IN THE UNITED STATES DISTRICT COURT

FOR THE DISTRICT OF DELAWARE

BOSTON SCIENTIFIC CORPORATION and BOSTON SCIENTIFIC SCIMED INC.,	)	
Plaintiffs,	)	Civ. No. 07-333-SLR; Civ. No. 07-348-SLR; Civ. No. 07-409-SLR; and Civ. No. 07-765-SLR
v.	)	
JOHNSON & JOHNSON INC. and CORDIS CORPORATION,	)	
Defendants.	)	

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MEMORANDUM OPINION

Dated: January 20, 2010
Wilmington, Delaware

ROBINSON, District Judge

I. INTRODUCTION

This is a consolidated patent infringement action. Plaintiffs Boston Scientific Corporation and Boston Scientific Scimed, Inc. (collectively, "BSC") have four complaints against defendants Johnson & Johnson, Inc. and Cordis Corporation ("Cordis") (collectively, "J&J"), seeking a judgment that each of four J&J patents are invalid: U.S. Patent Nos. 7,217,286 ("the '7286 patent") (Civ. No. 07-333, D.I. 1); 7,223,286 ("the '3286 patent") (Civ. No. 07-348, D.I. 1); 7,229,473 ("the '473 patent") (Civ. No. 07-409, D.I. 1); and 7,300,662 ("the '662 patent") (Civ. No. 07-765, D.I. 1). J&J counterclaimed for infringement.[1] The court previously denied J&J's motion to dismiss or, in the alternative, for transfer to the District of New Jersey, where J&J has sued Abbott Cardiovascular Systems, Inc. ("Abbott") for infringement of the '7286, '3286, '473 and '662 patents. *See Boston Scientific Corp. v. Johnson & Johnson, Inc.*, 532 F. Supp. 2d 648 (D. Del. 2008). Currently pending before the court are several summary judgment motions: BSC's motion for summary judgment of invalidity of each patent pursuant to 35 U.S.C. § 112; BSC's motion for summary judgment of invalidity of the '7286, '3286, and '471 patents pursuant to 35 U.S.C. § 103; BSC's motion for summary judgment of noninfringement of the asserted claims of the '7286, '3286, and '473 patents; and J&J's motion for infringement of claim 9 of the '3286 patent. The court held a claim construction hearing and heard oral argument on the pending motions on October 30, 2009. This matter is scheduled for trial beginning February 4, 2010. For the reasons that follow, the court grants BSC's motion for summary

[1]Wyeth co-owns the '662 patent with Cordis and is also a party in the action involving the '662 patent. Cordis is the assignee of the '7286, '3286, and '473 patents in suit.

judgment of invalidity based on 35 U.S.C. § 112 and denies the other motions.

II. BACKGROUND

A. Overview

The four patents at issue relate generally to drug-eluting coronary stents which are used in the treatment of coronary artery disease. The '7286, '3286, and '473 patents are all members of the same patent family and issued from continuation applications, each claiming priority to the same patent. Each of these patents share a common specification. The '662 patent shares two common inventors with the '7286, '3286, and '473 patents, but is not a member of the same patent family.

BSC sells the Promus Everolimus-Eluting Coronary Stent System (the "Promus stent"). The Promus stent elutes the drug everolimus,[2] which is designed to diminish reblocking (restenosis) of a patient's blood vessel following implantation. The Promus stent is a private-labeled "XIENCE V Everolimus-Eluting Coronary Stent System" (hereinafter, the "Xience stent") manufactured by Abbott. This action was initiated in May 2007; BSC obtained FDA approval for the Promus stent in July 2008.

B. The Patents at Issue

The '7286, '3286 and '473 patents are all entitled "Local delivery of rapamycin for treatment of proliferative sequelae associated with PTCA procedures, including delivery using a modified stent." Their common specification is directed to methods of preparing polymeric-coated rapamycin[3] or rapamycin analog eluting intravascular stents and

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[2]The chemical name for everolimus is 40-O-(2-hydroxyethyl)-rapamycin. Everolimus is used as an immunosuppressant to prevent rejection of organ transplants.

[3]Rapamycin, also called "sirolimus," is also an immunosuppressive drug that targets certain proteins in cellular fluid. The precise mode of action of rapamycin, known to the patentees by 2004 when the '662 patent was filed, is to bind to the

methods of treating a coronary artery using these stents.[4]

The '7286 patent issued on May 15, 2007 from U.S. Patent Application No. 11/467,035. Robert Falotico ("Falotico") and Gerarh H. Llanos ("Llanos") are named inventors. The '7286 patent has five claims; all are asserted by J&J to be infringed by the Promus stent. These claims read as follows:

> 1. A device comprising a metallic stent, a biocompatible, nonabsorbable polymeric carrier, and a therapeutic agent, wherein: said polymeric carrier comprises an acrylate-based polymer or copolymer, a fluorinated polymer, or a mixture thereof, and said therapeutic agent is rapamycin, or a macrocyclic lactone analog thereof, and is present in an amount effective to inhibit neointimal proliferation.
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> 2. The device according to claim 1 wherein said therapeutic agent is a macrocyclic lactone analog of rapamycin.
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> 3. The device according to claim 1 that provides a controlled release of said therapeutic agent over a period of several weeks.
>
> 4. The device according to claim 2 that provides a controlled release of said therapeutic agent over a period of several weeks.
>
> 5. A method of inhibiting neointimal proliferation in a coronary artery resulting from percutaneous transluminal coronary angioplasty comprising implanting a device according to any one of claims 1 to 4 in the lumen of said coronary artery.

The '3286 patent issued on May 29, 2007 from U.S. Patent Application No. 10/951,385. Falotico, Llanos, Carol Wright, Ronald Rakos, and Kristin King are named inventors. J&J is asserting infringement of claims 9, 10, 21, 25, 27-39, 51-52, 63, 67, and 69-77.[5] The asserted claims depend either directly or indirectly on non-asserted

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cytosolic FK-binding protein 12 (or "FKBP12"). Everolimus is made by modifying sirolimus at a single location.

[4]Because the '7286, '3286 and '473 patents share a common specification and all claim priority to applications filed in 1997 or 1998, they are referred to by the parties as the "1997 patents."

[5]J&J has executed a covenant not to sue BSC for infringement of claims 1, 2, 5, 6, 40, 41, 44, 47, and 48 of the '3286 patent. (Civ. No. 07-333, D.I. 314 at A1198-1202)

claims 1 and 40, as reproduced below.

> 1. A stent having a coating applied thereto, wherein said coating comprises a biocompatible polymer/drug mixture and said drug is rapamycin or a macrocyclic lactone analog thereof.
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> 40. A device comprising a metallic stent, a biocompatible polymeric carrier and a drug, wherein said drug is rapamycin or a macrocyclic lactone analog thereof and is present in an amount effective to inhibit neointimal proliferation.

The '473 patent issued on June 12, 2007 from U.S. Patent Application No. 11/466,983. Falotico and Llanos are named inventors. J&J is asserting infringement of each of the five claims of the '473 patent, which read as follows:

> 1. A metallic stent having a coating applied thereto, wherein: said coating comprises a mixture of a biocompatible polymeric carrier and a therapeutic agent; said polymeric carrier comprises at least one nonabsorbable polymer; said therapeutic agent is rapamycin, or a macrocyclic lactone analog thereof, present in an amount effective to inhibit neointimal proliferation; and said stent provides a controlled release of said therapeutic agent over a period of several weeks.
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> 2. The metallic stent according to claim 1 wherein said therapeutic agent is a macrocyclic lactone analog of rapamycin.
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> 3. The metallic stent according to claim 1 wherein said biocompatible polymeric carrier comprises a fluorinated polymer.
>
> 4. The metallic stent according to claim 3 wherein said biocompatible polymeric carrier further comprises an acrylate-based polymer or copolymer.
>
> 5. A method of inhibiting neointimal proliferation in a coronary artery resulting from percutaneous transluminal coronary angioplasty comprising implanting a metallic stent according to any one of claims 1 to 4 in the lumen of said coronary artery.

