NOT FOR PUBLICATION

UNITED STATES DISTRICT COURT
DISTRICT OF NEW JERSEY

SCHERING CORPORATION, et al., Plaintiffs, v. MYLAN PHARMACEUTICALS, INC., et al., Defendants.	Civil Action No.: 09-6383 (JLL) **OPINION**

LINARES, District Judge.

This matter comes before the Court by way of an application for claim construction by Plaintiffs, Schering Corporation and MSP Singapore Company LLC (collectively, "Schering"), and Defendants, Mylan Pharmaceuticals, Inc. ("Mylan"), Teva Pharmaceuticals USA, Inc., and Teva Pharmaceuticals Industries Ltd. (collectively, "Teva").[1] The parties seek construction of certain language contained in claims 8, 9, 12, and 13 of United States Patent No. RE37,721 ("the '721 patent") and claims 1 and 3 of United States Patent No. 5,846,966 ("the '966 patent") (collectively, the "patents-in-suit"). The Court held a Markman hearing on May 9, 2011. The Court has considered the parties' written and oral arguments and sets forth herein its construction of the disputed claim terms.

[1]The litigation between Schering and Teva has been temporarily stayed by joint stipulation of the parties.

I. BACKGROUND

This patent infringement case involves two patents, the '721 patent and the '966 patent. The '721 patent discloses the hydroxylsubstituted azetidinone compound ezetimibe, which is marketed and sold commercially as the drug Zetia. Schering Corporation is the holder of the '721 patent, and MSP Singapore Company LLC is the exclusive licensee for Zetia. In non-scientific terms, Zetia is used to reduce cholesterol levels by blocking the absorption of cholesterol from a person's diet. Schering first filed the '721 patent on September 21, 1993. The United States Patent and Trademark Office ("PTO") issued the original patent in 1998 as U.S. Patent No. 5,757,115 ("the '115 patent") and thereafter reissued it as the '721 patent on May 28, 2002. The Food and Drug Administration ("FDA") approved ezetimibe on October 25, 2002. The patent contains three different types of claims: claims to (1) compounds (claims 1, 10, 11); (2) pharmaceutical compositions (claims 8, 12); and (3) methods of treating atherosclerosis using ezetimibe (claims 9, 13).

The '966 patent discloses the combination of ezetimibe with simvastatin. This combination is marketed and sold commercially as the drug Vytorin. Like ezetimibe, simvastatin is a drug that is designed to reduce cholesterol; however, statins, the class of drugs of which simvastatin is a member, work differently from ezetimibe in that they inhibit 3-hydroxy-3-methyglutaryl coenzyme A reductase ("HMG CoA reductase"), an enzyme that plays a role in the body's production of cholesterol. The application that led to the '966 patent was filed on October 14, 1997 as a division of the application which led to the '115 patent. The '966 patent contains two types of claims: claims to (1) compositions containing certain compounds in combination with HMG CoA reductase inhibitors (claims 1–5); and (2) methods of treating

atherosclerosis using those compositions (claims 6–10).

On March 22, 2007, prior to any of the complaints in this consolidated action being filed, Schering initiated an infringement action against Glenmark Pharmaceuticals, Inc. ("Glenmark"). In that case, Schering alleged that Glenmark's ANDA filing in connection with a generic version of Zetia infringed certain claims of the '721 patent. On September 15, 2008, this Court issued a Markman Opinion construing the terms "administering" and "in need of such treatment" as used in claims 9 and 13 of the '721 patent. See Schering Corp. v. Glenmark Pharmaceuticals Inc., Civ. No. 07-1334, 2008 WL 4307189 (D.N.J. Sept. 16, 2008).

On or about November 5, 2009, Mylan filed an filed an abbreviated new drug application ("ANDA") with the FDA, seeking to market a generic version of Vytorin. Schering initiated the instant infringement action against Mylan on December 16, 2009, and on June 16, 2010, Schering initiated a second action against Mylan (Civil Action No. 10-3085). On or about February 19, 2010, Teva filed an ANDA with the FDA, seeking to market a generic version of Vytorin. On March 2, 2010, Schering initiated an infringement action against Teva (Civil Action No. 10-1058), and on September 1, 2010, Schering initiated a second action against Teva (Civil Action No. 10-4473). On December 13, 2010, the Court consolidated these four civil actions. In this consolidated action, Schering asserts that Mylan and Teva infringed claims 3, 7, 8, 9, 10, 11, 12, and 13 of the '721 patent and claims 2, 3, 4, 7, 8, and 9 of the '966 patent.

