UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF NEW JERSEY

WYETH, et al. Plaintiffs, v. ABBOTT LABORATORIES, et al. Defendants.	Civil Action No. 09-4850 (JAP) **OPINION**

PISANO, District Judge.

Plaintiffs Wyeth, Cordis Corporation and Cordis LLC (together, "Cordis" or "Plaintiffs") bring this patent infringement action alleging Defendants Abbott Laboratories and Abbott Cardiovascular Systems, Inc. (together, "Abbott") and Boston Scientific Corporation and Boston Scimed, Inc. (together, "BSC") infringe U.S. Patent No. 7,591,844 (the "'844 patent"), entitled "Medical Devices, Drug Coatings and Methods for Maintaining Drug Coatings Thereon" and U.S. Patent No. 6,746,773 (the "'773 patent"), entitled "Coatings for medical devices." These patents relate to drug-eluting coronary stents that are used in the treatment of coronary artery disease. Plaintiffs Wyeth and Cordis Corporation own the patents, and Cordis LLC is the exclusive licensee of the patents.

Presently before the Court is the parties' request for claim construction. The Court held a *Markman* hearing on September 28, 2011. This Opinion addresses the proper construction of the disputed claim terms.

I. The Technology and Patents-In-Suit

For several decades, physicians have treated coronary artery disease – a condition in which the coronary arteries become narrowed by plaque – with a procedure known as balloon angioplasty. This procedure involved a physician expanding a narrowed coronary artery by inflating a balloon that has been inserted into the artery at the site of the blockage. In more recent years, physicians have been able to use the balloon catheter to deliver a stent, *i.e.*, a permanent implant, which remains in place to hold open the newly expanded artery.

While early commercial stents were metallic, later stents carried a coating that delivered a drug at the implantation point. The drug delivered by the coated stent elutes into the artery wall and bloodstream in order to deliver its therapeutic benefit to patients; thus, these stents are referred to as "drug-eluting stents". The patents-in-suit relate to such drug-eluting stents. In particular, the patents disclose a particular copolymer used to coat such stents comprised of two specific monomers -- vinylidenefluoride ("VDF") and hexfluoropropylene ("HFP"). Plaintiff alleges that the Xience stent, made by Abbott, and the Promus stent, made by BSC, contain such a coating and infringe the patents-in-suit.

The '844 patent issued on September 22, 2009 and contains 24 claims. The '773 patent originally issued on June 8, 2004. The '773 patent was subject to an *ex parte* reexamination by the Patent and Trademark Office and a reexamination certificate issued on July 13, 2010 amending the patent by cancelling four of five claims (claims 1-3 and 5), amending one claim (claim 4), and adding four new claims (claims 6-9).

II. Standards for Claim Construction

In order to prevail in a patent infringement suit, a plaintiff must establish that the patent claim "covers the alleged infringer's product or process." *Markman v. Westview*

Instrs., Inc., 517 U.S. 370, 116 S.Ct. 1384, 134 L.Ed.2d 577 (1996). Consequently, the first step in an infringement analysis involves determining the meaning and the scope of the claims of the patent. *Johnson Worldwide Assocs., Inc. v. Zebco Corp.*, 175 F.3d 985, 988 (Fed. Cir. 1995). Claim construction is a matter of law, *Markman v. Westview Instrs., Inc.*, 52 F.3d 967, 979 (Fed. Cir. 1995) *aff'd* 517 U.S. 370 (1996), therefore, it is "[t]he duty of the trial judge . . . to determine the meaning of the claims at issue." *Exxon Chem. Patents, Inc. v. Lubrizoil Corp.*, 64 F.3d 1553, 1555 (Fed. Cir. 1995).

The Federal Circuit has emphasized that "[i]t is a bedrock principle of patent law that the claims of a patent define the invention to which the patentee is entitled the right to exclude." *Phillips v. AWH Corp.*, 415 F.3d 1303, 1312 (Fed. Cir. 2005) (internal quotations omitted) (citing *Vitronics Corp. v. Conceptronic, Inc.*, 90 F.3d 1576, 1582 (Fed. Cir. 1996) ("we look to the words of the claims themselves . . . to define the scope of the patented invention"); *Markman*, 52 F.3d at 980 ("The written description part of the specification itself does not delimit the right to exclude. That is the function and purpose of claims."). Generally, the words of a claim are given their "ordinary and customary meaning," which is defined as "the meaning that the term would have to a person of ordinary skill in the art in question at the time of the invention." *Phillips*, 415 F.3d at 1312-13 (citations omitted). In this regard, the Federal Circuit has noted that

> It is the person of ordinary skill in the field of the invention through whose eyes the claims are construed. Such person is deemed to read the words used in the patent documents with an understanding of their meaning in the field, and to have knowledge of any special meaning and usage in the field. The inventor's words that are used to describe the invention--the inventor's lexicography--must be understood and interpreted by the court as they would be understood and interpreted by a person in that field of technology. Thus the court starts the decisionmaking process by reviewing the same resources as would that person, viz., the patent specification and the prosecution history.