The covenant not to sue divests the court of declaratory judgment jurisdiction vis-a-vis those claims. *See Amana Refrigeration, Inc. v. Quadlux, Inc.*, 172 F.3d 852, 855 (Fed. Cir. 1999); *Super Sack Mfg. Corp. V. Chase Packaging Corp.*, 57 F.3d 1054, 1060 (Fed. Cir. 1995). This does not affect asserted dependent claims.

The '662 patent is entitled "Drug/drug delivery systems for the prevention of vascular disease." It issued November 27, 2007 from U.S. Application No. 10/829,074. Priority is claimed to 2000. Falotico, Llanos, and Gregory A. Kopia are named inventors. The '662 patent is co-owned by Cordis and Wyeth. Only the validity of the '662 patent is at issue with respect to the motions at bar.

The '662 patent claims a stent ("drug delivery device") containing "rapamycin or a macrocyclic triene analog thereof that binds FKBP12" and a method of inhibiting neointimal proliferation in a human coronary artery using such a stent. Independent claims 1 and 9 are representative, and read as follows:

> 1. A drug delivery device comprising: an intraluminal stent; a biocompatible, nonerodible polymeric coating affixed to the intraluminal stent; and from about 64 μg to about 197 μg of rapamycin or a macrocyclic triene analog thereof that binds FKBP12 incorporated into the polymeric coating, wherein said device provides an in-stent late loss in diameter at 12 months following implantation in a human of less than about 0.5 mm, as measured by quantitative coronary angiography.
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> 9. A method of inhibiting neointimal proliferation in a human coronary artery resulting from percutaneous transluminal coronary angioplasty comprising implanting in the lumen of said coronary artery a drug delivery device comprising: an intraluminal stent; a biocompatible, nonerodible polymeric coating affixed to the intraluminal stent; and from about 64 μg to about 197 μg of rapamycin or a macrocyclic triene analog thereof that binds FKBP12 incorporated into the polymeric coating, wherein said method provides an in-stent late loss in diameter at 12 months following implantation of less than about 0.5 mm, as measured by quantitative coronary angiography.

C. The Promus Stent

The parties do not dispute the following facts. The Promus stent is available for sale in a variety of different lengths and diameters; depending on these parameters, either the "Multi-Link Vision" or "Multi-Link Mini Vision" bare metal coronary stent is used as the underlying platform. There are two coatings on the Promus stent. A drug-free poly(n-butyl methacrylate) ("PBMA") "primer" coating is deposited directly on the underlying bare metal stent surface. Atop this PBMA layer is a layer consisting of a vinylidene flouride and hexaflouropropylene copolymer ("PVDF-HFP") co-formulated with the drug everolimus.

III. STANDARD OF REVIEW

A court shall grant summary judgment only if "the pleadings, depositions, answers to interrogatories, and admissions on file, together with the affidavits, if any, show that there is no genuine issue as to any material fact and that the moving party is entitled to judgment as a matter of law." Fed. R. Civ. P. 56(c). The moving party bears the burden of proving that no genuine issue of material fact exists. *See Matsushita Elec. Indus. Co. v. Zenith Radio Corp.*, 475 U.S. 574, 586 n.10 (1986). "Facts that could alter the outcome are 'material,' and disputes are 'genuine' if evidence exists from which a rational person could conclude that the position of the person with the burden of proof on the disputed issue is correct." *Horowitz v. Fed. Kemper Life Assurance Co.*, 57 F.3d 300, 302 n.1 (3d Cir. 1995) (internal citations omitted). If the moving party has demonstrated an absence of material fact, the nonmoving party then "must come forward with 'specific facts showing that there is a genuine issue for trial.'" *Matsushita*,

475 U.S. at 587 (quoting Fed. R. Civ. P. 56(e)). The court will "view the underlying facts and all reasonable inferences therefrom in the light most favorable to the party opposing the motion." *Pa. Coal Ass'n v. Babbitt*, 63 F.3d 231, 236 (3d Cir. 1995). The mere existence of some evidence in support of the nonmoving party, however, will not be sufficient for denial of a motion for summary judgment; there must be enough evidence to enable a jury reasonably to find for the nonmoving party on that issue. *See Anderson v. Liberty Lobby, Inc.*, 477 U.S. 242, 249 (1986). If the nonmoving party fails to make a sufficient showing on an essential element of its case with respect to which it has the burden of proof, the moving party is entitled to judgment as a matter of law. *See Celotex Corp. v. Catrett*, 477 U.S. 317, 322 (1986).

IV. DISCUSSION

A. Infringement

BSC moves for summary judgment that the Promus stent does not infringe any asserted claim of the '7286, '3286, or '473 patents. J&J moves for summary judgment that the Promus stent infringes claim 9 of the '3286 patent.

1. Standard

A patent is infringed when a person "without authority makes, uses or sells any patented invention, within the United States . . . during the term of the patent." 35 U.S.C. § 271(a). A two-step analysis is employed in making an infringement determination. *Markman v. Westview Instruments, Inc.*, 52 F.3d 967, 976 (Fed. Cir. 1995). First, the court must construe the asserted claims to ascertain their meaning and scope. *Id.* Construction of the claims is a question of law subject to de novo

review. *See Cybor Corp. v. FAS Techs.*, 138 F.3d 1448, 1454 (Fed. Cir. 1998). The trier of fact must then compare the properly construed claims with the accused infringing product. *Markman*, 52 F.3d at 976. This second step is a question of fact. *See Bai v. L & L Wings, Inc.*, 160 F.3d 1350, 1353 (Fed. Cir. 1998).

"Direct infringement requires a party to perform each and every step or element of a claimed method or product." *BMC Res., Inc. v. Paymentech, L.P.*, 498 F.3d 1373, 1378 (Fed. Cir. 2007). "If any claim limitation is absent from the accused device, there is no literal infringement as a matter of law." *Bayer AG v. Elan Pharm. Research Corp.*, 212 F.3d 1241, 1247 (Fed. Cir. 2000). If an accused product does not infringe an independent claim, it also does not infringe any claim depending thereon. *Wahpeton Canvas Co. v. Frontier, Inc.*, 870 F.2d 1546, 1553 (Fed. Cir. 1989). The patent owner has the burden of proving infringement and must meet its burden by a preponderance of the evidence. *SmithKline Diagnostics, Inc. v. Helena Lab. Corp.*, 859 F.2d 878, 889 (Fed. Cir. 1988) (citations omitted).