While the parties have agreed to constructions of a number of claim terms, the parties[2]

[2]Teva did not submit claim construction briefs in connection with this Markman decision. Teva instead requested that the Court adopt the same constructions as in Glenmark, including both the joint constructions adopted by the parties in that case and this Court's constructions of the disputed terms. Teva takes no position on the disputed terms of the '966 patent.

dispute the interpretation of claims 8, 9, 12, and 13 of the '721 patent and claims 1 and 3 of the '966 patent.[3] Claims 8 and 12 of the '721 patent read as follows, with the disputed terms indicated by emphasis:[4]

> 8. A pharmaceutical composition for the treatment or prevention of atherosclerosis, or for the reduction of plasma cholesterol levels, comprising an effective amount of a compound of claim 1 in a pharmaceutically acceptable carrier.
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> 9. A method of treating or preventing atherosclerosis or reducing plasma cholesterol levels comprising administering to a mammal in need of such treatment an effective amount of a compound of claim 1.

The parties agree that claim 1 of the '721 patent claims a class of hydroxy-substituted azetidinone hypocholesterolemic agents, of which ezetimibe is a member. Claims 12 and 13 are essentially identical to claims 8 and 9, respectively, except that they depend from claims 10 and 11, rather than claim 1. The parties agree that claims 10 and 11 claim ezetimibe itself. (Joint Claim Construction and Prehearing Stmt. at 3.)

The disputed claims of the '966 patent read as follows, with the disputed terms indicated by emphasis:

> 1. A pharmaceutical composition for the treatment or prevention of atherosclerosis, or for the reduction of plasma cholesterol levels, comprising an effective amount of a compound represented by the formula I . . . or a pharmaceutically acceptable salt thereof . . . in combination with an HMG CoA reductase inhibitor in a pharmaceutically acceptable carrier.
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> 3. A composition of claim 1 wherein the HMG CoA reductase inhibitor is selected from the group consisting of lovastatin, pravastatin, fluvastatin, simvastatin and atorvastatin.

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[3]Claims 2, 3, and 4 of the '966 patent depend on claim 1.

[4]The parties' claim construction briefs also dispute the terms "prevention of," "preventing," and "atherosclerosis," but a joint construction of these terms was reached prior to the Markman hearing.

The "formula I" referenced in claim 1 depicts the class of hydroxy-substituted azetidinone hypocholesterolemic agents of which ezetimibe is a member. The specifications of the '721 patent and the '966 patent are essentially identical.

II. LEGAL STANDARD

A court's analysis of a patent infringement claim is two-fold. Tate Access Floors, Inc. v. Interface Architectural Resources, Inc., 279 F.3d 1357, 1365 (Fed. Cir. 2002). The court must first define the meaning and scope of the patent claims as a matter of law. Markman v. Westview Instruments, Inc., 52 F.3d 967, 978 (Fed. Cir. 1995) (en banc), aff'd, 517 U.S. 370 (1996). The court then engages in a comparison of the claims as construed to the alleged infringing product (or method). Tate, 279 F.3d at 1365. At this stage, the Court must only engage in the first step.

Claim construction is a matter of law to be determined solely by the court. Phillips v. AWH Corp., 415 F.3d 1303, 1312 (Fed. Cir. 2005), cert. denied, 546 U.S. 1170 (2006). "It 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." Id. at 1312 (quotations omitted). In construing the terms of a patent, a court should look first to the language of the claim itself. Vitronics Corp. v. Conceptronic, Inc., 90 F.3d 1576, 1582 (Fed. Cir. 1996). The terms in the claim "are generally given their ordinary and customary meaning." Id. at 1582.[5] "[T]he ordinary and customary