Id. (quoting *Multiform Desiccants, Inc. v. Medzam, Ltd.*, 133 F.3d 1473, 1477 (Fed.Cir. 1998)).

In the process of determining the meaning of a claim as understood by a person of ordinary skill in the art, a court may look to various sources from which the proper meaning may be discerned. These sources include "the words of the claims themselves, the remainder of the specification, the prosecution history, and extrinsic evidence concerning relevant scientific principles, the meaning of technical terms, and the state of the art." *Phillips*, 415 F.3d at 1314. Claim construction focuses upon the claims, specification and prosecution history –*i.e.*, the intrinsic evidence – because intrinsic evidence is "the most significant source of the legally operative meaning of disputed claim language." *Vitronics Corp.*, 90 F.3d at 1582. While a court is permitted to turn to extrinsic evidence, such evidence is generally of less significance and less value in the claim construction process. *Phillips*, 415 F.3d at 1317. Extrinsic evidence would include evidence that is outside the patent and prosecution history, and may include expert testimony, dictionaries and treatises. *Id.* The Federal Circuit has noted that caution must be exercised in the use of extrinsic evidence, as this type of evidence may suffer from inherent flaws affecting its reliability in the claim construction analysis. *Id.* at 1319 ("We have viewed extrinsic evidence in general as less reliable than the patent and its prosecution history in determining how to read claim terms."). While "extrinsic evidence may be useful to the court, . . . it is unlikely to result in a reliable interpretation of patent claim scope unless considered in the context of the intrinsic evidence." *Id.*

III. The Disputed Claim Terms

The parties have identified a number of disputed claim terms in each patent. The Court addresses each of these in turn.

1. The '844 Patent

a. *"an adherent coating that remains adhered to the device upon expansion of the balloon-expandable stent"*

This clause appears in claim 19 of the '844 patent. This claim of the '844 patent reads as follows:

> A method for preparing a device for providing prolonged release of a pharmaceutical agent when implanted in a vessel, said method comprising the steps of:
>
> combining said pharmaceutical agent with a biocompatible polyfluoro copolymer that comprises about eighty-five weight percent vinylidinefluoride copolymerized with about fifteen weight percent hexafluoropropylene to provide a coating; applying said coating to a balloon expandable stent; and drying the balloon expandable stent comprising said coating at a maximum temperature no greater than 60^{o} C. to thereby provide *an adherent coating that remains adhered to the device upon expansion of the balloon-expandable stent*.

'844 patent, claim 19 (emphasis added).

Plaintiffs contend that "an adherent coating that remains adhered to the device upon expansion of the balloon-expandable stent" means "an attached coating that is sufficiently secured to the device upon expansion of the balloon-expandable stent so as to be suitable for use." Although Abbott and BSC contend that his claim language does not require construction, they appear to be arguing that the plain language of the claim requires that the coating remain completely adhered to the device at all times. Thus, difference in the Plaintiffs' and Defendants' positions boils down to how much adhesion the claim requires. Because the parties disagree on whether the claim allows for, for example, an inconsequential

amount of the coating to flake off upon expansion, the Court must resolve the dispute. *See O2 Micro Int'l Ltd. v. Beyond Innovation Tech. Co.*, 521 F.3d 1351, 1360 (Fed. Cir. 2008) ("When the parties raise an actual dispute regarding the proper scope of these claims, the court, not the jury, must resolve that dispute.")