2. Analysis

In order to prevail on its motion for summary judgment of non-infringement, the court must adopt each of BSC's proffered claim definitions. The court has declined to do so, necessitating the denial of BSC's motion. The court briefly addresses several illustrative points in this regard.

i. "Biocompatible"

All of the asserted claims of the '7286, '3286 and '473 patents include limitations requiring the use of "biocompatible" polymeric carrier. By its order of the same date,

the court has construed "biocompatible" to mean that the carrier (or "material that carries the drug") is "able to perform its function in the body with an acceptable biological response." BSC propounded a definition mandating that a "biocompatible" carrier not elicit **any** negative tissue reaction or promote mural thrombosis formation. BSC does not dispute that, when implanted in a body, the Promus stent (with its PVDF-HFP coating) elicits some inflammation (D.I. 260 at 18)[6]; BSC characterizes this inflammation as a negative tissue reaction. Because the court does not define "biocompatible" as precluding some benign level of inflammation (or negative tissue reaction), so long as the functionality of the stent is unaffected, the Promus stent may meet this limitation.[7]

J&J's expert, Dr. Antonios G. Mikos, has opined that the Promus stent literally meets the "biocompatible" limitation because any tissue reaction elicited by implanting the stent is acceptable and, therefore, not negative. (D.I. 314 at A4, ¶¶ 9-10) J&J also intends to rely on statements made by Abbott that it conducted biocompatibility testing and "had high confidence in the biocompatibility of the individual components" of the Xience stent delivery system, such as PVDF-HFP. (*Id.* at A2403-04) J&J has proffered sufficient evidence to withstand summary judgment on this issue.[8]

ii. "Coating . . . applied thereto"

In the context of its motion, BSC argues that the Promus stent does not include a

[6]All D.I. numbers reference Civ. No. 07-333.

[7]BSC's expert, Dr. Harold B. Hopfenberg, agrees that the Promus stent may be "biocompatible" in the conventional sense. (D.I. 302 at 7)

[8]A summary of J&J's proffered evidence can be found in its responsive brief. (D.I. 305 at 5-7) The court need not address J&J's additional assertions under the doctrine of equivalents. (*Id.* at 8-10)

"coating" which is "applied [ ]to" the stent as required by claims 9, 10, 21, 25, and 27-39 of the '3286 patent and all asserted claims of the '473 patent. According to BSC, the term "coating" refers to a "distinct covering layer of a particular composition." These terms are also relevant to J&J's motion for partial summary judgment of infringement of claim 9 of the '3286 patent.[9]

The court has construed "coating" as simply a "covering layer." In its moving papers, J&J cites to an Abbott document[10] stating that the Xience stent "has **a coating** consisting of two layers: a primer layer and a drug reservoir [PVDF-HVP] layer[.]"[11] (D.I. 268 at 5, citing D.I. 274, ex. 4 at A113) (emphasis added) In its response to BSC's motion, J&J points to Dr. Mikos's declaration stating that the "stent" to which the PVDF-HFP polymer layer is applied includes both the underlying metal structure and the PBMA primer layer. (D.I. 314 at A9, ¶ 22) It seems, therefore, that J&J advances two separate infringement theories: (1) the PBMA layer and PVDF-HFP layers comprise one "coating" which is, logically, "applied to" the stent (as supported by the Abbott document); or (2) the PVDF-HFP layer is the "coating" applied to the stent, which is made up of the bare metal portion plus PBMA layer.

BSC asserts that: (1) J&J is precluded from asserting that the PBMA and

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[9]Claim 9 of the '3296 patent depends from claim 1, as follows:

1. A stent having a coating applied thereto, wherein said coating comprises a biocompatible polymer/drug mixture and said drug is rapamycin or a macrocyclic lactone analog thereof.

9. A stent according to claim 1 wherein the coating comprises a nonabsorbable polymer.

[10]The copy submitted is an excerpt and does not contain a cover page. J&J does not describe the document.

[11]BSC does not address this document.

PDVF-HFP/everolimus layers together meet the "coating" limitation;[12] and (2) Dr. Mikos contrasted the prior art "Ding '536 patent" on the basis that its claims "are directed to polymer coatings with two separate and distinct layers" (D.I. 304, ex. 2 at 45). (D.I. 302 at 5-6)

The only document cited by BSC, the "Instructions for Use" for the Promus stent, does not speak to the presence or absence of PBMA in the drug layer or whether the "stent" comprises the primer layer.[11] (D.I. 260 at 21, citing D.I. 263, ex. 19 at BSC-SJA-0717) BSC does not cite any expert testimony (or other evidence) of its own supporting its assertions that the PBMA layer and PVDF-HFP layer constitute two "coatings," or that the PVDF-HFP layer is "applied to" the PBMA layer, not "applied to" the stent as required by the claims. (D.I. 260 at 20-22; D.I. 302 at 5-7; D.I. 322 at 8-10)

On this scant record, a jury could reasonably find for either party on whether the Promus stent has, essentially, one or two coatings. Dr. Mikos's seemingly contrasting positions should be fleshed out at trial;[12] summary judgment for J&J is inappropriate at this time.

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[12]Dr. Mikos's expert report dated September 2, 2009 is the subject of a motion to strike. (D.I. 251) BSC asserts that Dr. Mikos's opinions regarding the presence of drug in the PBMA primer layer were not disclosed in expert reports by the date required by the court, or July 28, 2009. (*Id.*) J&J relies on Dr. Mikos's rebuttal expert report of August 7, 2009 as disclosing, inter alia, that "the 'coating' in claim 1 of the '3286 patent includes the 'polymer drug mixture,' but may also include additional elements such as a primer layer." The August 7, 2009 report is not addressed by BSC's motion. The court's copy of the August 7 report was obtained at oral argument.

[11]The court's construction of "stent," "a device for providing support for a lumen in the body," is a broad one.

[12]The court typically does not admit evidence of reexamination proceedings at trial. The parties shall be prepared to address, at the pre-trial hearing, the admissibility of Dr. Mikos's statements (cited by BSC) made during the co-pending reexamination for impeachment purposes.

iii. "Polymer" limitations

The asserted claims of the '7286 patent require that the drug-eluting stent's "polymeric carrier" "comprise[ ] an acrylate-based polymer or copolymer, a flourinated polymer, or a mixture thereof." Claims 9, 10, 21, 25, and 27-39 of the '3286 patent require that the claimed drug-eluting stent include a "polymer/drug mixture." Claims 1-5 of the '473 patent require the "polymeric carrier" to "comprise[ ] at least one nonabsorbable polymer"; claim 3 contains the "flourinated polymer" limitation, and claim 4 requires that the carrier further comprise "an acrylate based-polymer or copolymer."

BSC's argument with respect to these limitations is that the Promus stent cannot infringe because PBMA is not a "polymeric carrier" co-formulated with a drug. BSC also argues that the polymeric carrier – PVDF-HFP, a flourinated copolymer – is not a "polymer" (i.e., a homopolymer containing repeating units of the same monomer).

The court has construed "polymer" as "a material formed by polymerization and comprising repeating units of the same (homopolymer) or different (copolymer) types of monomers"; a "copolymer" is "a polymer having two or more different types of monomers." A "flourinated polymer" is "a polymer containing one or more flourine atoms." Because the court has not restricted a "polymer" to homopolymers, its definitions do not preclude PVDF-HFP.

Claims 21, 36, 39, 63, 73 and 77 of the '3286 patent require that the "coating" comprise "an acrylate based" polymer or copolymer, or "a polymer in which at least one of the types of monomers is based on the structure of a salt or ester of acrylic acid." BSC asserts that the Promus stent cannot meet this limitation because it does not have a "distinct covering material;" it has two layers of materials (PBMA primer and PVDF-

HFP). The court has defined "coating" as simply a "covering layer." The acrylate-based PBMA primer layer is not necessarily precluded from meeting the court's definitions of "coating" simply because it is covered with PVDF-HFP. Put another way, the court's construction has not foreclosed the argument that the two layers (PBMA primer and PVDF-HFP) comprise one "coating." Under this paradigm, PBMA covered by PVDF-HFP may be viewed as a "polymeric carrier," or "a material comprised of at least one polymer that is formulated with the therapeutic agent."