[5]The Court recognizes that two situations exist in which it must enter a definition different from the ordinary and customary meaning: (1) where the "patentee has chosen to be his or her own lexicographer by clearly setting forth an explicit definition for a claim term," Johnson Worldwide Assocs., Inc. v. Zebco Corp., 175 F.3d 985, 990 (Fed. Cir. 1999) (citing In re Paulsen, 30 F.3d 1475, 1480 (Fed. Cir. 1994)), and (2) where "the term or terms chosen by the patentee so deprive the claim of clarity that there is no means by which the scope of the claim may be ascertained from the language used," id. (citing Eastman Kodak Co. v. Goodyear Tire &

meaning of a claim term is the meaning that the term would have to a person of ordinary skill in the art in question at the time of the invention, i.e., as of the effective filing date of the patent application." Phillips, 415 F.3d at 1313.[6] A court "must look at the ordinary meaning in the context of the written description and the prosecution history." Medrad, Inc. v. MRI Devices Corp., 401 F.3d 1313, 1319 (Fed. Cir. 2005). The court should turn to "those sources available to the public that show what a person of skill in the art would have understood disputed claim language to mean." Innova/Pure Water, Inc. v. Safari Water Filtration Sys., Inc., 381 F.3d 1111, 1116 (Fed. Cir. 2004).

To this end, the court should first examine the intrinsic record—the patent itself, including the claims, the specification and, if in evidence, the prosecution history. Vitronics, 90 F.3d at 1582 (citing Markman, 52 F.3d at 979). The specification "acts as a dictionary when it expressly defines terms used in the claims or when it defines terms by implication." Id. Indeed, the Federal Circuit has explained that the specification is " 'usually . . . dispositive . . . [and] the single best guide the meaning of a disputed term.' " Phillips, 415 F.3d at 1315 (quoting Vitronics, 90 F.3d at 1582). It is "entirely appropriate for a court, when conducting claim construction, to rely heavily on the written description for guidance as to the meaning of the claims." Id. at 1317. The specification is also an important guide in claims construction as it

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Rubber Co., 114 F.3d 1547, 1554 (Fed. Cir. 1997)). Neither of these situations apply here.

[6]Mylan posits that a person of ordinary skill in this case would have "at least a Ph.D. in organic or medicinal chemistry or in pharmacology or the equivalent, followed by at least two years of post-doctoral training or practical experience in drug design or a degree in medicine with at least two years of post-doctoral training or practical experience in hyperlipidemia, hypercholesterolemia or other related disorders." (Mylan's Opening Br. in Support of its Claim Constr. ["Mylan's Opening Br."] at 8.) Schering does not appear to dispute this characterization.

may contain "an intentional disclaimer, or disavowal, of claim scope by the inventor." Id. at 1316.

Additionally, the court should consult the patent's prosecution history as it "provides evidence of how the PTO and the inventor understood the patent." Id. Courts should be circumspect in reviewing a prosecution history as it represents "an ongoing negotiation between the PTO and the applicant, rather than the final product of the negotiation . . . ." Id. A district court may also examine extrinsic evidence: "all evidence external to the patent and prosecution history." Markman, 52 F.3d at 980; Phillips, 415 F.3d at 1317-18 (stating that the Federal Circuit "ha[s] authorized district courts to rely on extrinsic evidence"). Such evidence consists of testimony by the inventor or by experts, dictionaries, and treatises. Markman, 52 F.3d at 980. In particular, a court may find reference to technical dictionaries useful "in determining the meaning of particular terminology." See Phillips, 415 F.3d at 1318. However, extrinsic evidence is generally thought to be less reliable than the patent and prosecution history, id. at 1318-19; in essence, it is "less significant than the intrinsic record in determining the legally operative meaning of claim language," C.R. Bard, Inc. v. U.S. Surgical Corp., 388 F.3d 858, 862 (Fed. Cir. 2004) (quotation omitted). With this framework in mind, the Court now turns to the disputed claim language.

III. DISCUSSION

The parties have agreed that certain identical or similar terms used in the disputed claims should be construed together. The Court will thus address (A) the term "treatment of,"[7] as used

[7]For simplicity, the Court abbreviates the claim language "treatment . . . of" to "treatment of."

in claims 8 and 12 of the '721 patent and claim 1 of the '966 patent, together with the term "treating," as used in claims 9 and 13 of the '721 patent; (B) the term "reduction of plasma cholesterol levels," as used in claims 8 and 12 of the '721 patent and claim 1 of the '966 patent, together with the term "reducing plasma cholesterol levels," as used in claims 9 and 13 of the '721 patent; (C) the term "administering," as used in claims 9 and 13 of the '721 patent; (D) the term "an effective amount," as used in claims 8, 9, 12, and 13 of the '721 patent and claim 1 of the '966 patent; (E) the term "pharmaceutically acceptable carrier," as used in claims 8 and 12 of the '721 patent and claim 1 of the '966 patent; and (F) the term "HMG CoA reductase inhibitor," as used in claims 1 and 3 of the '966 patent, together with the terms "lovastatin," "simvastatin," "pravastatin," "fluvastatin," and "atorvastatin," as used in claim 3 of the '966 patent.

