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

POLY-MED, INC., Plaintiff, v. NOVUS SCIENTIFIC PTE LTD., NOVUS SCIENTIFIC, INC. and NOVUS SCIENTIFIC AB, Defendants.	CIVIL ACTION NO. 8:15-cv-01964-JMC **FINDINGS OF FACT, CONCLUSIONS OF LAW, AND ORDER AND OPINION DENYING POLY-MED'S MOTION FOR PRELIMINARY INJUNCTION**[1]

Plaintiff Poly-Med, Inc. ("Poly-Med"), filed this action against Defendants Novus Scientific Pte. Ltd. ("Novus Singapore"), Novus Scientific, Inc. ("Novus USA"), and Novus Scientific AB ("Novus Sweden") (collectively "Novus Defendants") seeking monetary damages, injunctive, and equitable relief. (ECF No. 1.)

This matter is before the court on Poly-Med's Motion for Preliminary Injunction, which is opposed by Novus Defendants. (ECF Nos. 97 & 126.) For the reasons set forth in detail below, the court **DENIES** Poly-Med's Motion for Preliminary Injunction.

I. FINDINGS OF FACT RELEVANT TO PENDING MOTION

1. 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

[1] Rule 52 of Federal Rules of Civil Procedure requires the court to "state the findings and conclusions that support" the "granting or refusing [of] an interlocutory injunction." Fed. R. Civ. P. 52(a)(2). To the extent any findings of fact constitute conclusions of law, they are adopted as such; to the extent any conclusions of law constitute findings of fact, they are so adopted.

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.)

2. "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.)

3. 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.)

4. 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.)

5. The Agreement required Poly-Med to "develop and manufacture at least six different types of Absorbable Composite Meshes for sale to and use by Radi" in "hernial repair products." (ECF No. 126-1 at 4 ¶ 2(a).) 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).)

6. 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.)

7. 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.)

8. 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.)

9. In December 2008, Radi transferred its rights under the Agreement to Novus Singapore.[2] (ECF No. 126-5 at 2 ¶ 4.)

10. Upon receipt of an application, the U.S. Food and Drug Administration ("FDA")

[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.)

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 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.)

11. After receiving 510(k) clearance, Novus Singapore began marketing and selling TIGR®Mesh. (ECF No. 126-5 at 2 ¶ 5.)

12. In the fall of 2010, "Poly-Med learned TIGR®Mesh was used in studies for TRAM flap procedures (or abdominal wall reconstruction surgery) whereby 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.) 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." (*Id.*; *see also* ECF No. 126-5 at 2 ¶ 7.)

13. In December 2010, an employee of Poly-Med, Shawn J. Peniston ("Peniston"),

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[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.*

[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.)

presented a dissertation with the "primary goal" of developing and characterizing "a fully absorbable bicomponent mesh (ABM) for hernia repair which can modulate biomechanical and physical properties to work with the expected needs of the wound healing process." (ECF No. 126-25 at 3.) Peniston's dissertation described "a bioengineering approach that was used to develop and evaluate a novel hernia mesh which considers the temporal needs of the wound healing process, as well as the device functional needs to improve biocompatibility." (*Id.* at 15.)

14. On or about February 27, 2013, Novus Singapore transferred its interest in the Agreement to its Swedish entity, Novus Sweden. (ECF No. 126-8 at 1 ¶ 2.)

15. "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.)

16. "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.)

17. "Poly-Med has accepted royalty payments arising from all end uses." (*Id.*)

18. On May 8, 2015, Poly-Med filed the instant action 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.)

19. On June 8, 2016, Poly-Med moved for a preliminary injunction based on its breach of contract and misappropriation of trade secrets causes of action. (ECF No. 97-1.) Poly-

Med alleges that Novus Defendants breached the Agreement by (1) "using, manufacturing and selling the mesh for purposes other than hernia repair"; and (2) by filing certain patent applications without notice to Poly-Med and not in its name. (*Id.* at 2.) Further, Poly-Med contends that Novus Defendants have misappropriated certain alleged trade secrets provided to Novus Defendants pursuant to the Agreement. (*Id.)*