The specification explains that "[i]t would be advantageous to develop coating for implantable medical devices … that possess physical and mechanical properties effective for use in such devices." '844 patent, col. 5, lines 11-17. One such property is the ability of the coating to adhere to the device, which the specification makes clear is a matter of degree. *See* '844 patent, col. 19, lines 65-66 (stating that the coating in Example 2 were "more adherent" than those of Example 1); col. 19, line 40 (films "adhered poorly"). The specification teaches that the degree of adhesion required for the invention is that which is "adequate" for the coating to be effective for use:

> The present invention comprises polyfluoro copolymers that provide improved biocompatible coatings or vehicles for medical devices. These coatings provide inert biocompatible surfaces to be in contact with body tissue of a mammal, for example, a human, sufficient to reduce restenosis, or thrombosis, or other undesirable reactions. While many reported coatings made from polyfluoro homopolymers are insoluble and/or require high heat, for example, greater than about one hundred twenty-five degrees centigrade, to obtain films with adequate physical and mechanical properties for use on implantable devices, for example, stents, or are not particularly tough or elastomeric, films prepared from the polyfluoro copolymers of the present invention provide *adequate adhesion*, toughness or elasticity, and resistance to cracking when formed on medical devices. In certain exemplary embodiments, this is the case even where the devices are subjected to relatively low maximum temperatures.

'844 patent, col. 14, lines 51-65 (emphasis added). Thus, the Court finds that Plaintiffs' proposed construction is consistent with the intrinsic evidence.

The Court rejects Defendants' contention that Plaintiffs, through their proposed construction, are improperly attempting to substitute the terms "attached" or "secured" for

"adherent." Rather, Plaintiffs have proposed how they believe the Court should define the claim terms at issue, and Plaintiffs' proposed construction simply explains the meaning of the disputed claim terms by defining them. Finding that Plaintiffs' proposed construction is more consistent with the intrinsic evidence, the Court adopts Plaintiffs' proposed construction, and shall construe the clause "an adherent coating that remains adhered to the device upon expansion of the balloon-expandable stent" to mean "an attached coating that is sufficiently secured to the device upon expansion of the balloon-expandable stent so as to be suitable for use."

b. *"applying said coating to a balloon-expandable stent"*

This phrase appears in Claims 19 of the '844 patent. Plaintiffs contend that it should be construed to mean "putting said coating on a balloon-expandable stent." Abbott argues that the phrase means "spreading said coating on the surface of a balloon-expandable stent."[1] The proposed constructions first differ in that in that Plaintiffs use the more general term "putting" while Abbott uses the more specific term "spreading." The Court, however, finds nothing in the evidence that limits application of the coating by means of "spreading." Indeed, according to the specification, the coating may be "applied to the stent in a number of ways, including, though not limited to, dip, spray, or spin coating processes." '844 patent, col. 4, lines 59-62.

The main dispute between the parties over this claim term is whether it allows for the "coating" to be applied over a primer. Plaintiffs assert that it does, while Abbott argues that the coating must be applied directly to the stent's surface absent primer. The Court finds that

[1] BSC offers no construction.

Abbott's proposed construction is not supported by plain language of the claim or the relevant evidence.

First, as has been noted by another district court addressing a similar claim construction issue involving coronary stent products, it is commonly understood, for example, that "one can 'apply' a coat of paint to a wall, even if there are multiple coats of primer and old paint on the wall already." *Boston Scientific Corporation v. Johnson & Johnson, Inc.*, Civil No. 07-333, Memorandum Order at D.I. 361 (D. Del. January 20, 2010). Second, Abbott errs in basing its construction on what it describes that two distinct and mutually exclusive embodiments of the invention described in the specification. The first is as follows:

> In accordance with another aspect, the present invention is directed to a method of coating a medical device with a therapeutic agent. The method comprises the steps of creating a polymer utilizing vinylidene fluoride and hexafluoropropylene, adding one or more therapeutic agents to the polymer to create a polymer and therapeutic agent mixture, and applying the polymer and therapeutic agent mixture to the medical device.

'844 patent, Col. 6, lines 42-49.

The second is as follows:

> In accordance with another aspect, the present invention is directed to a method of coating a medical device with a therapeutic agent. The method comprises the steps of creating a polymer utilizing vinylidene fluoride and hexafluoropropylene in a batch emulsion polymerization process, priming the medical device with the polymer utilizing a dip coating process, creating a polymer and therapeutic agent mixture, applying the polymer and therapeutic agent mixture on the primer layer utilizing a spin coating process, and drying the medical device in a vacuum oven for approximately sixteen hours at a temperature in the range of fifty to sixty degrees centigrade.

'844 patent, Col. 6:14-24.