A. "treatment of" / "treating"

The term "treatment of" is used in claims 8 and 12 of the '721 patent and claim 1 of the '966 patent. The term "treating" is used in claims 9 and 13 of the '721 patent. The parties agree that a common construction should be adopted for both terms. Schering proposes the construction, "to care for medically," while Mylan proposes, "stopping, slowing or reversing the progression of a disease."

Schering argues that the plain meaning of "treating" or "treatment" is to provide care to a patient and that the treatment of a medical condition does not imply that such treatment will be successful, i.e., stopped, slowed, or reversed. Schering points to several dictionary definitions to support its position. (See Schering's Opening Claim Constr. Br. ("Schering's Opening Br.") at 11.) Mylan responds that Schering's construction is overly vague, arguing that it could include non-pharmacological methods of treatment, such as physical therapy. (Tr. of Proceedings, May

9, 2011["Hr'g Tr."]), 11:15–12:19.) Mylan further argues that one does not "care for" a disease, but rather a patient, and the claims themselves state that it is the disease condition, atherosclerosis, that is actually treated, not the patient.[8] Mylan asserts that Schering's dictionary evidence in fact supports this interpretation, as one such dictionary refers to "car[ing] for a patient" but "manag[ing] a disease by medical, surgical or other measures." (See Mylan's Resp. Br. in Opp'n to Pl.'s Opening Claim Construction Br. ["Mylan's Resp. Br."] at 10 (quoting Stedman's Medical Dictionary 1626 (25th ed. 1990).)

To support its construction, Mylan points to intrinsic evidence by way of an article cited in the specifications by D. Roger Illingworth, An Overview of Lipid-Lowering Drugs, 36 (Suppl. 3) Drugs 63–71 (1988) (the "Illingworth reference"). The Illingworth reference states that "[t]he rationale for identification and treatment of patients with [high cholesterol levels] . . . is based on evidence that a reduction in plasma concentrations of known atherogenic lipoproteins will lead to a slower rate of progression of atherosclerosis, the arrest of this process altogether or potentially a reversal in previously developed arteriosclerotic lesions." (Mylan's Opening Br., Decl. of Srilakshmi M. Ravi ("Ravi Decl."), Ex. 25 at SPV00182904 (emphasis added).) Mylan states that its proposed construction of "stopping, slowing or reversing the progression of a disease" mirrors the Illingworth reference's statement that the rationale for treatment is to achieve a "slower rate of progression," "arrest," or "reversal" of the disease. Schering responds that Mylan's construction implies that a treatment must achieve some level of success, which it argues is unwarranted by the plain meaning of the term. (Hr'g Tr. 82:20–83:11.)

[8]The parties agree that "atherosclerosis," as used in the relevant claim language, refers to a disease condition. (Hr'g Tr. 6:1–15.)

The Court agrees with Mylan that Schering's proposed construction is no less ambiguous than the disputed term, but agrees with Schering that the treatment of a patient or disease does not necessarily imply success. The claims provide for the "treatment . . . of atherosclerosis or for the reduction of plasma cholesterol levels . . . ."[9] The claims thus contemplate the treatment of a disease, atherosclerosis. At oral argument, counsel for Schering proposed a modification to Mylan's construction in order to remove the implication that treatment implied success. Schering proposed, "given for the purpose of stopping, slowing or reversing the progression of a disease." (Id. at 89:5–7.) Mylan objected to this construction, noting that the claim terms refer explicitly to treating atherosclerosis, not attempting to do so. (Id. at 88:3–89:1.) The Court, however, agrees that Schering's modified formulation best reflects the ordinary and customary meaning of term and comports with the intrinsic and extrinsic evidence. The Illingworth reference shows that a person of ordinary skill in the art would have understood the term "treatment" as used in the claims to refer to pharmacological methods or compositions directed to slowing, arresting, or reversing the progression of atherosclerosis. To treat a disease does not imply that the progression of the disease will actually be slowed, arrested, or reversed, but the plain meaning of "treatment" does imply a goal of achieving those results. The testimony of Mylan's expert, Antonio Gotto, M.D., supports this conclusion. (See Ravi Decl., Ex. 38 at 206:25–207:3 ("The goal of treatment is to either eradicate something or keep it from . . . progressing and causing further difficulties or to cure it").) The Court therefore adopts the construction "giving for the purpose of stopping, slowing or reversing the progression of a