20. The court heard argument from the parties on this matter on August 16, 2016. (ECF No. 135.) As discussed below, upon review of the extensive briefing on the instant Motion and hearing the parties' detailed arguments, it appears to this court that there are a number of significant factual disputes at this stage of the case. The briefs and declarations in support of and in opposition to Poly-Med's Motion illustrate the parties' divergent views on numerous issues (*see* ECF Nos. 97-1, 126, and 133) and the court finds it unnecessary to summarize here their very different versions of the events underlying this action. Rather, it is sufficient at the outset for the court to note that it has carefully considered the parties' briefing and arguments, and it finds the many contested factual issues weigh against granting Poly-Med the requested relief. *See Price v. City of Fayetteville, N.C.*, No. 5:13-CV-150-FL, 2013 WL 1751391, at *4 (E.D.N.C. Apr. 23, 2013) (explaining that courts in the Fourth Circuit have recognized that, "[w]hen the facts are sharply disputed, a preliminary injunction will not be granted" because a preliminary injunction requires a "clear showing") (quoting *Prudential Sec., Inc. v. Plunkett*, 8 F. Supp. 2d 514, 516 (E.D. Va. 1998)); *Wellin v. Wellin*, No. 2:13-cv-1831-DCN, 2013 WL 6175829, at *4 (D.S.C. Nov. 22, 2013). The parties' positions are discussed in greater detail below in the context of Poly-Med's specific allegations.

II. LEGAL STANDARD AND ANALYSIS

A. Preliminary Injunctions Generally

11. The court's authority to issue preliminary injunction arises from Rule 65,[5] but "it is an extraordinary remedy never awarded as of right." *Winter v. Nat'l Res. Def. Council, Inc.*, 555 U.S. 7, 24 (2008). A party seeking a preliminary injunction must establish all four of the following elements: (1) he is likely to succeed on the merits; (2) he is likely to suffer irreparable harm in the absence of preliminary relief; (3) the balance of equities tips in his favor; and (4) an injunction is in the public interest. *Id.*; *The Real Truth About Obama, Inc. v. Fed. Election Comm'n*, 575 F.3d 342, 346–47 (4th Cir. 2009).

12. The Fourth Circuit no longer recognizes a "flexible interplay among the four criteria for a preliminary injunction." *Real Truth*, 575 F.3d at 347. Each of these requirements "must be fulfilled as articulated." *De la Fuente v. S.C. Dem. Party*, CA No. 3:16-cv-00322-CMC, 2016 WL 741317, at *2 (D.S.C. Feb. 25, 2016). A plaintiff must first prove the first two elements before a court considers whether the balance of the equities tips in his favor. *See Real Truth*, 575 F.3d at 346–47. Additionally, the court pays particular attention to the public consequences of employing this extraordinary form of relief via injunction. *Real Truth*, 575 F.3d at 347 (*citing Winter*, 555 U.S. at 24).

13. "The traditional purpose of a preliminary injunction is to protect the status quo and to prevent irreparable harm during the pendency of the lawsuit ultimately to preserve the court's ability to render a meaningful judgment on the merits." *De La Fuenta*, 2016 WL 741317, at *2. The parties dispute whether Poly-Med is seeking a prohibitory or a mandatory preliminary injunction and, as such, which standard is to be applied. However, because the preliminary

[5] The court observes that "rule" refers to the Federal Rules of Civil Procedure.

injunction Poly-Med seeks is not appropriate under the less stringent standard, the court need not resolve this dispute.

B. Poly-Med's Request for Relief

14. Poly-Med seeks a preliminary injunction that: (a) enjoins Novus Defendants from using or disclosing Poly-Med's trade secrets; (b) enjoins Novus Defendants from promoting, advertising, manufacturing, distributing, offering for sale, or selling TIGR®Mesh or any other surgical mesh developed with confidential information or trade secrets of Poly-Med; and (c) enjoins Novus Defendants from filing any Mesh Patent Applications. (ECF No. 97 at 32.)

C. The Court's Review

15. In support of its Motion for Preliminary Injunction, Poly-Med relies on its Memorandum of Law (ECF No. 97-1) and Declarations from Philip Green (ECF Nos.102-1 & 131-5), Christina Ramberg (ECF Nos. 103-1 & 131-4), David Shalaby (ECF Nos. 104-1 & 131-6), Scott Taylor (ECF No. 131-2), Kimberly Carpenter (ECF No. 131-3) and Sean Peniston (ECF No. 139-1).

16. In opposition to the Motion for Preliminary Injunction, Novus Defendants rely on their Memorandum of Law (ECF No. 126) and Declarations from Torbjörn Mathisen (ECF Nos. 126-2 & 134), Thomas Engstrom (ECF No. 126-5), Stefan Sowa (ECF Nos. 126-8 & 126-16), Henrik Magnusson (ECF No. 126-15), Tac-Whei Ong (ECF No. 126-17), Roger Johansson (ECF No. 126-24), and Charles L. Alford Ph.D. (ECF No. 126-29.)

