complaint on March 14, 2016, the parties engaged in discovery. On November 22, 2016, the court granted Poly-Med's Motion for Leave to Amend Complaint (ECF No. 118) and it filed its Amended Complaint on November 29, 2016. (ECF Nos. 149, 153.) Thereafter, on July 6, 2017, the court granted Poly-

Med's Motion for Leave to Amend and Supplement the Amended Complaint (ECF No. 167) and it filed its Second Amended Complaint on July 10, 2017. (ECF Nos. 179, 181.) In the Second Amended Complaint, Poly-Med alleged claims against Novus Defendants for breach of contract, tortious interference with contract and violation of the SCUTPA. (ECF No. 181 at 4 ¶ 89–27 ¶ 160.)

On October 5, 2017, Novus Defendants moved for partial summary judgment on Poly-Med's breach of contract cause of action. (ECF No. 209.) After the parties submitted their Response in Opposition (ECF No. 216) and Reply in Support (ECF No. 222), the court heard argument from the parties on this matter on January 22, 2018. (ECF No. 231.) On April 24, 2018, the court granted Defendants' Motion for Partial Summary Judgment (ECF No. 252).

In the present Motion, Poly-Med requests that the court certify for interlocutory appeal the court's Order and Opinion ("Order) (ECF No. 252) granting Defendants' Motion for partial Summary Judgment (ECF No. 209), and to stay proceedings until the interlocutory appeal is resolved. (ECF No. 257 at 1.) In the alternative, Poly-Med moves the court to certify a question of state law to the South Carolina Supreme Court pursuant to Rule 244 of the South Carolina Appellate Rules and to stay the proceedings until the certified question is answered. (*Id*.) In support of this Motion, Poly-Med states as follows:

1. The Order involves the controlling question of law of whether South Carolina recognizes the continuing-breach theory to extend the life of a breach of contract cause of action;
2. That question of state law is determinative of Poly-Med's breach of contract claims, which the court has ruled are barred by the statute of limitations if they are not extended under the continuing-breach theory;
3. There is a substantial difference of opinion concerning the controlling question of law, which has not yet been the subject of a South Carolina appellate decision;
4. The available state law is clearly insufficient to answer the controlling and determinative question of law;

5. An immediate appeal from the Order may materially advance the ultimate termination of this litigation by avoiding the necessity of a second trial just on Poly-Med's breach of contract claims if the Order is reversed on appeal only after the parties' other claims have been tried; and
6. The proceedings should be stayed until the interlocutory appeal is resolved or the certified question is answered to avoid the extensive duplication of effort that would occur if two trials are held, one limited solely to Poly-Med's breach of contract claims and the second to determine the parties' other claims.

(*Id*.)

In their opposition, Defendants state that (1) Poly-Med has not met the high burden for Section 1292(b) certification, and (2) the Fourth Circuit frowns upon certification of questions after a party receives an adverse decision, and certification is not warranted in any event as sufficient law existed to guide this court. (ECF No. 262).

II. LEGAL STANDARD

A district court may certify an order entered in a civil action for interlocutory review when the court is of the opinion that "(1) its order involves a controlling question of law, (2) as to which there is substantial ground for difference of opinion, and (3) the immediate appeal of the prior order may materially advance the ultimate termination of the litigation." *See* 28 U.S.C. § 1292(b); *Ashmore v. Sullivan*, No. 8:15-CV-00563-JMC, 2017 WL 4074565, at *4 (D.S.C. Sept. 14, 2017). All three elements must be satisfied for certification. *Id.* Whether to certify an order for interlocutory appeal is within the district court's discretion. *See Swint v. Chambers County Comm'n*, 514 U.S. 35, 47 (1995); *Warwick v. S.C. Elec. & Gas Co.*, No. 3:15-CV-04897-JMC, 2016 WL 3085808, at *3 (D.S.C. June 2, 2016).

Rule 244 of the South Carolina Appellate Court Rules provides that the South Carolina Supreme Court in its discretion may answer questions of law certified to it by a federal court, if there are involved in a proceeding before the certifying court "questions of law of this state which may be determinative of the cause then pending in the certifying court when it appears to the

certifying court there is no controlling precedent in the decisions of the Supreme Court." SCACR 244(a). A federal court should certify a determinative question to the South Carolina Supreme Court when "the available state law is clearly insufficient" to resolve the question. *Ashmore v. Sullivan*, No. 8:15-CV-00563-JMC, 2016 WL 6927888, at *1 (D.S.C. Nov. 28, 2016) (quoting *Roe v. Doe*, 28 F.3d 404, 407 (4th Cir. 1994)).