[9]The Court quotes claims 8 and 12 of the '721 patent and claim 1 of the '966 patent. The alternative formulation, in claims 9 and 13 of the '721 patent, reads, "treating . . . atherosclerosis or reducing plasma cholesterol levels . . . ."

disease" for the disputed claim terms "treatment of" and "treating."[10]

B. "reduction of plasma cholesterol levels" / "reducing plasma cholesterol levels"

The term "reduction of plasma cholesterol levels" is used in claims 8 and 12 of the '721 patent and claim 1 of the '966 patent, and the term "reducing plasma cholesterol levels" is used in claims 9 and 13 of the '721 patent. The parties agree that a common construction should be adopted for both terms. Schering proposes the construction, "lowering the total plasma cholesterol level," while Mylan proposes "reducing (a reduction of) the amount of low density lipoprotein (LDL) cholesterol in the plasma."

Schering argues that its construction is appropriate because the claim language uses the term "plasma cholesterol levels," and the specifications recognize that low density lipoprotein ("LDL") is only one component of the total cholesterol contained within the blood plasma. Mylan responds that the specifications teach otherwise, quoting sections in which the specifications recognize that "LDL are the predominant cholesterol-carrying lipoproteins in the plasma and an increase in their concentration is correlated with increased atherosclerosis" and that "the net effect of inhibiting intestinal cholesterol absorption is a decrease in plasma cholesterol levels." (Mylan's Resp. Br. at 11 (quoting U.S. Patent No. RE37,721 col. 2:3–12; U.S. Patent No. 5,846,966 col. 2:3–12).) Mylan argues that the specifications show that these drugs are directed to lowering LDL only, as LDL would be understood by a person of ordinary skill in the art to be the type of cholesterol that leads to atherosclerosis. Mylan further points to an article cited in the specifications by Joseph L. Witztum, Current Approaches to Drug Therapy

[10]The Court substitutes "giving" for "given" in Schering's proposed construction for grammatical reasons only.

for the Hypercholesterolemic Patent, 80(5) Circulation 1101–1114 (Nov. 1989), which states that LDL is "believed to be the exclusive source of the cholesterol that is deposited" in the arteries. (Ravi Decl. Ex. 23.) Mylan notes that LDL predominates among the plasma cholesterols and states that the only practical way to lower total plasma cholesterol is to lower LDL. (Hr'g Tr. 23:3–18, 25:21–26:11.) Schering responds that the Court must view the person of ordinary skill in the art at the time of the application, arguing that in the early 1990s doctors typically referred to total cholesterol levels and "the focus on identifying what your LDL level was . . . something that came along later," (id. at 93:7–8), pointing to specification language that provides the total cholesterol level at which the risk atherosclerotic coronary heart disease becomes significantly elevated, (id. at 93:18–22 (quoting U.S. Patent No. 5,846,966 col. 1:31–32 ("A total cholesterol level in excess of 225–250 mg/dl is associated with significant elevation of risk of [coronary heart disease].") (emphasis added))). Indeed, Mylan's expert, Morris Brown, M.D., testified that at the time of the invention, medical practice was such that "total cholesterol was measured probably at least as commonly if not more than LDL." (Schering's Opening Br., Decl. of James Suh ["Suh Decl."], Ex. 28 at 106:2–4.)

The Court agrees with Schering that the claim terms are directed to lowering total cholesterol levels. The claims themselves expressly call for "the reduction of plasma cholesterol levels," and while the specifications do recognize the harmful effects of LDL, they repeatedly reference the reduction of "plasma" or "serum" cholesterol. See, e.g., U.S. Patent No. RE37,721 col. 2:11–12, 2:15–16, 3:44–49, 20:52–53. The Court sees no reason to limit the disputed term to LDL levels alone, given that both parties freely acknowledge that plasma cholesterol is made up of other lipoproteins in addition to LDL. Both the claim language and the specifications

consistently refer to "plasma" or "serum" cholesterol, and medical practice at the time of the invention commonly focused on lowering total cholesterol levels. While a key goal of current treatment may be the lowering of LDL, the evidence shows that at the time of the invention a person of ordinary skill in the art would have understood the disputed term to refer to the lowering of total cholesterol levels, i.e., the cholesterol levels within the blood plasma as a whole. The Court thus construes the terms "reduction of plasma cholesterol levels" and "reducing plasma cholesterol levels" to mean "lowering the total plasma cholesterol level."