17. The court heard oral argument from the parties' counsel on August 16, 2016. (ECF No. 135.)

18. Both parties make a plethora of arguments regarding the meritorious value of Poly-Med's breach of contract and trade secrets claims. This court finds that Poly-Med has not

met its burden under the standard the Supreme Court set out in *Winter*. Because Poly-Med has not shown that each element required for injunctive relief has been met, the court refuses to grant injunctive relief to Poly-Med. The court addresses below the vitality of Poly-Med's assertions under each of the four requirements set forth in *Winter* and reiterated by the Fourth Circuit in *Real Truth*.

III. SPECIFIC FINDINGS AND CONCLUSIONS

A. Clear Showing of Likely Success on the Merits

19. "[P]laintiffs seeking preliminary injunctions must demonstrate that they are likely to succeed on the merits." *Pashby v. Delia*, 709 F.3d 307, 321 (4th Cir. 2013) (citing *Winter*, 555 U.S. at 20). "Although this inquiry requires plaintiffs seeking injunctions to make a 'clear showing' that they are likely to succeed at trial, *Real Truth*, 575 F.3d at 345, plaintiffs need not show a certainty of success, *see* 11A Charles Alan Wright *et al.*, Federal Practice & Procedure § 2948.3 (2d ed. 1995). *Pashby*, 709 F.3d at 321.

i. *Poly-Med Cannot Establish a Clear Showing of Likely Success as to the Merits of Its Breach of Contract Claim Due to Unanswered Factual Issues Relevant to the Application of Swedish Law to the Parties' Agreement.*

20. Firstly, as a preliminary matter, the court observes that the parties do not dispute that Swedish law governs the Agreement regarding substantive legal issues related to the contract. (*See* ECF Nos. 97-1 at 10–11 & 126 at 12–13; *see also* ECF No. 126-1 at 27 ¶ 28 ("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 . . . .").) Accordingly, the court is asked to apply the heavily fact specific analysis employed by courts resolving contract disputes applying Swedish law.

21. "Under Swedish contract law, the contents of a contract are established on the basis of the parties' common (subjective) intention." (ECF No. 103-1 at 3 ¶ 9.) "[T]he following

factors are relevant to establish the contents of a contract: 10.1. the wording of the contract; 10.2. the underlying law (default law); 10.3. the parties' preliminary negotiations in connection with the formation of a contract; 10.4. the parties' conduct subsequent to the formation of the contract; 10.5. practices which the parties have established between themselves in earlier dealings; 10.6. the nature and purpose of the contract; 10.7. the meaning of the terms and concepts (notions) in the relevant industry; 10.8. trade usages; 10.9. the structure of the contract; and, 10.10. reasonableness, good faith and fair dealing." (*Id.* at 3–4 ¶¶ 10–10.10.)

22. The court finds that it is not clear that Poly-Med will succeed on the merits of its breach of contract claim under this fact specific review because a number of facts are still adamantly disputed by the parties. (*See* ECF Nos. 103-1 at ¶¶ 14–15 & 126-20 at 8.) The parties dispute how to interpret the Agreement, the trade practices that the parties have established between themselves in earlier dealings, and the Agreement's inclusion of a limitation on patent filings and uses of the TIGR®Mesh to hernia repair.

23. The parties further contest the contents of preliminary negotiations in connection with the Agreement and the vitality of the Agreement at present. Without resolution of these facts, the success of Poly-Med's claims is debatable, at best, and does not warrant preliminary injunction.

ii. Poly-Med Cannot Establish a Clear Showing of Likely Success as to the Merits of Its Breach of Contract Claim Due to Unanswered Factual Issues Relevant to the Application of South Carolina's Statute of Limitations on Contract Claims Under S.C. Code Ann. § 15-3-530(1) (2016).

24. While choice of law provisions, such as the Swedish law provision of the Agreement, govern substantive issues with the contract, the law of the forum state governs purely procedural issues. *Stern v. Shelley*, 781 F. Supp. 2d 281, 284 (D.S.C. 2011). A "statute of limitations, which requires an action to be brought within a fixed time following accrual of a

cause of action, is generally procedural because it affects the remedy rather than the right." *Thornton v. Cessna Aircraft Co.*, 703 F. Supp. 1228, 1230 (D.S.C. 1988). Thus, the law of the forum ordinarily governs the selection and application of the appropriate statute of limitations. *Gattis v. Chavez*, 413 F. Supp. 33, 35 (D.S.C. 1976).

