# IN THE UNITED STATES DISTRICT COURT FOR THE EASTERN DISTRICT OF TEXAS MARSHALL DIVISION

BRUCE N. SAFFRAN, M.D., PH.D.,	§
Plaintiff,	§
	§
V.	§ CIVIL ACTION NO. 2:07-CV-451 (TJW)
	§
JOHNSON & JOHNSON and CORDIS	§
CORPORATION,	§
Defendants.	§

## MEMORANDUM OPINION AND ORDER

## I. INTRODUCTION

Pending before the Court is Defendants' Motion for Summary Judgment of No Infringment. (Dkt. No. 161.) Upon careful consideration of the parties' arguments and for the reasons stated below, the Court DENIES Defendants' Motion for Summary Judgment.

## II. FACTUAL AND PROCEDURAL BACKGROUND

Plaintiff Bruce N. Saffran, M.D., Ph.D. has brought the abovestyled patent infringement lawsuit against Defendants Johnson & Johnson (J&J) and Cordis Corporation (Cordis') (collectively 'Defendants'). Saffran asserts U.S. Patent No. 5,653,760 (the '760 Patent) in this lawsuit. The '760 Patent describes a medical device directed towards the treatment of damaged tissue, including, for example, broken bones or injured blood vessels. The Court has already performed claim construction (Dkt. No. 111) and the various claim constructions that are relevant to this Motion are referenced as appropriate.

The accused products in this case are Cordis's Cypher drug-eluting stents. (Dkt. No. 161.) There are no relevant material differences in any of the different versions of the Cypher stent for the purposes of this case, and the parties have agreed that if any Cypher stent is deemed to infringe any claim of the '760 Patent then all Cypher stents are deemed to so infringe that claim.

(Dkt. No. 234, at 5.) The Cypher stent has three components: a bare metal stent, a first drug-free layer of Parylene C polymer, and a drug-eluting layer that is made of two polymers, poly-n-butyl methacrylate (PBMA') and poly(ethylene-co-vinyl acetate) (PEVA'), and the drug sirolimus (also known as rapamycin). (Dkt. No. 161, at 3.) Plaintiff Saffran contends that Defendants infringe claims 1-4, 6-11, 13, and 15-18 of the '760 Patent in connection with Cordis's manufacture and/or sale of its Cypher stents, either by direct or indirect infringement. (Dkt. No. 234, at 3.) This Memorandum Opinion and Order concerns Defendants' Motion for Summary Judgment of No Infringement. (Dkt. No. 161.)

#### III. LEGAL STANDARDS

Summary judgment is proper if the pleadings and evidence show that "there is no genuine issue as to any material fact and the moving party is entitled to judgment as a matter of law." Fed. R. Civ. P. 56(c); *Celotex Corp. v. Catrett*, 477 U.S. 317, 322-23 (1986); *Anderson v. Liberty Lobby, Inc.*, 477 U.S. 242, 248-55 (1986). A "genuine issue" is an issue that "can be resolved only by a finder of fact because . . . [it] . . . may reasonably be resolved in favor of either party." *Anderson*, 477 U.S. at 248. When the summary judgment movants demonstrate the absence of a genuine dispute over any material fact, the burden shifts to the non-movant to show there is a genuine factual issue for trial. *Celotex*, 477 U.S. at 323-24. The Court must draw all reasonable inferences in favor of the non-moving party and refrain from making credibility determinations or weighing the evidence. *Delta & Pine Land Co. v. Nationwide Agribusiness Ins. Co.*, 530 F.3d 395, 398 (5th Cir. 2008).

A determination of infringement requires a two-step analysis. *Gentry Gallery, Inc. v. Berkline Corp.*, 134 F.3d 1473, 1476 (Fed. Cir. 1998). 'First, the claim must be properly construed to determine its scope and meaning. Second, the claim as properly construed must be

compared to the accused device or process." *Id.* (quoting *Carroll Touch, Inc. v. Electro Mech. Sys., Inc.*, 15 F.3d 1573, 1576 (Fed. Cir. 1993)). "Literal infringement requires that every limitation of the patent claim be found in the accused device." *Gen. Mills, Inc. v. Hunt-Wesson, Inc.*, 103 F.3d 978, 981 (Fed. Cir. 1997).