C. "administering"

The term "administering" is used in claims 9 and 13 of the '721 patent. Schering proposes the construction, "to provide externally," while Mylan proposes, "to provide externally an effective amount of the recited compound(s) by way of any dosage form and does not include a metabolite (active compound) that forms inside the patient's body."

The dispute over this term raises an issue that this Court already addressed in Glenmark. As here, Glenmark considered whether claims 9 and 13 of the '721 patent are directed to the administration of the claimed compound itself or to the administration of a "prodrug" that metabolizes in vivo to form the claimed compound. Glenmark, 2008 WL 4307189, at *3. This Court construed the term "administering" as used in claims 9 and 13 of the '721 patent to mean "to provide externally by way of ingestion." Id. at *8. This Court held:

> After careful consideration of the intrinsic evidence, importantly the patent specification, as well as guidance from the Federal Circuit and the extrinsic evidence, particularly the Merck Manual, the Court finds that the term "administering" in claims 9 and 13 of the '721 patent includes only administering the pharmaceutical compound ezetimibe and not the metabolite that forms in vivo upon administration.

Id. (emphasis in original).

While Schering states that it would be "perfectly happy" if the construction from Glenmark were adopted here, it proposes that the "by way of ingestion" qualification be removed because it is unnecessary. (Hr'g Tr. at 120:8–17.) Mylan responds that Schering's proposed modification of the Glenmark construction evidences a change in position by Schering since that litigation. Mylan argues that during Glenmark Schering consistently argued that the specification of the '721 patent "contemplates the administration of the claimed compounds" only, and that Schering's proposed removal of the "by way of ingestion" limitation in this litigation is an attempt to open the door for a construction that covers the administration of compounds that form the claimed compounds in vivo as metabolites. (Mylan's Opening Br. at 18–19.) Mylan apparently proposes the additional language regarding an "effective amount of the recited compound(s) by way of any dosage form" and excluding "a metabolite . . . that forms inside the patient's body" as a means to ensure that the disputed term could not be construed to cover the external provision of compounds other than ezetimibe.

As an initial matter, the parties here have produced no additional intrinsic or extrinsic evidence that was not considered by this Court in the Glenmark litigation. The parties have further stated that they fundamentally agree with the construction adopted in that case. Mylan's proposed additional language appears to be largely redundant, as other elements of claims 9 and 13 address the "effective amount" of the claimed compounds, and the Court's construction in Glenmark makes clear that the claims contemplate that only the administration of the claimed compounds themselves. Schering's suggestion to remove the "by way of ingestion" limitation is also unwarranted, as while the specification does contemplate non-oral dosage forms, such references are made only with respect to combination drugs, citing advantages that may be

obtained from administering ezetimibe separately from its companion drug. See U.S. Patent. No. RE37,721 col. 21:60–22:8 (describing a "kit" containing two separate units). With respect to the administration of ezetimibe alone, however, the specification cites "oral dosage forms" as preferable, specifically describing the administration of the drug as a "capsule, tablet, powder, cachet, suspension or solution." Id. at col. 21:19-21:21. Extrinsic evidence cited in Glenmark, including medical dictionaries and the Merck Manual, further shows that "administering" implies ingestion. See 2008 WL 4307189, at *7. Thus, for the reasons stated here and for the reasons given in this Court's Opinion in Glenmark, the Court adopts the same construction of "administering" here as in Glenmark: "to provide externally by way of ingestion."

D. "an effective amount"

The term "an effective amount" is used in claims 8, 9, 12, and 13 of the '721 patent and claim 1 of the '966 patent. Schering proposes the construction, "an amount that elicits a therapeutic effect of the type identified in the preamble," while Mylan proposes, "a dose amount of the recited compound(s) that elicit a therapeutic effect of the type identified in the preamble." The preambles to the disputed claims are all substantially the same, claiming a pharmaceutical composition or method "for the treatment or prevention of atherosclerosis or for the reduction of plasma cholesterol levels."

The parties agree that "an effective amount" is one that "elicits a therapeutic effect of the type identified in the preamble" and dispute only the appropriateness of the additional language proposed by Mylan that would limit the term to a "dose amount of the recited compound(s)."[11]

[11]Mylan has clarified that the term "dose amount" is not intended to refer to the administration of the claimed compounds at a single time and in a single dose, but that multiple doses may be administered. (Mylan's Resp. Br. at 13.)