25. Courts in South Carolina apply their own statutes of limitations to actions sounding in contract. *Id.* Accordingly, a party has three (3) years from the time it knew or reasonably should have known that the alleged breach occurred to file suit. S.C. Code Ann. § 15-3-530(1) (2016). The aforementioned statute of limitations is modified by the "discovery rule" wherein "the statute of limitations [only] begins to run from the date the injured party either knows or should know, by the exercise of reasonable diligence, that a cause of action exists for the wrongful conduct." *True v. Monteith*, 489 S.E.2d 615, 616 (S.C. 1997). This rule does not require that the party have actual notice of the full extent of damages or of the claim itself; simply a party must act promptly to investigate the existence of a claim when facts and circumstances indicate that one might exist. *Brooks v. GAF Materials Corp.,* 284 F.R.D. 352, 357–58 (D.S.C. 2012), *amended in part*, 2012 WL 5195982 (D.S.C. 2012).

26. Although the court does not decide at this time whether the statute of limitations has run on Poly-Med's breach of contract claims, it notes that this is a particular point of contention between the parties. Poly-Med asserts that its breach claims related to limited use of the TIGR®Mesh and to patent filings involve "recurring and ongoing violations," each triggering its own limitations period. (ECF No. 133 at 11 (citing, *e.g.*, *Dave & Buster's Inc. v. White Flint Mall, LLP*, 616 F. App'x 552, 558 (4th Cir. 2015)).) Yet, Poly-Med has not overcome the high burden of showing that it clearly would succeed on the merits of its claims. The disputed facts could suggest it knew as early as 2010 of actions it now seeks to enjoin, and there are legitimate

questions as to whether those "acts" are continuous in and of themselves. (ECF Nos. 126 at 12, 126-11 at 5, 133 at 13 & 104-1 at 16 ¶ 62.) Thus, this point of basis alone is enough to undermine the likelihood of Poly-Med's success on the merits.

iii. *Poly-Med Cannot Establish a Clear Showing of Likely Success as to the Merits of Its Misappropriation of Trade Secrets Claim Due to Unanswered Factual Issues Relevant to the Application of South Carolina Trade Secrets Act.*

27. "To establish a claim for misappropriation of trade secrets under the South Carolina Trade Secrets Act, a plaintiff must show: (1) the existence of a trade secret; (2) misappropriation, wrongful use, or wrongful disclosure of a trade secret by the defendant; and (3) damages." *Sonoco Products Co. v. Guven*, No. 4:12-CV-00790-BHH, 2015 WL 127990, at *6 (D.S.C. Jan. 8, 2015); *Nucor Corp. v. Bell*, 482 F. Supp. 2d 714, 725–26 (D.S.C. 2007); S.C. Code Ann. § 39-8-30(C) (2016).

28. Information qualifies as a trade secret only if: (a) it "derives independent economic value, actual or potential, from not being generally known to, and not being readily ascertainable by proper means by the public or by any other person who can obtain economic value from its disclosure or use," and (b) it "is the subject of efforts that are reasonable under the circumstances to maintain its secrecy." S.C. Code Ann. § 39-8-20(5)(a) (2016).

29. A plaintiff also "must adequately identify and describe the subject matter of its alleged trade secrets in sufficient detail to establish each element of a trade secret and to enable the jury to differentiate that which is claimed as a trade secret from 'matters of general knowledge in the trade.'" *Vessel Med., Inc. v. Elliott*, No. 6:15-cv-00330-MGL, 2015 WL 5437173, at *7 (D.S.C. Sept. 15, 2015).

30. Misappropriation can occur in various ways, *Hoechst Diafoil Co. v. Nan Ya Plastics Corp.*, 174 F.3d 411, 417 (4th Cir. 1999), but the statute generally defines

misappropriation as involving improper acquisition, disclosure, or use of a trade secret, *see* S.C. Code Ann. § 39-8-20(2) (2016) (defining "misappropriation").

31. To show that it is entitled to a preliminary injunction, Poly-Med must make a clear showing that it is likely to succeed in proving that Novus Defendants committed an act of misappropriation as defined in the statute.