#### IV. DISCUSSION

Defendants' Motion argues four grounds why summary judgment of no infringement should be granted: (1) Cypher has two layers and does not satisfy the single layer requirement; (2) the Cypher stent's drug-eluting layer is not 'minimally porous' to macromolecules; (3) Plaintiff Saffran cannot prove that the Cypher stent's drug-eluting layer meets the 'release means' claim limitation; and (4) Saffran cannot prove that the Cypher stent's drug-eluting layer meets the 'manipulable' claim limitation. (Dkt. No. 161.) The most substantial ground is that Cypher has two layers and does not satisfy the single layer requirement, and this ground is discussed in detail below. For all other grounds, the Court DENIES the Motion and holds that Defendants have not met their burden of showing that there are not genuine issues of material fact and that they are entitled to judgment as a matter of law.

Regarding ground number one above, the Court also disagrees with Defendants and DENIES Defendants' Motion on this ground. During the claim construction briefing, the parties disputed the meaning of the term 'layer' in the claims of the '760 Patent. (Dkt. No. 111, at 16.) Defendants sought to limit the term 'layer' to a 'single layer,' and the Court agreed and construed 'layer' to mean 'a single layer.' (*Id.*) It is undisputed that the Cypher stent has two layers: a Parylene C polymer layer (the 'Parylene C Layer') and a drug-eluting polymer layer (the 'Polymer Layer'). Defendants argue that this undisputed fact alone is sufficient for summary judgment to Defendants, because the Court required the 'layer' in the '760 Patent claims to be 'a single layer.'

The Court noted in its Claim Construction Order, however, that "the claims, such as claim 1, use the open-ended 'comprising' language." (Dkt. No. 111, at 19.) The Court also stated that 'Plaintiff will be able to take advantage of the 'comprising' language when proving infringement of those claims including that phrase." (*Id.* at 20.) The term "comprising," as used in claim 1 and other claims in the '760 Patent, is a transitional term in patent law that is inclusive or open-ended and does not exclude additional elements or steps. *CollegeNet, Inc. v. ApplyYourself, Inc.*, 418 F.3d 1225, 1235 (Fed. Cir. 2005). In context of this case, for the purposes of infringement, this means that the Cypher stent may have additional layers, or any other elements, and still literally infringe as long as every limitation can be found in the Cypher stent. More specifically, the Cypher stent may have more than one layer and still literally infringe as long as "a single layer" of the Cypher stent can perform all of the "layer" limitations.

Plaintiff Saffran does not dispute that the Cypher stent has two layers, that is, the Parylene C Layer and the Polymer Layer. But Plaintiff argues that the Polymer Layer is 'a single layer' that performs all of the required 'layer' limitations in the claims of the '760 Patent. Plaintiff also argues the Parylene C Layer, instead, is merely an adhesive layer to attach the Polymer Layer to the metal stent. Plaintiff's expert, Dr. Freeman, details in his expert report how the Polymer Layer alone performs all the required 'layer' elements of the '760 Patent claims. (See Dr. Freeman's Expert Report, attached as Ex. 57 to Dkt. No. 210, at ¶¶ 54-123.) If Plaintiff's expert is correct that the Polymer Layer alone performs all the 'layer' elements, then the additional Parylene C Layer does not preclude infringement by itself. Defendants only "agree to disagree' about Plaintiff's argument regarding the Parylene C Layer being merely an adhesive layer; therefore Defendants have not met their burden of showing there is not a genuine issue of material fact.

#### V. CONCLUSION

<sup>&</sup>lt;sup>1</sup> See Def.'s Reply Br., Dkt. No. 228, at 3.

For the foregoing reasons, the Court DENIES Defendants' Motion for Summary Judgment.

# IT IS SO ORDERED.

SIGNED this 20th day of January, 2011.

T. JOHN WARD

UNITED STATES DISTRICT JUDGE