Mylan contends that Schering's definition is overly broad, arguing that it would encompass the administration of any amount that elicits a therapeutic effect, including prodrugs that metabolize to form the claimed compounds. Mylan's arguments thus derive from the same concern underlying its arguments regarding the construction of "administering"—that Schering has changed positions since the Glenmark litigation and is now proposing to construe the disputed claims to cover prodrugs. Apparently aiming to prevent this, Mylan proposes to modify "amount" to become "a dose amount of the recited compound(s)." As the Court noted in Glenmark, the specification uses the term "administering" primarily in conjunction with the terms "dose" or "dosage," and "administering" contemplates the external provision of ezetimibe by way of ingestion. However, "administering" appears only in claims 9 and 13 of the '721 patent. Claims 8 and 12 of the '721 patent and claim 1 of the '966 patent do not contain the term "administering" and thus do not necessarily imply the limitation that the Court's construction of that term provides. These claims instead recite a composition of the ezetimibe with a "pharmaceutically acceptable carrier," an approach which the Federal Circuit has suggested a "skilled drafter" might employ to claim a metabolite. See Schering Corp. v. Geneva Pharms., Inc., 339 F.3d 1373, 881 (Fed. Cir. 2003). In light of this potential distinction, the Court analyzes the term "an effective amount" as used in the claims 9 and 13 of the '721 patent separately from that term as used in claims 8 and 12 of that patent and in claim 1 of the '966 patent.[12]

[12]The Court notes that in Glenmark it found the dicta in Geneva regarding a "skilled drafter" to be persuasive, reasoning that the fact that Schering had not claimed the use a pharmaceutically acceptable carrier in claims 9 and 13 suggested that the claims did not refer to a metabolite. See 2008 WL 4307189, at *7. Here, the Court acknowledges that the inclusion of such language in claims 8 and 12 at least suggests that a person of ordinary skill in the art would

1. As Used in Claims 8 and 12 of the '721 Patent

The Court does not construe claims 8 and 12 of the '721 patent to refer to a metabolite. Aside from the reference to a "pharmaceutically acceptable carrier," the claims and specification of the '721 patent lack any explicit reference to compounds formed in vivo or to the ingestion of a metabolic precursor of ezetimibe. The Court has already ruled that a person of ordinary skill in the art would understand the methods recited in claims 9 and 13 to be directed to the external provision of ezetimibe itself, and the parties have pointed to no intrinsic or extrinsic evidence to support a conclusion that such person of ordinary skill would understand the pharmaceutical compositions recited in the neighboring claims, 8 and 12, to be somehow directed to prodrugs that metabolize into ezetimibe. Indeed, the claims contain a great deal of common language and differ mainly in the ends to which they are directed, i.e., pharmaceutical compositions versus methods. Related claims should be interpreted consistently. See Phillips, 415 F.3d at 1314. It is thus appropriate for the Court to specify that the "amount that elicits [the] therapeutic effect" is the amount that is actually administered. The Court therefore construes "an effective amount," as used claims 8 and 12 of the '721 patent, to mean "an amount of the recited compound(s) that, when provided externally by way of ingestion, elicits a therapeutic effect of the type identified in the preamble."

2. As Used in Claims 9 and 13 of the '721 Patent

As the Court has already stated, claims 9 and 13 of the '721 patent contemplate the external provision of ezetimibe by way of ingestion. The Court thus adopts the same construction for claims 9 and 13 as it did for claims 8 and 12: "an amount of the recited

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understand the claims to refer to a metabolite.

compound(s) that, when provided externally by way of ingestion, elicits a therapeutic effect of the type identified in the preamble."[13]