To this end, J&J has proffered evidence that the two layers are not distinct. Dr. Mikos has opined that, as a result of the manufacturing process, some everolimus is present in the PBMA layer. (D.I. 314 at A11, ¶¶ 28, 29) J&J also points to a 2009 article (entitled "Xience V Stent Design and Rationale") by Nadine Ding et. al of Abbott, describing an entanglement between the polymer chains at the PBMA and PVDF-HFP layers' interface.[14] (D.I. 314 at A1104) The credibility of J&J's argument is left to the determination of the jury.

iv. Present in "an amount effective to inhibit neointimal proliferation"

Finally, BSC argues that the Promus stent does not meet the "present in an amount effective to inhibit neointimal proliferation" limitation of claims 1-5 of the '7286 patent, claims 32-39, 51-52, 63, 67, and 69-77 of the '3286 patent, and claims 1-5 of the '473 patent. It is undisputed that the implantation of a Promus stent does not stop all neointimal proliferation. The court has declined to adopt BSC's claim construction,

[14]"PBMA is partially miscible with PVDF-HFP. Hence, the adhesion of the PVDF-HFP drug reservoir to the primer layer is high as the PBMA and PVDF-HFP polymer chains are entangled at the interface." (D.I. 314 at A1104)

however, which would have limited the term to "an amount sufficient to **stop** neointimal proliferation." (emphasis added) The court found this interpretation inconsistent with the plain and ordinary language (of "inhibit").[15]

v. Conclusion

Based on the foregoing, BSC has not demonstrated the absence of any genuine issues of material fact regarding whether the Promus stent infringes the asserted claims. BSC's motion (D.I. 259) is denied.

B. Obviousness

With respect to claims 1, 3, and 5 of the '7286 patent, claims 1, 2, 5, 6, 9, 10, 21, 25, 28, 30, 32, 40, 41, 44, 47, 48, 51, 52, 63, 67, 70 and '74 of the '3286 patent, and claims 1, 3, 4 and 5 of the '473 patent, BSC asserts obviousness through the combination of U.S. Patent No. 5,464,650 to Berg et al. ("Berg") and U.S. Patent No. 5,516,781 to Morris et al. ("Morris"). BSC also asserts obviousness through the combination of Berg and Morris in view of U.S. Patent No. 5,508,286 to Skotnicki et al. ("Skotnicki") with respect to claims 2 and 4 of the '7286 patent, claims 27, 29, 31, 33, 34, 35, 36, 37, 38, 39, 69, 71, 72, 73, 75, 76 and 77 of the '3286 patent, and claim 2 of the '473 patent. The combination of Berg and Morris is common to all of BSC's claims.

1. BSC's arguments

BSC does not cite any expert testimony in support of its obviousness position.[16]

[15]The court heard argument that, in biological processes, one rarely completely stops a phenomenon from occurring. Although it does not issue a factual finding in this regard, this logic buttresses the court's conclusion.

[16]The Federal Circuit has stated that, "while an analysis of obviousness always depends on evidence that supports the required *Graham* factual findings, it also may include recourse to logic, judgment, and common sense available to the person of ordinary skill that do not necessarily require explication in any reference or expert

BSC nevertheless argues that, with the exception of the use of rapamycin (or its analogs), Berg discloses all of the limitations of the '7286, '3286 and '473 patents' claims. Berg discloses a coated drug-eluting stent that can be used with "any therapeutic substance which possesses desirable therapeutic characteristics for application to a blood vessel." (Berg at col. 5:19-22) BSC asserts that Berg also discloses controlled drug delivery (*id.* at col. 2:21-23, col. 2:52-63) and the controlled release of a drug (dexamethasone) from a polymer coating (poly(L-lactic acid)) (*id.* at col. 5:19-39).[17] (D.I. 262 at 11-12)

Morris discloses that rapamycin is an anti-inflammatory, anti-proliferative, and anti-restenoic agent and explains that rapamycin, which can be delivered via a stent, can be used to treat restenosis. BSC cites Morris's disclosure that "rapamycin is useful in treating intimal smooth muscle cell hyperplasma, restenosis, and vascular occlusion in a mammal[.]" (Morris at col. 3:51-56) Claim 1 of Morris discloses a method of treating restenosis in a mammal comprising administering an antirestenosis-effective amount of rapamycin to said mammal "via a vascular stent impregnated with rapamycin." According to Morris, rapamycin is useful "for the prevention of restenosis." (*Id.* at col. 4:3-4)

It is BSC's position that a motivation to combine Berg and Morris existed because both patents discussed a common purpose (treatment of restenosis) and had

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opinion." *Perfect Web Technologies, Inc. v. InfoUSA, Inc.*, No. 2009-1105, --- F.3d ---, 2009 WL 4281939, *4 (Fed. Cir. Dec. 2, 2009). There is no cross-motion for summary judgment of nonobviousness, and the court has not been specifically asked to assess whether the technology and disclosures at issue in this action require elucidation by an expert.

[17]The parties do not appear to dispute that Berg discloses the use of a metal stent platform and applying a polymer/drug coating to the stent.

related disclosures. (D.I. 262 at 21, 25) BSC argues that there was a reasonable expectation of success with respect to the combination because, as disclosed in the 1997 patents themselves, the drug-eluting stent of Berg was viewed as the "conventional approach" and the prior art "clearly support[ed] the potential use of rapamycin in the clinical setting of post-angioplasty restenosis." (*Id.* at 22, 26)

BSC points to documents indicating that, according to J&J's own scientists, the "Cypher" stent (embodying the 1997 patents) was simply "the successful integration of existing technologies." (D.I. 264, ex. 76 at BSC-SJA-1438; see also *id.*, ex. 95 at BSC-SJA-1554 at 254:14-255:24 & ex. 96 at BSC-SJA-1555 (characterization of the Cypher stent as a combination of "a drug patented by AHP, a delivery approach patented by MDT, and a polymer coating patented by SurModics"); *id.*, ex. 97 at BSC-SJA-1564 (similar disclosure)) BSC states that, in connection with prior litigation before this court (Civ. No. 03-283-SLR), J&J made statements that polymer coatings were well known in the art. (D.I. 262 at 35-37) BSC also argues that, in prior litigation in the U.K., J&J's expert (Dr. Campbell Rogers) stated that "researchers in the field generally were fairly confident that anti-proliferative drugs would work to treat restenosis." (*Id.* at 38; ex. 106 at BSC-SJA-1619, ¶ 67) Finally, BSC points to statements in the patents' specification describing technology similar to Berg as the "conventional approach" ('7286 patent at col. 3:48-50) and stating that prior art relating to rapamycin "clearly support[s] the potential use of rapamycin in the clinical setting of post-angioplasty restenosis" (*id.* at col. 5:56-58).