32. Turning to the merits, there is some question as to whether the "trade secret" alleged by Poly-Med is not, in fact, publicly disclosed information. Indeed, Novus Defendants draw this court's attention to Dr. Shawn Peniston's dissertation, overseen by Dr. Shalaby W. Shalaby of Poly-Med, where the TIGR®Mesh is discussed in great detail in December 2010. (ECF No. 126-25.) The court also points to the numerous applications filed by Poly-Med, and its concession that the trade secrets were publicly disclosed. While Poly-Med maintains that it still possesses some trade secrets that Novus Defendants misappropriated, supported by the Declarations of Kimberly A. Carpenter (ECF Nos. 131-3 at 3 ¶ 7–5 ¶ 8 & 133 at 11) and Scott Taylor (ECF Nos. 131-2 at 3 ¶ 7–7 ¶ 27 & 133 at 11), Novus Defendants submitted Declarations of three witnesses, Dr. Torbjörn Mathisen, Stefan Sowa, and Thomas Engström, who directly contradict Poly-Med's allegations. (ECF Nos. 126-2 at 6 ¶¶ 21–23, 126-5 at 7 ¶ 24, 126-8 at 1 ¶ 3 & 134 at 2 ¶ 4.) The Declaration of Carpenter, in particular, is adamantly disputed because Novus Defendants assert that Poly-Med never provided Novus Defendants with information of trade secrets pointed to in this Declaration.

33. Due to the aforementioned dispute, Poly-Med has failed to clearly show that it will likely succeed in proving its prima facie case of misappropriation of trade secrets.

34. Even in Poly-Med's attempt to show that trade secrets were disclosed, the specific make up of these guarded materials described by Poly-Med is too broad for this court to

adjudicate and monitor through injunctive relief. Poly-Med contends that, "[o]ver the years, Poly-Med sent Radi numerous emails, confidential Activity Reports and Design Review documents that contain trade secrets on how the Select Absorbable Composite Mesh was designed and developed," and the documents it identified in its motion were merely "examples." (ECF No. 133 at 10–11.) Further, Poly-Med makes the general statement that its trade secrets include "various aspects of the design, construction, development and performance of the TIGR®Mesh." (ECF No. 97-1 at 22.)

35. To the extent Poly-Med seeks a preliminary injunction based on the assertion that it has other information that is a trade secret that it has not specifically identified in conjunction with this proceeding, the court finds that such information has not been identified in sufficient detail. Such general statements do not provide information sufficient to establish each element of a trade secret, as opposed to matters of general knowledge in the trade. *Trandes Corp. v. Guy F. Atkinson Co.*, 996 F.2d 655, 661–62 (4th Cir. 1993).

36. Finally, Poly-Med contends that information in Novus Defendants' patent applications constitutes misappropriation of trade secrets. (ECF Nos. 104-9, 131-20, 133 at 11 & 131-2 at 3 ¶ 7–7 ¶ 27.) Poly-Med has also not shown it is likely to succeed on these claims because there is a legitimate question as to whether this information was actually publicized through the Peniston Dissertation in 2010.

37. Further, information, for which Poly-Med offers a somewhat unclear description could have been disclosed in Poly-Med's own U.S. Patent No. 8,709,023, which was published on January 22, 2009, the application that matured into Novus Defendants' U.S. Patent No. 8,083,755. (*See* ECF No. 131-2 at 7 ¶¶ 25–27.)

iv. Poly-Med Cannot Establish a Clear Showing of Likely Success as to the Merits of Its Misappropriation of Trade Secrets Claim Due to Unanswered Factual Issues Relevant to the Application of South Carolina's Statute of Limitations on Trade Secrets Claims Under S.C. Code Ann. § 39-8-70 (2016).

38. There is also a potential statute of limitations issue that arises under the claim for misappropriation of trade secrets, as well. The statute of limitations for trade secret misappropriation is three years. S.C. Code Ann. § 39-8-70 (2016).

39. Counsel for Novus Defendants stated that they notified Poly-Med of a patent application via an October 15, 2010 letter (ECF No. 126-19) and Poly-Med conceded that it knew about this patent application in 2010. Thus, Novus Defendants notably argue that the statute of limitations has run on Poly-Med's trade secrets misappropriation claims, as well.

40. Novus Defendants further contend that misappropriation does not qualify as a continuing violation in the context of the statute of limitations. (ECF No. 126 at 28.) As observed above, it is not necessary at this time for the court to determine whether the statute of limitations has run on Poly-Med's trade secret misappropriation claims because its Motion for Preliminary Injunction does not meet the burden laid out in *Winter*. Still, it is merely possible that Poly-Med could win on this procedural issue, if argued before the court, and probability is required for injunctive relief.