The Court agrees with Plaintiffs that these embodiments are not mutually exclusive; rather, one is intended to be a more specific variant of the other. Consequently, finding that

Plaintiff's proposed construction of the disputed language is supported by both the ordinary meaning of the term as well as the intrinsic evidence, the Court shall construe "applying said coating to a balloon-expandable stent" consistent with Plaintiffs' proposed construction as ""putting said coating on a balloon-expandable stent."

c. *"polyfluro copolymer that comprises about eighty-five weight percent vinylidenefluoride copolymerized with about fifteen weight percent hexafluoropropylene"*

This clause appears in claim 19 of the '844 patent. Plaintiffs argue that this clause should be construed to mean "polyfluoro copolymer that includes approximately eighty-five weight percent vinylidenefluoride and approximately fifteen weight percent hexafluoropropylene." Abbott contends that it means "a polyfluoro copolymer produced by polymerizing together about eighty-five weight percent vinylidinefluoride with about fifteen weight percent hexafluoropropylene." Lastly, BSC argues that the claim is indefinite, but to the extent that the Court does not find it to be indefinite, BSC argues the clause means "produced from eighty-five weight percent vinylidinefluoride and fifteen weight percent hexafluoropropylene."

As an initial matter, the Court does not find that the disputed language is indefinite as BSC contends. To be sufficiently definite, a patent specification must "conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention." 35 U.S.C. § 112, ¶ 2. The boundaries of the claim must be discernible to one skilled in the art based on the language of the claim, the specification, and the prosecution history, as well as that person's knowledge of the relevant field of art. *See Halliburton Energy Servs., Inc. v. M-I LLC*, 514 F.3d 1244, 1249-51 (Fed. Cir. 2008). Claims that are "not amenable to construction" or "insolubly ambiguous" are indefinite. *Datamize*

LLC v. Plumtree Software, Inc., 417 F.3d 1342, 1347 (Fed. Cir.2005). The Federal Circuit has noted that "because claim construction frequently poses difficult questions over which reasonable minds may disagree, proof of indefiniteness must meet an exacting standard." *Haemonetics Corp. v. Baxter Healthcare Corp.*, 607 F.3d 776, 783 (Fed. Cir. 2010) (quotations omitted).

"[A] claim is indefinite only if the 'claim is insolubly ambiguous, and no narrowing construction can properly be adopted.' " *Honeywell Int'l, Inc. v. Int'l Trade Comm'n*, 341 F.3d 1332, 1338-39 (Fed. Cir. 2003) (quoting *Exxon Research & Eng'g Co. v. United States*, 265 F.3d 1371, 1375 (Fed. Cir. 2001).). As the Federal Circuit has noted, "[i]f the meaning of the claim is discernible, even though the task may be formidable and the conclusion may be one over which reasonable persons will disagree, we have held the claim sufficiently clear to avoid invalidity on indefiniteness grounds." *Exxon*, 265 F.3d at 1375. BSC has simply not carried its heavy burden to show that the meaning of the claim is not discernable.

The question for the Court to resolve in construing this claim is whether the weight percentages recited in the disputed clause specify, as Defendants contend, the weight percentages of vinylidinefluoride ("VDF") and hexafluoropropylene ("HFP")) at the start of the copolymerization process or, as Plaintiffs contend, the weight percentages present in the finished product. Here, the Court agrees with Plaintiffs and finds that the issue is principally resolved by the specification, which provides an illustration of a copolymer that may be used in the invention: "A polyfluro copolymer (Solef® 21508) comprising 85.5 weight percent vinylidinefluoride copolymerized with 14.5 weight percent HFP, as determined by F^{19}NMR…" '844 patent, Col. 19, lines 52-54. Solef 21508 is a commercial, finished copolymer with a weight percentage in the final copolymer of 85.5% VDF and 14.5% HFP.

As such, the only reasonable construction of the disputed phrase is that the weight percentages refer to the components of the finished copolymer, which could have been measured using routine analytical techniques. Indeed, the specification refers to the analytical technique Fluroine-19 Nuclear magnetic Resonance (F^{19}NMR), which measures final weight percentages of the starting materials (as opposed to starting weight percentages) in a final copolymer. *See, e.g.*, Weiner Decl., Ex. Q (D.I. 159-3), Saltzman Dep. at 89:17-23 (testifying that one cannot use F^{19}NMR on a final copolymer to determine the relative amounts of the starting materials). Although Abbott argues that the reference in the specification to F^{19}NMR is not conclusive because the technique may also be used to determine the composition of the starting materials, a person would have to have the starting materials to perform such an analysis. *Id.* at 89:4-6 ("If one wanted to know the composition of the starting materials, one could do F19 NMR on the starting materials."). This would not be the case if one was using a commercial, finished copolymer such as Solef 21508.