2. J&J's response

As J&J points out, BSC offers no documentary evidence or testimony regarding what Berg and Morris would have disclosed to a person of ordinary skill in the art. J&J has provided expert declarations that directly contradict BSC's argument. Specifically, Dr. Mikos opines that Berg would not have directed a person of ordinary skill in 1997 to the use of nonabsorbable polymers (rather than biodegradable polymers); no polymers were used in Berg's examples. (D.I. 316 at A107, ¶¶ 54-56)[18] Further, Berg expressed a concern that a nonerodable polymer would "be present long after implantation" causing "adverse, chronic local response" in the artery. (*Id.* at ¶ 55) Berg discloses the use of anti-restenotic agents, but does so broadly among a long list of possible drugs that provides no guidance to a person of ordinary skill. (*Id.* at ¶¶ 51, 56-57) Dr. Mikos also opines that Berg fails to teach the release of rapamycin or an analog thereof over the claimed timed periods. (*Id.* at A108, ¶ 58) Finally, Dr. Mikos states that Morris would not have directed a person of ordinary skill toward the use of stent delivery, as its examples involved systemic delivery, and stent delivery was only mentioned as part of a discussion that included many possible ways of delivering rapamycin. (*Id.* at A125-26, ¶¶ 107, 109)

3. Discussion

BSC was not necessarily required to retain an expert to opine on the prior art; at the same time, BSC's ability to demonstrate the absence of a genuine issue of material fact regarding the obviousness of a presumably valid patent by clear and convincing

[18]Dr. Mikos's declaration in support of J&J's opposition to the obviousness motion is dated October 2, 2009. It is not addressed in BSC's motion to strike, which was filed prior to this date. *See supra* n.12. There is no indication of record, however, that BSC seeks to amend its motion to include this declaration.

evidence is certainly hindered by its strategic decision. BSC's position is, essentially, that a plain reading of Berg and Morris evidences a motivation to combine the references, insofar as both relate to treating restenosis. BSC buttresses this interpretation with J&J's documents and prior assertions which support the proposition that the components of the Cypher stent were known in the art, but do not specifically speak to a motivation to combine those components (as would result from a combination of Berg and Morris). Even assuming that the Cypher stent was only the "integration of existing technologies," this does not necessarily compel a finding of obviousness. *See KSR*, 550 U.S. at 419, 418 ("[I]nventions in most, if not all, instances rely upon building blocks long since uncovered"; "a court must ask whether the improvement is more than the predictable use of prior art elements according to their established functions.").

The court notes that Berg and Morris were of record during prosecution of the 1997 patents, making BSC's burden to demonstrate obviousness "especially difficult." See *Hewlett-Packard Co. v. Bausch & Lomb Inc.*, 909 F.2d 1464, 1467 (Fed. Cir. 1990) ("[T]he burden of showing, by clear and convincing evidence, the invalidity of [patent claims] is especially difficult when the prior art was before the PTO examiner during the prosecution of the application."). The court does not view the statements in the specification as compelling evidence of the obviousness of the patents in which they appear.

For these reasons, BSC's evidence does not, in the court's opinion, rise to the level of clear and convincing. Although J&J does not dispute the specific content of Berg and Morris, it has proffered the opinion of Dr. Mikos who propounds a very

different reading of the disclosures of Berg and Morris than does BSC.[19] Insofar as there are conflicting interpretations of Berg and Morris of record, summary judgment is inappropriate. Because the court finds that a factual dispute exists with respect to what Berg and Morris would have taught a person of ordinary skill in the art in 1997, the court need not address either Skotnicki or the alleged indicia of nonobviousness. BSC's motion is denied.

C. 35 U.S.C. § 112

BSC has filed a motion for summary judgment that the asserted claims of the 1997 patents and '662 patent are invalid for nonenablement, lack of written description, and indefiniteness. The patents each have claims directed to "macrocyclic lactone analogs" (1997 patents) or "macrocyclic triene analogs" ('662 patent) of rapamycin. BSC asserts that the inventors did not provide any meaningful disclosure regarding such analogs, such as examples, figures, diagrams, structures, formulae or physical properties, and there is no indication that the inventors ever possessed such analogs. Likewise, BSC asserts that there is no disclosure regarding how to make or use these embodiments.[20]

1. Applicable standards

a. Indefiniteness

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[19] BSC characterizes Dr. Mikos's opinion as "self-serving;" the credibility of Dr. Mikos would be an issue for the jury.

[20]The court notes the following relationship between BSC's obviousness and § 112 arguments. With respect to the known analogs of rapamycin, BSC asserts that the claims are obvious. To the extent the claims encompass unknown analogs, the claims are not enabled. The court does not agree with J&J that BSC's § 103 and § 112 arguments are inherently inconsistent.

The definiteness requirement is rooted in § 112, ¶ 2, which provides that "the specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention." "A determination of claim indefiniteness is a legal conclusion that is drawn from the court's performance of its duty as the construer of patent claims." *Personalized Media Comm., LLC v. Int'l Trade Com'n*, 161 F.3d 696, 705 (Fed. Cir. 1998).

> Determining whether a claim is definite requires an analysis of whether one skilled in the art would understand the bounds of the claim when read in light of the specification . . . If the claims read in light of the specification reasonably apprise those skilled in the art of the scope of the invention, § 112 demands no more.

Id. (citing *Miles Lab., Inc. v. Shandon, Inc.*, 997 F.2d 870, 875 (Fed. Cir. 1993)).

b. Enablement and written description

The statutory basis for the enablement and written description requirements, § 112 ¶1, provides in relevant part:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same . . . .

To satisfy the enablement requirement, a specification must teach those skilled in the art how to make and use the full scope of the claimed invention without undue experimentation. *Genentech*, 108 F.3d at 1365. "While every aspect of a generic claim certainly need not have been carried out by the inventor, or exemplified in the specification, reasonable detail must be provided in order to enable members of the public to understand and carry out the invention." *Id.* at 1366. The specification need

not teach what is well known in the art. *Hybritech v. Monoclonal Antibodies, Inc.*, 802 F.2d 1367, 1384 (Fed. Cir. 1986).

The enablement requirement is a question of law based on underlying factual inquiries. *Wands*, 858 F.2d at 737. Enablement is determined as of the filing date of the patent application. *In re Brana*, 51 F.3d, 1560, 1567 n.19 (Fed. Cir. 1995). The burden is on one challenging validity to show, by clear and convincing evidence, that the prophetic examples, together with the other parts of the specification, are not enabling. *Atlas Powder Co. v. E.I. Du Pont de Nemours & Co.*, 750 F.2d 1569, 1577 (Fed. Cir. 1984).

Some experimentation may be necessary in order to practice a claimed invention; the amount of experimentation, however, "must not be unduly extensive." *Id.* at 1576. The test for whether undue experimentation would have been required is not merely quantitative, since a considerable amount of experimentation is permissible if it is merely routine, or if the specification in question provides a reasonable amount of guidance with respect to the direction in which the experimentation should proceed to enable the determination of how to practice a desired embodiment of the invention claimed. *PPG Indus. Inc. v. Guardian Indus. Corp.*, 75 F.3d 1558, 1564 (Fed. Cir. 1996) (citation omitted). A court may consider several factors in determining whether undue experimentation is required to practice a claimed invention, including: (1) the quantity of experimentation necessary; (2) the amount of direction or guidance disclosed in the patent; (3) the presence or absence of working examples in the patent; (4) the nature of the invention; (5) the state of the prior art; (6) the relative skill of those

in the art; (7) the predictability of the art; and (8) the breadth of the claims. *In re Wands*, 858 F.2d 731, 737 (Fed. Cir. 1988). These factors are sometimes referred to as the "Wands factors." A court need not consider every one of the Wands factors in its analysis. Rather, a court is only required to consider those factors relevant to the facts of the case. *See Amgen, Inc. v. Chugai Pharm. Co., Ltd.*, 927 F.2d 1200, 1213 (Fed. Cir. 1991).