41. For the reasons stated above, Poly-Med has not demonstrated that it is clearly likely to succeed on the merits of its breach of contract or trade secret misappropriation claims and injunctive relief is inappropriate.

B. Likelihood of Suffering Irreparable Harm Absent an Injunction

42. *Winter* also requires that the party requesting injunctive relief demonstrate that it is likely it will suffer irreparable harm absent the preliminary injunction. *Winter*, 555 U.S. at 22–23. The harm to be prevented must be of an immediate nature and not simply a remote

possibility. *Am. Whitewater v. Tidwell*, No. 8:09-cv-02665-JMC, 2010 WL 5019879, at *11 (D.S.C. Dec. 2, 2010) (citing *In re Microsoft Corp. Antitrust Litig.*, 333 F.3d 517, 525 (4th Cir. 2003)).

43. "When analyzing the irreparable harm element, there are two inquiries: 1) whether the plaintiff is indeed suffering actual and imminent harm; and 2) whether that harm is truly irreparable, or whether it can be remedied at a later time with money damages." *Sauer-Danfoss Co. v. Nianzhu Luo*, C/A No. 8:12-3435-HMH, 2012 WL 6042831, at *1 (D.S.C. Dec. 5, 2012) (quoting *First Quality Tissue SE, LLC v. Metso Paper USA, Inc.*, C/A No. 8:11-2457-TMC, 2011 WL 6122639, at *2 (D.S.C. Dec. 9, 2011)).

i. Is the Alleged Harm Suffered by Poly-Med Actual?

44. Poly-Med contends it is suffering irreparable harm because the actions of Novus Defendants have resulted in Poly-Med losing (a) control of its trade secrets; (b) the benefit of its own intellectual property; (c) the ability to pursue business opportunities and negotiate adequate compensation; and (d) credit for creation of the TIGR®Mesh and the goodwill associated with its development. (ECF Nos. 97-1 at 23–29 & 102-1 at 9 ¶ 36.)

45. Poly-Med's first contention is that it has "lost control of its trade secrets" because of Novus Defendants' actions leading to immeasurable harm. However, Poly-Med has failed to show how any loss of trade secrets is not the result of the actions of its own employees and publications on the Internet, such as Peniston's dissertation (ECF No. 126-25) and the numerous patent applications. Poly-Med's position is not persuasive because it is circular reasoning to suggest that a party who is indeed the catalyst for the harm that it suffered can then claim it is suffering from said harm.

46. Additionally, Poly-Med argues that it is not able to "enjoy the benefits of its

intellectual property" because Novus Defendants are developing and using the TIGR®Mesh outside the scope of the Agreement. In a linked argument, Poly-Med claims that Novus Defendants filed patent applications in their own name, rather than in Poly-Med's name, and these applications affect Poly-Med's ongoing business opportunities and compensation for these patents. (*See* ECF No. 97-1 at 25–27.) Poly-Med contends that it cannot license its technology to a third party where it is unable to ensure a future licensee that it could fully exploit a licensed field of use. (*See* ECF No. 102-1 at 12 ¶ 53.) However, the record indicates that reasonable minds could differ as to the cause of the barrier to commercialization experienced by Poly-Med. Novus Defendants argue that Poly-Med is actually suffering the ramifications of patents that Novus Defendants filed in 2004, prior to the Agreement with Poly-Med—patents that predated the parties' relationship altogether. (ECF No. 126 at 32.) The record is not fully developed such that the court can decisively conclude Novus Defendants did not have a right to file patents separate from the Agreement with Poly-Med resulting in the alleged harm. Moreover, this alleged harm does not suggest that Poly-Med's business is suffering in light of these patents. Indeed, it appears that Poly-Med is receiving royalties such that it is benefiting from these patents. (*See* ECF Nos. 126-5 at 3 ¶ 11 & 126-8 at 2 ¶ 9.) This court finds that Poly-Med has not clearly shown that it is likely to suffer irreparable harm on this ground.

47. Poly-Med next argues that it is has lost the ability to pursue business opportunities and negotiate adequate compensation, such that it is suffering an irreparable harm. The fact that communications and royalties are still passing amongst the parties suggests otherwise. This point, in particular, is arguably vague, such that this court cannot render judgment on the impact of this alleged harm.