Overall, the Court finds that Plaintiffs' proposed construction to be more consistent with the plain meaning of the claim terms and the intrinsic evidence, and reflects a more common sense construction of the disputed clause. Accordingly, the Court construes "polyfluro copolymer that comprises about eighty-five weight percent vinylidenefluoride copolymerized with about fifteen weight percent hexafluoropropylene" consistent with Plaintiffs' proposed construction to mean "polyfluoro copolymer that includes approximately eighty-five weight percent vinylidenefluoride and approximately fifteen weight percent hexafluoropropylene."

d. *"polyfluoro copolymer consists of 85.5 weight percent vinylidenefluoride copolymerized with 14.5 weight percent hexafluoropropylene"*

This clause appears in claim 20 of the '844 patent. Plaintiffs argue that the clause means "polyfluoro copolymer contains 85.5 weight percent vinylidenefluoride and 14.5 weight percent hexafluoropropylene." Abbott contends that it means "a polyfluoro copolymer produced by polymerizing together 85.5 weight percent vinylidinefluoride with 14.5 weight percent hexafluoropropylene." Lastly, BSC argues that the claim is indefinite, but to the extent that the Court does not find it indefinite, it means "produced from 85.5 weight percent vinylidinefluoride and 14.5 weight percent hexafluoropropylene." For the reasons expressed above in section III(1)(a) of this Opinion, the Court construes "polyfluoro copolymer consists of 85.5 weight percent vinylidenefluoride copolymerized with 14.5 weight percent hexafluoropropylene" consistent with Plaintiffs' proposed construction to mean "polyfluoro copolymer contains 85.5 weight percent vinylidenefluoride and 14.5 weight percent hexafluoropropylene."

e. *"drying the balloon-expandable stent comprising said coating at a maximum temperature no greater than 60 ºC"*

This phrase appears in claims 19 of the '844 patent. Plaintiffs urge the Court to construe the phrase to mean "performing a process for removing solvent from said coating while maintaining a temperature in the immediate vicinity of the balloon-expandable stent which is no greater than 60 ºC." Abbott and BSC argue that the phrase should be construed to mean "removing solvent from the balloon-expandable stent comprising said coating via heat where during solvent removal the maximum temperature is no greater than 60º C." After the parties filed their opening claim construction briefs, it became apparent that both parties agree

that "drying" means the manner in which solvent is removed from the stent coating. The key difference in the parties' positions centers in large part on Plaintiffs' use of the terms "performing a process for" in its proposed construction. The dispute boils down to whether this claim limitation refers to a discrete step in the manufacturing process in which the drying takes place (as Plaintiffs contend) or if it refers to any point in the manufacturing process in which any drying takes place (as Defendants contend), even if such "drying" – *i.e.*, solvent being removed – is merely incidental.

The Court finds Plaintiffs' proposed construction to be more consistent with the intrinsic evidence and, indeed, a plain reading of the claim itself. The language of the claim itself describes a discrete drying step in the manufacturing process. The specification references such a step as well. According to the specification, "drying" is a particular step in the coating application process in which solvent is removed from the coating using heat within a particular temperature range. The specification states:

> the present invention is directed to a method of coating a medical device with a therapeutic agent. The method comprises *the steps* of [1] creating a polymer utilizing vinylidene fluoride and hexafluoropropylene in a batch emulsion polymerization process, [2] priming the medical device with the polymer utilizing a dip coating process, [3] creating a polymer and therapeutic agent mixture, [4] applying the polymer and therapeutic agent mixture on the primer layer utilizing a spin coating process, and [5] *drying the medical device in a vacuum oven for approximately sixteen hours at a temperature in the range of fifty to sixty degrees centigrade*.

'844 patent, col. 6, lines 14-25 (emphasis added). It appears to be undisputed that a drying step is commonly used during the manufacturing of drug eluting stents. Ruane Decl. (D.I. 120) at ¶ 12.

Consequently, the Court shall adopt Plaintiffs' proposed construction. The Court construes "drying the balloon-expandable stent comprising said coating at a maximum

temperature no greater than 60 ºC" to mean "performing a process for removing solvent from said coating while maintaining a temperature in the immediate vicinity of the balloon-expandable stent which is no greater than 60 ºC."

2. The '773 Patent

a. *"effective amounts of a therapeutic and/or pharmaceutical agent"*

> This phrase appears in claim 4 of the '773 patent. Claim 4 reads as follows:
>
> An implantable medical device comprising a metallic stent and a biocompatible film coating effective to provide an inert surface to be in contact with the body tissue of a mammal upon implantation of said device in said mammal, said film coating comprising a polyfluro copolymer comprising about 85 weight percent of polymerized residue of vinyldenefluoride and about 15 weight percent of polymerized residue of hexafluoropropylene mixed with effective amounts of a therapeutic and/or pharmaceutical agent.