A patent must also contain a written description of the invention. 35 U.S.C. § 112, ¶ 1. The written description requirement is separate and distinct from the enablement requirement.[21] *See Carnegie Mellon Univ. v. Hoffman-LaRoche Inc.*, 541 F.3d 1115, 1121 (Fed. Cir. 2008) (citation omitted). It ensures that "the patentee had possession of the claimed invention at the time of the application, i.e., that the patentee invented what is claimed." *LizardTech, Inc. v. Earth Resource Mapping, Inc.*, 424 F.3d 1336, 1344-45 (Fed. Cir. 2005). Whether the written description requirement is met is a question of fact. *Martek Biosciences Corp. v. Nutrinova, Inc.*, Nos. 2008-1459 & 2008-1476, 2009 WL 2780367 at *3 (Fed. Cir. Sept. 3, 2009) (citing *Wang Labs., Inc. v. Toshiba Corp.*, 993 F.2d 858, 865 (Fed. Cir. 1993)). In this regard, BSC must provide clear and convincing evidence that persons skilled in the art would not recognize in the disclosure a description of the claimed invention. *See PowerOasis, Inc. v. T-Mobile USA, Inc.*, 522 F.3d 1299, 1307 (Fed. Cir. 2008) (citing *Invitrogen Corp.*, 429 F.3d at 1072-73 (Fed. Cir. 2005)); *In re Alton*, 76 F.3d 1168, 1175 (Fed. Cir. 1996); *Rambus Inc. v. Hynix Semiconductor Inc.*, 569 F. Supp. 2d 946, 994 (N.D. Cal. 2008).

[21]The Supreme Court has declined to review the Federal Circuit's (non-panel) decisions in this regard. *See Univ. of Rochester v. G.D. Searle & Co., Inc.*, 543 U.S. 1015 (2004) (denying certiorari).

2. Definiteness and written description: 1997 patents

By its order of the same date, the court has determined that a person of ordinary skill in the art would interpret the limitation "rapamycin or a macrocyclic lactone analog thereof" as "sirolimus or a macrocyclic lactone molecule with a structure similar to sirolimus." That is, a person of ordinary skill in the art would understand the bounds of the claims as construed by the court. The 1997 patents' specification describes experiments using, as agents, "[r]apamycin (sirolimus) structural analogs (macro-cyclic lactones) and inhibitors of cell-cycle progression." ('7286 patent at col. 6:4-5) The patents disclose, therefore, that structural similarity to rapamycin is required. The limitation is sufficiently definite.

The court turns next to written description. That "the precise mechanism of rapamycin [was] still under active investigation" at the time the 1997 patents were filed (*id.* at col. 5:36-37) does not diminish the ability of a person of ordinary skill in the art to determine whether a given compound had a similar structure to rapamycin. On the other hand, this disclosure in no way restricts the universe of potential analogs fitting the limitations as construed by the court.

The Federal Circuit has stated that,

> [i]n claims involving chemical materials, generic formulae usually indicate with specificity what the generic claims encompass. One skilled in the art can distinguish such a formula from others and can identify many of the species that the claims encompass. Accordingly, such a formula is normally an adequate description of the claimed genus.

The Regents of the Univ. of California v. Eli Lilly and Co., 119 F.3d 1559, 1568 (Fed. Cir. 1997) (hereinafter, "*Eli Lilly*"). Besides the requirement that the compounds be

"structur[ally] similar" to rapamycin, the 1997 patents' specification provides no further guidance regarding the claimed analogs. No formulae or structures of any analogs are disclosed. There are no definitions, examples, or experimental models provided for determining whether a compound is a structurally similar analog as contemplated by the patentees.

> To satisfy the written description requirement in the case of a chemical or biotechnological genus, more than a statement of the genus is normally required. One must show that one has possession, as described in the application, of **sufficient species** to show that he or she invented and disclosed the totality of the genus.

Carnegie Mellon Univ., 541 F.3d at 1126 (emphasis added). J&J does not identify, and the court has not located, a single instance in the specification where an analog is discussed or exemplified. The parties do not genuinely dispute that, at the time of the inventions, a small number of such analogs were known,[22] but many more existed.[23]

Although the claimed genus is not necessarily an unbounded class, there is no indication of how many compounds are truly "structur[ally] similar" to rapamycin in the manner contemplated by the patents. As BSC points out, inventor Llanos testified that analogs were not his focus in 1997. (D.I. 258, ex. 13, BSC-SJA-2005 at 58-59[24])

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[22]J&J's expert, Dr. David M. Sabatini, has pointed to a prior art reference (international patent application No. WO/94/09010) disclosing 25 macrocyclic lactone analogs before the filing date of the 1997 patents. (D.I. 312, A9 at ¶ 22) BSC does not dispute that the prior art disclosed rapamycin analogs. (D.I. 262 at 10)

[23]According to BSC, tens of thousands of potential macrycyclic lactone analogs exist; there are 144 atoms in rapamycin which may be altered. (D.I. 257 at 10) J&J does not specifically contest these representations in its responsive brief. (D.I. 313) During his deposition, Dr. Sabatini stated that he could not predict the entire universe of macrocyclic lactone analogs. (D.I. 320, ex. 38, BSC-SJA-2327 at 159-160, 219) The court does not issue a factual finding with respect to the quantity, but notes a general agreement among the parties that there are numerous potential analogs of rapamycin.

[24]"I ha[d] no reason to search the literature for structural analogs of rapamycin. It didn't matter to me in my program whether I had analogs or not, so why would I have

Falotico testified that he did not work with analogs until at least 2001. (*Id.*, ex. 14, BSC-SJA-2014 at 1150-51,[25] 1213-14[26]). It follows that, if the complete universe of "macrocyclic lactone analogs" of rapamycin were unknown to the inventors, it could not have been adequately described (or enabled) by a specification that does not even attempt to discuss the term.[27]

J&J points to no evidence that contradicts the inventors' deposition testimony or otherwise indicates that the inventors had possession of the full scope of the invention as claimed. J&J relies only on its experts (Dr. Sabatini, Dr. Mikos, and Dr. Campbell Rogers) who opine that the inventors had possession of the full scope of the claimed invention because they provided that the analogs have a particular end function (e.g., to "inhibit[ ] cell-cycle progression." (D.I. 306 at 24-26, citing D.I. 312 at A12, ¶¶ 28-30; *id.* at A19-21, ¶¶ 5-9; *id.* at A38-39, ¶¶ 12-13) J&J's experts essentially assert that a person of ordinary skill in the art could use the disclosed functionality to identify acceptable (structurally similar) analogs. As noted, there is no description of the analogs in the patents. Moreover, describing certain functions of the genus of claimed analogs does not equate to a description of the claimed analogs themselves. *See Enzo*

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searched? There's no reason to."

[25]Stating that no "empirical work where we handled [the] compound and were doing actual empirical studies with an analog" was done by J&J.

[26]"We hadn't tested analogs, but that's not to say that there wasn't information on compounds like everolimus that we were able to draw from. . . . All of our attention at the time was focused on developing a sirolimus-eluting stent. So to the extent that we were very busy on that, we didn't have time to focus on analogs. . . .We had done no empirical studies with a sirolimus analog studying release from a stent [or pharmokinetics] [before 2001]."

[27]Utility is also questionable, as there is no indication that all (or a substantial amount of) embodiments are useful in the context of the invention. The parties have not addressed this issue.

Biochem, Inc. v. Gen-Probe Inc., 323 F.3d 956, 968 (Fed. Cir. 2002) ("A description of what a material does, rather than of what it is, usually does not suffice. The disclosure must allow one skilled in the art to visualize or recognize the identity of the subject matter purportedly described.") (citing *Eli Lilly*, 119 F.3d at 1568 (Fed. Cir. 1997)[28]).