III. ANALYSIS

A. Interlocutory Appeal

"The Fourth Circuit has cautioned that § 1292(b) should be used sparingly and . . . that its requirements must be strictly construed." *Myles v. Laffitte*, 881 F.2d 125, 127 (4th Cir. 1989). First, a controlling question of law is not involved in this case because reversal would not terminate this litigation. A question of law is generally considered to be controlling within the meaning of § 1292(b) only if the action would have been terminated had the district court ruled the opposite way. *Weichert Real Estate Affiliates, Inc. v. Dean Kelby Realty, LLC*, No.: 2:08-cv-2652-RMG, 2010 WL 11530906, at *2 (Dec. 10, 2010) (citing *City of Charleston v. Hotels.Com, LP*, 586 F. Supp. 2d 538, 542 (D.S.C. 2008)). Here, a controlling question of law is not present because even if this court were to certify the issue for interlocutory appeal, the court of appeals were to accept the interlocutory appeal, and the court of appeals were to decide in favor of Poly-Med, both parties would still be before this court to litigate the remaining causes of action and defenses.

Next, there is no substantial ground for difference of opinion because case law from this District supports the court's Order on the Partial Summary Judgment Motion. The court cited ample support for its conclusion that South Carolina would not recognize a continuing-breach theory with respect to Poly-Med's breach of contract claim. (*See* ECF No. 252 at 12-17); *see*

also For Legal Reform v. Rabowsky, No. 3:14-cv-01674-JFA, 2014 WL 6389709, at *4 (D.S.C. No. 14, 2014) (supporting conclusion that South Carolina would not adopt Poly-Med's desired theory in this case). "The mere fact that a party disagrees with the district court's ruling is insufficient to establish that there is a substantial ground for a difference of opinion." *Southern U.S. Trade Ass'n v. Unidentified Parties*, No. 10-1669, 2011 WL 2790182, at *2 (E.D. La. 2011).

Lastly, permitting an immediate appeal would not materially advance the ultimate termination of the litigation, but rather prolong the proceedings. Staying this matter to permit an appeal would only serve to delay the end of the case. Certification "is not intended as a vehicle to provide early review of difficult rulings in hard cases. Nor is it appropriate for securing early resolution of disputes concerning whether the trial court properly applied the law to the facts." *City of Charleston*, 586 F. Supp. 2d at 548 (quoting *Abortion Rights Mobilization, Inc. v. Regan*, 552 F. Supp. 364, 366 (S.D.N.Y. 1982)). Certification of an interlocutory appeal is limited to extraordinary cases where significant effort and expense would be spared by appellate review prior to the entry of final judgment. *Id.* at 542 (internal quotations and citations omitted). Because this litigation will continue before this court regardless of what an appellate court may decide, certifying the order for interlocutory appeal would not materially advance this litigation towards a more efficient and expedient conclusion.

B. Certification of State Law Question

Certification should be denied when sufficient jurisprudence exists to guide the federal court on what the state court would do when confronted with the same fact pattern. *Assurance Co. of Am. v. Penn-America Ins. Co.*, No.: 4:11-cv-03425-RBH, 2013 WL 1282141, at *4 (March 27, 2013). Poly-Med raised certification for the first time after the court issued its Order on Partial Summary Judgment against Poly-Med. Courts "do not look favorably, either on trying to

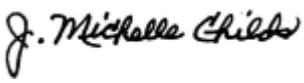
take two bites at the cherry by applying to the state court after failing to persuade the federal court, or on duplicating judicial effort." *S.C. Dep't of Mental Health v. Hoover Universal, Inc.*, Nos. 3:03-4118-JFA; 6:04-1219-JFA, 2006 WL 6463481, at *3 (D.S.C. March 6, 2006) (quoting *Fischer v. Bar Harbor Banking & Trust Co.*, 857 F.2d 4, 8 (1st Cir. 1988)); *see also Hall v. Greystar Mgmt. Servs., L.P.*, 637 F. App'x 93, 100–01 (4th Cir. 2016) (citing with approval decisions from several circuit courts of appeal that uniformly reject granting certification after the issuance of an adverse ruling).

Federal courts in diversity cases apply the law of the forum state. *Erie Railroad Co. v. Tompkins*, 304 U.S. 64, 75 (1930). Where there is no case law from the forum state which is directly on point, the district court attempts to do as the state court would do if confronted with the same fact pattern. *Wilson v. Ford Motor Co.*, 656 F.2d 960 (4th Cir. 1981); *Empire Distributors of N.C. v. Schieffelin & Co.*, 859 F.2d 1200, 1203 (4th Cir. 1988); *Doe v. Doe*, 973 F.2d 237, 240 (4th Cir. 1992). Only if the available state law is clearly insufficient should the court certify the issue to the state court. *Smith v. FCX, Inc.*, 744 F.2d 1378, 1379 (4th Cir. 1984), *cert. denied*, 471 U.S. 1103 (1985). An Article III court sitting in diversity is equipped to opine in this matter, and the court adequately did so.

IV. CONCLUSION

Based on the foregoing, the court **DENIES** Poly-Med's Motion to Certify Order for Interlocutory Appeal and to Stay the Proceedings, or in the Alternative, to Certify a Question of State Law to the South Carolina Supreme Court and to Stay (ECF No. 257).

IT IS SO ORDERED.



United States District Judge

May 29, 2018
Columbia, South Carolina