Plaintiffs assert that the phrase "effective amounts of a therapeutic and/or pharmaceutical agent" means "an amount of a therapeutic and/or pharmaceutical agent that is capable of producing a result." Abbott and BSC argue that the claim term is indefinite under U.S.C. § 112(2).

The Court finds that the claim is not indefinite as it is capable of construction. Decisions of the Federal Circuit are clear that "effective amount" is "a common and generally acceptable term for pharmaceutical claims," and that a claim of an "effective amount" of a drug is "not ambiguous or indefinite, provided that a person of ordinary skill in the art could determine the specific amounts without undue experimentation." *Geneva Pharmaceuticals, Inc. v. GlaxoSmithKline PLC*, 349 F.3d 1383-84 (Fed. Cir. 2003). Here, the specification provides sufficient guidance as to the "effective amounts" referred to in the claim. First, the specification gives examples of the desired purposes of the pharmaceutical or therapeutic agents such as "reducing thrombosis or restienosis" ('773 patent, col. 2 line 66 to col. 3, line

2) and the claimed pharmaceutical or therapeutic agents may include, but are not limited to, antiproliferative/antimitotic agents, antibiotics, anticoagulants, anti-inflammatory agents, and angiogenic agents (*see id.*, col. 6, line 51 to col. 7, line 26). Second, the specification describes in one example a stent with a 750 microgram coating of which 30 percent (225 micrograms) was rapamycin. More, the specification teaches that "[t]he dosage can be tailored to the subject being treated, the severity of the affliction, the judgment of the prescribing physician, and the like." *Id.*, col. 8, lines 33-35. A person of ordinary skill in the art, therefore, could conduct a routine dose response study to determine the efficacy of a particular treatment. Buller Decl. ¶ 12.

Here, Defendants simply have not established by clear and convincing evidence that the disputed claim cannot be construed. *See Haemonetics Corp. v. Baxter Healthcare Corp.*, 607 F.3d 776, 783 (Fed. Cir. 2010) "An accused infringer must ... demonstrate by clear and convincing evidence that one of ordinary skill in the relevant art could not discern the boundaries of the claim based on the claim language, the specification, the prosecution history, and the knowledge in the relevant art."). The Court finds that the claim is amenable to construction, and shall construe the phrase "effective amounts of a therapeutic and/or pharmaceutical agent" to mean "an amount of a therapeutic and/or pharmaceutical agent that is capable of producing a result."

b. *"film coating effective to provide an inert surface to be in contact with body tissue of a mammal upon implantation of said device in said mammal"*

This appears in claim 4 of the '773 patent. Plaintiffs argue that it should be construed to mean "film coating [with a surface] that is able to perform its function in the body with an

acceptable biological response upon implantation of said device in said mammal." [2] Abbott argues that the phrase means "film coating effective to provide a biologically, chemically and physiologically inactive surface to be in contact with body tissue of a mammal upon implantation of said device in said mammal." [3]

The dispute over this claim language centers on the amount of activity that the "inert surface" can exhibit. Plaintiffs' construction allows for some activity, namely, activity that it defines as "an acceptable biological response." Under Abbott's construction, on the other hand, the inert surface must be inactive. Plaintiff objects to Abbott's construction because it would "arguably not cover a coating for which there was a tiny – and wholly immaterial – body reaction." Pl. Opening Br. at 17.

Abbott bases its construction largely on the plain meaning of the term "inert", which is generally understood to refer to a lack of active properties. *See* Merriam-Webster Dictionary at http://www.merriam-webster.com (defining inert at "deficient in active properties; especially : lacking a usual or anticipated chemical or biological action"). Plaintiff, on the other hand, contends that its proposed construction is supported by the specification, which, according to Plaintiffs, "describes the claimed inert and biocompatible coatings as minimizing (but not necessarily eliminating) adverse reactions." Pl. Opening Br. at 16. For example, Plaintiffs point to language in the specification that states: "[i]t would be advantageous to develop coating for implantable medical devices that will reduce thrombosis, restenosis, or other adverse reactions." '773 patent, col. 1, lines 60-67. Indeed, Plaintiffs point to several lines in the specification that refer to the reduction of undesirable reactions. *See* '773 patent,