48. Finally, Poly-Med argues irreparable harm because it is not getting credit for the

TIGR®Mesh. It asserts that Novus Defendants "falsely claim credit for developing the TIGR® Mesh" on their website and in industry publications. (ECF No. 97-1 at 29.) Novus Defendants respond that the statements on their website are true, and they have submitted declarations to that effect. (ECF Nos. 126 at 33, 126-5 at 19 ¶ 65 & 126-2 at 11 ¶ 34.) Further, the court notes that Poly-Med's argument for irreparable harm is undercut by the fact that Poly-Med's website advertises its experience with mesh products, equally claiming credit for the product. (ECF No. 126-32 at 2.) Accordingly, the court finds that Poly-Med has not shown that it is likely to suffer irreparable harm from any alleged false advertising.

49. In consideration of the foregoing, the court is unable to infer the actuality of the irreparable harm suffered by Poly-Med.

ii. Is the Alleged Harm Suffered by Poly-Med Imminent?

50. Because "an application for preliminary injunction is based upon an urgent need for the protection of [a] Plaintiff's rights, a long delay in seeking relief indicates that speedy action is not required." *Quince Orchard Valley Citizens Ass'n v. Hodel*, 872 F.2d 75, 80 (4th Cir. 1989). This court is hesitant to issue preliminary injunctions when "whatever harm Plaintiffs face . . . is very much the result of their own procrastination." *Id.* at 79.

51. In considering the imminency of the alleged harm suffered by Poly-Med, the court notes the obvious undue delay in the filing of Poly-Med's Motion for Preliminary Injunction. Even allowing time for predicate acts that Poly-Med asserts that it had to accomplish under the Agreement (*i.e.*, first send notice of default to Novus Defendants, notify Novus Defendants of the Agreement's termination, and allow a six-month period[6] for expiration of

[6] According to Poly-Med, that period expired on February 22, 2016, and that "was the earliest date Poly-Med could have sought an injunction." (*See* ECF no. 97-1 at 31 (citing § 21(a) of the Agreement).)

inventory), this court finds that a June 8, 2016 file date is delayed and weighs against granting preliminary injunction.

52. Nowhere in the Agreement does it state that allowing for a six-month inventory sell off period or termination of the Agreement are prerequisites to pursuing preliminary injunction or breach of contract claim. (ECF No. 126 at 31 (citing § 20 of the Agreement, which states: "The right to terminate this Agreement as provided herein is in addition to and not in lieu of the rights of the parties hereto in law or at equity with regard to a breach of this Agreement").) In this regard, the court is not persuaded that Poly-Med was prevented from filing suit and seeking a preliminary injunction in February or March 2015[7] when it alleges it first became cognizant of this claim.[8]

53. As a result of the foregoing, the court is unable to infer the imminency of the irreparable harm suffered by Poly-Med because its filing for injunctive relief on June 8, 2016, is simply too temporally removed from the spring of 2015.

iii. Are Monetary Damages Sufficient?

54. To demonstrate a need for injunctive relief, a plaintiff must show how the harm suffered is such that other forms of damages available in the normal course of litigation are not enough. "Mere injuries, however substantial, in terms of money, time and energy necessarily expended in the absence of a stay, are not enough," because of the "the possibility that adequate compensatory or other corrective relief will be available at a later date." *Hughes Network Sys. v.*

[7] "In or about February 2015, Poly-Med received a 'Med Watch' notice that a patient in Austria had developed a serious infection after TIGR®Mesh was implanted in the patient as part of a breast reconstruction." (ECF No. 104-1 at 20 ¶ 78.) On March 19, 2015, Poly-Med personnel viewed Novus Defendants' webpage showing their use of TIGR® Mesh for TRAM flap procedures. (ECF No. 104-19 at 3.)

[8] The court recognizes that this date may be much sooner if, in fact, Poly-Med is considered to be on notice of the cause of action when Novus Defendants filed with the FDA and started selling the TIGR®Mesh.

Interdigital Commc'ns Corp., 17 F.3d 691, 694 (4th Cir. 1994). This "weighs heavily against a claim of irreparable harm." ***Id.***

55. "A preliminary injunction is not normally available where the harm at issue can be remedied by money damages." ***Bethesda Softworks, LLC v. Interplay Entm't Corp.***, 452 F. App'x 351, 353 (4th Cir. 2011).[9]

56. Poly-Med arguably concedes in its Complaint that monetary damages are appropriate. (ECF No. 1 at 26 ¶¶ 1–3 & 7.)

57. Moreover, in the Agreement between Poly-Med and Radi, Poly-Med valued its "know-how" and patents at a 2% royalty on sales of the TIGR® Mesh. (*See* ECF No. 126-1 at 15 ¶ 11.)