J&J's expert declarations, therefore, do not raise an issue of fact with respect to whether persons of skill in the art would recognize in the 1997 patents' disclosure a description of the claimed analogs. Logically, the inventors could not have described a knowledge that they did not possess; moreover, as mentioned previously, there was no attempt in the specification to do so.[29] BSC has shown, by clear and convincing evidence, that no reasonable jury could find that the written description requirement has been met with respect to the claimed analogs.[30]

3. Enablement: 1997 patents

The foregoing informs the court's analysis with respect to enablement. The issue here is whether a person of ordinary skill in the art, knowing that the analogs must

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[28]"A definition by function . . . does not suffice to define the genus because it is only an indication of what the gene does, rather than what it is. It is only a definition of a useful result rather than a definition of what achieves that result. . . The description requirement of the patent statute requires a description of an invention, not an indication of a result that one might achieve if one made that invention."

[29]The court recognizes that "possession" is a stated **purpose** of the written description requirement, rather than a test. *See Enzo Biochem.*, 323 F.3d at 969. Notwithstanding, "[o]ne shows that one is 'in possession' of the invention by describing the invention, with all its claimed limitations." *Lockwood v. American Airlines, Inc.*, 107 F.3d 1565, 1571-72 (Fed. Cir. 1997).

[30]The claims of the 1997 patents are drawn to "rapamycin, **or** a macrocyclic lactone analog thereof." (emphasis added) The court has not found caselaw holding that one described and enabled **alternative embodiment** of a claim (set apart by an "or") prevents the invalidation of the claim as a whole. Courts are generally encouraged to preserve the validity of patents, for example, in claim construction, but are not permitted to redraft (or in this case, bifurcate) claims to preserve their validity.

be "structurally similar" to rapamycin and have particular functionality, could make and use the full scope of the claimed invention without undue experimentation.[31] *Genentech*, 108 F.3d at 1365.

As noted previously, the specification of the 1997 patents provides no methods for identifying appropriate analogs, nor does the specification describe or exemplify any stents using such analogs. Rather, the specification provides that "the precise mechanism of rapamycin is still under active investigation." If the mechanism of rapamycin was unknown, surely the mechanism of any "similar" molecules was also unknown. There is no clear starting point for the modification of rapamycin.

Against this backdrop, the parties debate whether there is an issue of fact regarding undue experimentation. Although it is BSC's burden to demonstrate invalidity by clear and convincing evidence, the court first notes J&J's very limited argument in response to BSC's motion: (1) some analogs were known in the art, and could have been tested; (2) according to Dr. Sabatini, "by April 1997, a person of ordinary skill would have understood that for a sirolimus analog to have biological activity similar to sirolimus, the analog would need to bind FKBP12 and [inhibit] TOR"; and (3) a person of ordinary skill in the art "would have been aware of routine tests to assess whether a given analog would bind to FKBP12 and [inhibit] TOR" or possess "anti-inflammatory and anti-proliferative properties."[32] (D.I. 306 at 32, citing D.I. 312, A8 at ¶ 18 & A10-11,

[31]With respect to both the 1997 patents and '662 patent, the parties focus on the experimentation required to select analogs to use. There is no argument with respect to the difficulty in making the claimed stents using such analogs.

[32]There is no significant difference between J&J's arguments with respect to the 1997 patents and the '662 patents; Dr. Sabatini's declaration is relied upon in both respects.

¶¶ 24-26)

The court notes in response that the specification of the 1997 patents does not mention FKBP12 or TOR. Methods outside the teachings of the 1997 patents cannot enable those patents.[33] Dr. Sabatini's declaration, therefore, does not create an issue of material fact on undue experimentation with respect to the 1997 patents.

All that is disclosed in the 1997 patents is that the macrocyclic lactone analogs are structurally similar to rapamycin, and produce the same result (e.g., prohibit cell cycle proliferation); there is no disclosure in the 1997 patents regarding how rapamycin (or the claimed analogs) work, which could aid a person of ordinary skill in the art in selecting macrocyclic lactone analogs to test. The fact that about twenty-five analogs of rapamycin were known does not enable the claims which, as written, implicate an indeterminable number of inoperative embodiments. *See In re Cavallito*, 282 F.2d 357 (C.C.P.A. 1960) ("[T]here should be a disclosure which gives reasonable assurance that all or substantially all of them are useful . . . An applicant is not entitled to a claim for a large group of compounds merely on the basis of a showing that a selected few are useful and a general suggestion of a similar utility in the others."); *see also In re Corkill*, 771 F.2d 1496, 1501 (Fed. Cir. 1985) ("Claims which include a substantial measure of inoperatives . . . are fairly rejected under 35 U.S.C. § 112") (citations omitted). For these reasons, and in view of the lack of any prophetic examples (or

[33] *See In re Ziegler*, 992 F.2d 1197, 1201 (Fed. Cir. 1993) ("The how to use prong of section 112 incorporates as a matter of law the requirement of 35 U.S.C. § 101 that **the specification** disclose as a matter of fact a practical utility for the invention.") (emphasis added) (citation omitted). If, contrary to law, the prior art could enable claims, one might ask why such art would not also render the patent obvious under § 103.

other description) in the 1997 patents' specification regarding the claimed analogs, the court finds that judgment of non-enablement is appropriate.[34]

For purposes of completeness, the court will briefly frame its conclusion under the *Wands* factors. With respect to factors (2) and (3), there is no direction or guidance disclosed in the patents and no working examples. With respect to factor (8), the claims are moderately broad insofar as there is no limit, aside from function (determined through experimentation), regarding the number of potential analogs. With respect to factors (4) and (6), there is no genuine dispute that the invention concerns a very complex chemical and biomechanical art germane to highly skilled cardiologists. With respect to factor (5), the 1997 patents were filed on the heels of a decade marked by failed attempts to reduce restenosis.[35] Relatedly, with respect to factor (7), the chemical arts have long been acknowledged to be unpredictable.[36] The *Wands* factors suggest, consistent with the above conclusion, that the limitations at issue are not enabled.

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[34]The court is cognizant of the fact that it is BSC's burden to prove nonenablement by clear and convincing evidence. BSC relies only on legal argument, and has adduced no evidence (expert testimony or otherwise) in support of its motion. (D.I. 257 at 18-21, 29-30; D.I. 319 at 12-15) Nevertheless, absent any disputed issues of fact, enablement is a legal determination for the court. It is the court's finding in this regard that the specification of the 1997 patents is devoid of guidance regarding the claimed macrocyclic lactone analogs. BSC's standard of proof ultimately does not affect this determination.

[35]J&J has provided an in-depth overview of the state of the art in its opposition papers to BSC's obviousness motion. (D.I. 313 at 5-12) In its reply papers, BSC did not take issue with J&J's descriptions, insofar as they did not relate to secondary considerations of nonobviousness. (D.I. 324)

[36]*See, e.g., Spectra-Physics, Inc. v. Coherent, Inc.*, 827 F.2d 1524, 1533 (Fed. Cir. 1983) ("If an invention pertains to an art where the results are predictable, e.g., mechanical as opposed to chemical arts, a broad claim can be enabled by disclosure of a single embodiment[.]") (citation omitted).