[2] The construction originally proposed by Plaintiffs did not include the language "with a surface." At oral argument, Plaintiffs offered this amended construction to clarify that their construction did not intend to read the term "surface" out of the claim. *See* Tr. 66:15-21.
[3] BSC takes no position.

col. 3, lines 24-29 ("biocompatible coatings … provide inert surfaces to be in contat wit body tissue of a mammal … sufficient to reduce … undesireable reactions"); col. 5, lines 63-66 ("biocompatible polymer coatings generally are applied to the stent in order to reduce local turbulence in blood flow through the stent, as well as adverse tissue reactions"). The prosecution history shows that the applicants likewise informed the examiner that the claimed biocompatible films "are to provide an inert surface contacting the tissue that reduces foreign body reactions that may be stimulated by implantation of the device into the body, e.g., thrombosis or restenosis. Weiner Decl., Ex. O, Response dated Aug. 29, 2003 at 3.

The problem the Court finds with Plaintiffs construction is two-fold. First, it does not entirely comport with the generally understood meaning of the term inert. Plaintiffs' citations to the specification are not sufficient to overcome that. Second, the definition appears to conflate the terms "biocompatible" and "inert" in the claim. The terms are used independently in the claim, yet Plaintiffs' proposed construction fails to take this into account. *See* claim 4 ("a biocompatible film coating effective to provide an inert surface…").

Consequently, the Court adopts Abbott's proposed construction and construes "film coating effective to provide an inert surface to be in contact with body tissue of a mammal upon implantation of said device in said mammal" to mean "film coating effective to provide a biologically, chemically and physiologically inactive surface to be in contact with body tissue of a mammal upon implantation of said device in said mammal." In adopting this construction, however, the Court notes that it makes no finding as to whether the claim covers "a tiny – and wholly immaterial – body reaction," as such an issue is more appropriately addressed at a later stage in this litigation.

c. *"polyfluoro copolymer comprising about 85 weight percent of polymerized residue of vinylidenefluoride and about 15 weight percent of polymerized residue of hexafluoropropylene"*

This phrase appears in claim 4 of the '773 patent. Plaintiffs allege that this clause means "polyfluro copolymer including approximately 85 weight percent vinylidenefluoride and approximately 15 weight percent hexafluropropylene." Defendants contend that this clause does not require construction. In their opening brief, Plaintiffs identify the dispute over this term as whether "the claimed weight percentages refer to starting materials or the finished copolymer." Pl. Br. at 11. However, briefing has revealed that there is actually no dispute among the parties. All parties agree that the claimed weight percentages refer to the finished polymer. Nevertheless, Plaintiffs urge the Court to adopt their proposed construction at this time, asserting that " 'polymerized residue' is not a term in the lexicon of the an average juror" and, therefore, their construction will assist the jury in understanding claim language. Pl. Responsive Br. at 16.

"The purpose of claim construction" at least at this phase of the litigation," is to *determine* the meaning and scope of the patent claims that the plaintiff alleges have been infringed." *Every Penny Counts, Inc. v. American Express Co.*, 563 F.3d 1378, 1381 (Fed. Cir. 2009) (emphasis added). Here, there is no dispute as to the meaning and scope of "polyfluoro copolymer comprising about 85 weight percent of polymerized residue of vinylidenefluoride and about 15 weight percent of polymerized residue of hexafluoropropylene." The Court is cognizant that at trial it will need to provide the jury with "instructions adequate to ensure that the jury fully understands the [C]ourt's claim construction rulings and what the patentee covered by the claims." *Sulzer Textil A.G. v.*

Picanol N.V., 358 F.3d 1356, 1366 (Fed. Cir. 2004). However, those issues need not be addressed at the present time. Indeed, another district court addressing an argument similar to Plaintiffs' invoked an oft-quoted proverb and aptly counseled the parties in that case that "in the context of claim construction, sufficient unto the day is the evil thereof."[4] *Rembrandt Data Storage, LP v. Seagate Technology LLC*, 2011 WL 4950088 at *14 (W.D. Wis. October 18, 2011). Finding that the parties had not "identif[ied] any issues of infringement or invalidity that [would have been] resolved by tinkering with the claim language," the court in *Rembrandt* declined to construe the relevant claim language at the *Markman* phase of the litigation. *Id.* Instead, that court invited any party that believed changes were necessary to help with a jury's understanding of a claim to raise that issue in a motion in limine at the time of trial. *Id.* This Court does the same.

d. *"polyfluoro copolymer comprises 85.5 weight percent vinylidenefluoride copolymerized with 14.5 weight percent of hexafluoropropylene"*