58. However, Poly-Med's damages expert, Philip Green ("Green"), opined that "even if Poly-Med's damages could be measured, Poly-Med cannot be adequately compensated by a judgment for monetary damages." (ECF No. 102-1 at 15 ¶ 66.)

59. In response to Green's opinion, Novus Defendants' damages expert observed:

> If Green means that it is impossible to adequately compensate Poly-Med for its lost profits, that is a meaningless statement unless there is no amount that could be viewed as adequate compensation, suggesting that lost profits must be infinite. If Green intends to say that Poly-Med cannot be adequately compensated because damages cannot be measured, the conclusion depends on the premise, which he has not demonstrated, explained, supported, or proved throughout the narrative of his report. If Green is referring to Novus's ability to pay, this conclusion has no

[9] The presumption against issuing preliminary injunctions where a harm suffered can be remedied by money damages at judgment stems from real concerns the issuance of a preliminary injunction remedy raises. These concerns include, for example, the fact that in issuing a preliminary injunction order, a district court is required, based on an incomplete record, to order a party to act in a certain way. *Hughes Network Sys., Inc. v. InterDigital Commc'ns Corp.*, 17 F.3d 691, 694 (4th Cir. 1994). Issuing an injunction further risks repetitive litigation, that which carries significant costs for both parties. *Id.* Thus, there are only "extraordinary circumstances" that are "quite narrow" in application, where preliminary injunction is appropriate notwithstanding monetary damages. *Id.* (discussing a Plaintiff's business not being able to survive as an example of such circumstances.)

> place in this part of his analysis because it certainly is not supported by his reason #3.

(ECF No. 126-29 at 12 ¶ 56.) Accordingly, Novus Defendants' damages expert explained that the loss of value of intellectual property, including patents, could be measured in monetary terms. (*Id.* at 11 ¶¶ 53–55.)

60. Additionally, Poly-Med contends that TIGR®Mesh is Novus Defendants' only revenue generating product and they do not have substantial assets in the United States. (ECF Nos. 97-1 at 30–31 & 102-1 at ¶ 38.) In asking the court to bar Novus Defendants from selling TIGR®Mesh, Poly-Med suggests that when Novus Defendants cannot generate revenue by selling the product, they will not be able to pay damages and that judgment against Novus Defendants will be unenforceable for lack of assets. (*Id.*)

61. Novus Defendants respond (ECF No. 126 at 30) noting first that they have made and continue to make all royalty payments into a designated account. (*See* ECF Nos. 126-5 at 3 ¶ 11 & 126-8 at 2 ¶ 9.) Novus Defendants likewise attest that they are not in financial distress, have not defaulted on payments owed to Poly-Med, and have the ability to pay any rational damages award. (ECF Nos. 126-5 at 7 ¶ 25 & 126-8 at 2 ¶ 10.).

62. Upon its review of the foregoing, the court is unable to conclude that money damages would be inadequate based on the current evidence of record.

C. The Balance of Equities and the Public Interest Factors

63. Generally, in determining whether to grant a motion for injunctive relief, "[t]he court must also consider the balance of hardships between the litigants and the impact on the public at large prior to issuing an injunction." *Uhlig, LLC v. Shirley*, C/A No. 6:08-cv-01208-JMC, 2012 WL 2458062, at *4 (D.S.C. June 27, 2012).

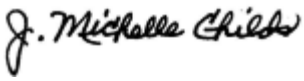
64. However, because Poly-Med has failed to clearly show likelihood of success on

the merits and likelihood of irreparable harm, this court, as stated above, need not address the "balance of equities" and "public interest" elements required for preliminary injunction. *Real Truth*, 575 F.3d at 346.

IV. CONCLUSION

65. In sum, Poly-Med has not established that it is clearly likely to succeed on the merits of its breach of contract or its trade secret misappropriation claims, and it has not shown that it will suffer irreparable harm absent entry of an injunction. For the foregoing reasons and after careful consideration of the entire record, the court **DENIES** Poly-Med's Motion for Preliminary Injunction (ECF No. 97.)

IT IS SO ORDERED.



United States District Judge

December 6, 2016
Columbia, South Carolina