4. The '662 patent

a. Definiteness

By its order of the same date, the court has determined that a person of ordinary skill in the art would interpret the limitation "macrocyclic triene analog" of rapamycin as "a macrocyclic triene molecule with a structure similar to rapamycin [sirolimus] and that binds FKBP12." The '662 patent's specification states that "[r]apamycin as used throughout this application shall include rapamycin, rapamycin analogs, derivatives and cogeners that bind FKBP12 and possess the same pharmacologic properties as rapamycin." ('662 patent at col. 5:48-51) The limitation is sufficiently definite.

b. Written description

As just noted, the '662 patent claims "rapamycin or a macrocyclic triene analog thereof that binds FKBP12[.]" The specification of the '662 patent explains that rapamycin binds FKBP12 which, in turn, binds to and inhibits the kinase TOR; this mechanism of action serves to inhibit neointimal hyperplasia and reduce restenosis. ('662 patent, col. 5:62-col.6:12)[37] The specification describes rapamycin as "a macrocyclic triene antibiotic produced by streptomyces hygroscopicus as disclosed in U.S. Patent No. 3,929,992." ('662 patent, col. 5:31-32) Notwithstanding the above disclosures, no macrocyclic triene analogs are named, structurally depicted, exemplified, or otherwise described in the '662 patent specification. No assays or other experimental models are provided with respect to testing an analog candidate's ability to function as rapamycin, that is, to bind FKBP12 which, in turn, binds to and inhibits

[37]In contrast to the 1997 patents, by the time the '662 patent was filed (in April 2004), the inventors knew and disclosed more about the mechanism of action of rapamycin.

the kinase TOR. There is no indication that the disclosed method for producing rapamycin would also produce the claimed analogs thereto.

Thus, although limited by function, the claims of the '662 patent are drawn to a genus of macrocyclic triene analogs without any description of any species within the genus. The Federal Circuit has required the identification of "sufficient species" to show that the totality of a claimed genus was invented and disclosed. *See Carnegie Mellon Univ.*, 541 F.3d at 1126. The *Eli Lilly* case is informative in this regard. That case involved a claim drawn to a recombinant procaryotic organism modified to contain "a nucleotide sequence having the structure of the reverse transcript of an mRNA of a [human], which mRNA encodes insulin." *Eli Lilly*, 119 F.3d at 1567. "Thus, the definition of the claimed microorganism [was] one that require[d] human insulin-encoding cDNA." *Id.* The Federal Circuit considered whether the description of a general method for obtaining human cDNA, and an example providing a process for obtaining the cDNA, sufficed to fulfill the written description requirement. The Court concluded that it did not.

> Whether or not it provides an enabling disclosure, it does not provide a written description of the cDNA encoding human insulin, which is necessary to provide a written description of the subject matter of claim 5. The name cDNA is not itself a written description of that DNA; it conveys no distinguishing information concerning its identity. . . Describing a method of preparing a cDNA or even describing the protein that the cDNA encodes, as the example does, does not necessarily describe the cDNA itself. No sequence information indicating which nucleotides constitute human cDNA appears in the patent[.]

Eli Lilly, 119 F.3d at 1567 (affirming the district court's finding of invalidity).[38]

Analogously, the '662 patent specification contains no distinguishing information

[38]*Eli Lilly* is not limited to biological inventions. *See Carnegie Mellon Univ.*, 541 F.3d at 1124 (citations omitted).

regarding the identity of the claimed analogs. *See id.* at 1568 ("A written description of an invention of a chemical genus, like a description of a chemical species, requires a precise definition, such as by structure, formula, [or] chemical name, of the claimed subject matter to distinguish it from other materials.") (citation and internal quotation omitted). Describing a preparation method (for rapamycin) does not describe the analogs themselves. *See id.* Moreover, a "definition by function" does not suffice to define or describe the genus. *See Enzo Biochem*, 323 F.3d at 968; *Eli Lilly*, 119 F.3d at 1568. Accordingly, the '662 patent specification's description of the claimed analogs' function (FKBP12 binding) does not suffice, even if a person of ordinary skill in the art could use, essentially, a "guess and check" method to find analogs having the appropriate behavior. *See id.; see also Univ. of Rochester v. G.D. Searle & Co., Inc.*, 358 F.3d 916, 923 (Fed. Cir. 2004) ("It is not a question whether one skilled in the art might be able to construct the patentee's device from the teachings of the disclosure of the application. Rather, it is a question whether the application necessarily discloses that particular device.") (quoting *Jepson v. Coleman*, 314 F.2d 533 (C.C.P.A. 1963)). The inventors were required to describe at least one[39] representative macrocyclic triene analog; having failed to do so, the '662 patent is invalid for lack of written description.

[39]More specifically, a "representative number of species" or "a sufficient variety of species to reflect the variation within the genus. . . . For inventions in an unpredictable art, adequate written description of a genus which embraces widely variant species cannot be achieved by disclosing only one species within the genus." *Carnegie Mellon Univ.*, 541 F.3d at 1124-25 (citing the 2001 "Guidelines for Examination of Patent Applications" under the written description requirement, found at 66 Fed. Reg. 10-99 (Jan. 5, 2001)). It is likely, therefore, that the disclosure of one macrocyclic triene analog, if present, would not have sufficed; the court, however, makes no explicit finding in this regard.

J&J argues that a factual issue exists with respect to written description. J&J relies on Dr. Sabatini, who opines that: (1) only certain modifications to rapamycin preserve the desired functions; (2) the literature (by 1997) described the binding action of rapamycin to FKBP12; and (3) a person of ordinary skill in the art would know, based on available knowledge, that "only a discrete set of compounds with [the] same macrocyclic ring structure and similar biological activity to [rapamycin]" are encompassed by the claims. (D.I. 306 at 24-25, citing D.I. 312, A8-9 at ¶¶ 19-21) Dr. Sabatini does not identify any particular analogs in his declaration. J&J also points out that BSC's expert admitted that many analogs were known as of 2001. (*Id.*) (citation omitted)[40] The fact that some macrocyclic triene analogs were known in the art does not alleviate J&J's obligation under § 112 to provide an example. If anything, it makes J&J's omission of that which (it admits) was known in the art even more perplexing. As discussed previously, the Federal Circuit has rejected J&J's argument that a description of function and biological properties may suffice. J&J has not demonstrated any genuine issue of material fact with respect to written description. BSC's motion is granted on this issue.[41]

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[40]BSC does not contest this representation and does not point to contrary testimony in its reply papers. (D.I. 319 at 16)

[41]Given the court's conclusion that the '662 patent is invalid for lack of a written description, the court does not rule on the issue of enablement, except to note the failure of the parties to adequately address whether a person of ordinary skill in the art was given reasonable means to determine a sufficient number of operative embodiments of macrocyclic triene analogs that: (1) have a structural similarity to rapamycin; (2) bind to FKBP12 which, in turn, bind to and inhibit TOR; (3) inhibit smooth cell proliferation with no interference with the re-endotheliazation of the vessel walls; and (4) meet the particular clinical results that are required in claims 1, 5, 9, and 13. *See, e.g., In re Cavallito*, 282 F.2d at 360-61; *see also, In re Corkill*, 771 F.2d at 1501.

V. CONCLUSION

For the foregoing reasons, the court denies BSC's motion for summary judgment of noninfringement of the 1997 patents (D.I. 259); denies J&J's motion for summary judgment of infringement of claim 9 of the '3286 patent (D.I. 265); denies BSC's motion for summary judgment of invalidity under 35 U.S.C. § 103 (D.I. 261); and grants BSC's motion for summary judgment of invalidity of the '7286, '3286, '473 and '662 patents under 35 U.S.C. § 112 (D.I. 256).[42] An appropriate order shall issue.

[42]As trial will not proceed to determine infringement of these patents found to be invalid, the court denies as moot BSC's motion to strike the supplemental expert report of Dr. Mikos. (D.I. 251)