This phrase appears in claim 6 of the '773 patent. Plaintiffs propose the following construction: "polyfluoro copolymer includes 85.5 weight percent vinylidenefluoride and 14.5 weight percent hexafluropropylene." Abbott contends that the clause means "a ployfluoro copolymer produced by polymerizing together 85.5 weight percent vinylidinefluoride with 14.5 weight percent hexafluoropropylene." BSC argues that the clause in indefinite, but to the extent that it is not indefinite, BSC asserts it means "produced from 85.5 weight percent vinylidinefluoride and 14.5 weight percent hexafluoropropylene." As with the similar language found in claim 19 of the '844 patent, the question here is whether the weight percentages recited specify the weight percentages of VDF and HFP at the

[4] Or, said another way, one should not worry about what may arise in the future, it is enough to worry about what is happening in the present. *See, e.g.*, Oxford Dictionary of Proverbs at 307 (5th ed. 2008).

start of the copolymerization process or the weight percentages present in the finished product. For substantially the same reasons expressed above in section III(1)(a) of this Opinion, the Court construes "polyfluoro copolymer comprises 85.5 weight percent vinylidenefluoride copolymerized with 14.5 weight percent of hexafluoropropylene" to mean "polyfluoro copolymer includes 85.5 weight percent vinylidenefluoride and 14.5 weight percent hexafluropropylene." *See* '773 patent, col. 9, lines 30-33 (referring to Solef 21508 comprising 85.5 weight perecent VDF copolymerized with 14.5 percent HFP, as determined by F^{19}NMR).

e. (1) *"said film coating is heated to a maximum temperature of less than about 100 º C"* and; (2) *"said film coating is heated to a maximum temperature of less than about 65 º C"*

These clause "said film coating is heated to a maximum temperature of less than about 100 º C" appears in dependent claim 8 of the '773 patent, and the clause "said film coating is heated to a maximum temperature of less than about 65 º C" appears in dependent claim 9 of the '773 patent. Plaintiffs propose the following constructions: (1) "said film coating attains, during the manufacturing process, a maximum temperature of less than approximately 100 º C" (claim 8) and "said film coating attains, during the manufacturing process, a maximum temperature of less than approximately 65 º C" (claim 9). Under these constructions proposed by Plaintiffs, the "is heated" claim language refers to heating during the manufacturing process only. Abbott contends that the clause needs no construction,[5] but asserts that the "is

[5] Abbott also raises the argument that the claim is indefinite, but barely expands upon it in its briefing. At oral argument, counsel for Abbott stated that the issue of indefiniteness could be addressed at a later time. Tr. 57:3. To the extent that the issue is presently before the Court, Abbott has not made the requisite showing of indefiniteness.

heated" claim language is not limited to only hearing during manufacture.[6] The Court, therefore must resolve the dispute as to whether the claim is so limited. *See O2 Micro*, 521 F.3d at 1360.

A reading of the specification makes clear that the maximum temperature limitation in the disputed claim language refers to heating during the manufacturing process. The specification distinguishes the copolymers of the invention with other copolymers, the latter of which require "high heat, *e.g.*, greater than about 125^{o} C, to obtain films with adequate physical and mechanical properties for use on … stents." '773 patent, col. 3, lines 30-34; *see also* col. 1, lines 54 to 59 (noting as undesirable certain homopolymers that are "difficult to apply as high quality films onto surfaces without subjecting them to relatively high temperatures"). Further, several of the examples in the '773 patent refer to temperatures during the manufacturing process. Accordingly, the Court construes "said film coating is heated to a maximum temperature of less than about 100 ^{o} C" to mean "said film coating attains, during the manufacturing process, a maximum temperature of less than approximately 100 ^{o} C", and construes "said film coating is heated to a maximum temperature of less than about 65 ^{o} C" to mean "said film coating attains, during the manufacturing process, a maximum temperature of less than approximately 65 ^{o} C."

[6] With regard to BSC, it is BSC's position that claims 8-9 are product-by-process claims and require no further construction. BSC did not brief its position but rather stated it in a footnote, and it noted the intention to raise the product-by-process issue later in this litigation. *See* BSC Opening Brf. at 20, n.13. Therefore, the Court will address the issue at a later time.

IV. Conclusion

For the reasons set forth above, the disputed claim terms will be construed as indicated. An appropriate Order shall accompany this Opinion.

/s/ Joel A. Pisano
JOEL A. PISANO, U.S.D.J.

Dated: November 21, 2011