3. As Used in Claim 1 of the '966 Patent

The Court adopts a slightly different construction for claim 1 of the '966 patent, which is directed to the combination of ezetimibe with an "HMG CoA reductase inhibitor." That claim reads, "an effective amount of [ezetimibe],[14] or a pharmaceutically acceptable salt thereof, . . .; in combination with an HMG CoA reductase inhibitor in a pharmaceutically acceptable carrier." The Court begins by observing that the term "an effective amount," as used in claim 1, could arguably be read to refer to ezetimibe alone, rather than to the combination of "ezetimibe" and the "HMG CoA reductase inhibitor." The parties, however, do not appear to dispute that "an effective amount" refers to both compounds of the combination drug (see Schering's Responsive Claim Constr. Br. at 9–10; Mylan's Resp. Br. at 13–15), and the Court notes that such a reading supports the internal consistency of the claims. Indeed, the specification refers to specific "dose" amounts of HMG CoA reductase inhibitors. See U.S. Patent No. 5,846,966 col. 21:27–42 (citing the provision of "10 to about 40 mg per dose" and a "total daily dose of about 10 to 80 mg"). The Court thus construes "an effective amount" with respect to both ezetimibe and "an HMG CoA reductase inhibitor."

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[13]The Court notes that portions of this construction are arguably redundant in light of the Court's construction of "administering." Any such redundancy, however, is merely the byproduct of the Court's adopting a consistent interpretation between related claims and should not be interpreted as adding any limitations beyond those stated here.

[14]The claim actually recites the hydroxy-substituted azetidinone hypocholesterolemic agent, which is the class of compounds that includes ezetimibe. For ease of reference, the Court substitutes the term "ezetimibe."

For the reasons already stated, the Court construes "an effective amount" to refer to the amount of ezetimibe itself, not a metabolic precursor. The parties have expressed their agreement with the Court's construction in Glenmark that the '721 patent contemplates the external provision of ezetimibe, and the '966 patent relies on the same specification. With respect to "an effective amount" of the "HMG CoA reductase inhibitor," however, the Court cannot so readily determine the precise compound to which "an effective amount" refers, as the term "an HMG CoA reductase inhibitor" is itself in dispute. The construction of that term is discussed below, and the analysis will not be repeated here, except to note that the Court construes the term to mean "a substance that, when provided externally, results in the inhibition of 3-hydroxy-3-methylglutaryl coenzyme A reductase." (emphasis added). The Court thus interprets an "effective amount" of both "an HMG CoA reductase inhibitor" and ezetimibe to refer to amounts of the recited compounds that are provided externally.

The intrinsic evidence does not, however, support a construction that the external provision of ezetimibe and "an HMG CoA reductase inhibitor" occurs by way of ingestion. As the Court observed in its analysis of "administering," the specification contemplates that the combination drug could be designed as a "kit," wherein ezetimibe and "an HMG CoA reductase inhibitor" may be given separately in different dosage forms, such as oral and parenteral. See U.S. Patent No. 5,846,966 col. 21:49–62. A person of ordinary skill in the art would understand this explicit reference to non-oral dosage forms to mean that the combination drug is not limited to the oral ingestion of ezetimibe or the "HMG CoA reductase inhibitor." The Court thus construes "an effective amount," as used in claim 1 of the '966 patent, to mean "an amount of the recited compound(s) that, when provided externally, elicits a therapeutic effect of the type

identified in the preamble," referring to both ezetimibe and "an HMG CoA reductase inhibitor."

E. "pharmaceutically acceptable carrier"

The term "pharmaceutically acceptable carrier" is used in claims 8 and 12 of the '721 patent and claim 1 of the '966 patent. Schering proposes the construction, "a conventional pharmaceutically acceptable excipient or additive including fillers, binders, disintegrants, buffers, preservatives, antioxidants, lubricants, flavorings, thickeners, coloring agents, emulsifiers and the like," while Mylan proposes, "ingredients suitable for formulation as a medicine without undue toxicity."

Schering indicates that its proposed construction was taken from the specifications, which state:

> The present invention also relates to a pharmaceutical composition comprising a compound of formula I [basically, ezetimibe] and a pharmaceutically acceptable carrier. The compounds of formula I can be administered in any conventional dosage form, preferably an oral dosage form such as a capsule, tablet, powder, cachet, suspension or solution. The formulations and pharmaceutical compositions can be prepared using conventional pharmaceutically acceptable excipients and conventional techniques. Such pharmaceutically acceptable excipients and additives include non-toxic compatible fillers, binders, disintegrants, buffers, preservatives, anti-oxidants, lubricants, flavorings, thickeners, coloring agents, emulsifiers and the like.

U.S. Patent No. 5,846,966 col. 21:3–16; U.S. Patent No. RE37,721 col. 21:16–28 (emphasis added).[15] Mylan argues that the specifications do not in fact define "pharmaceutically acceptable carrier" to mean the list of the excipients and additives that Schering recites, noting that the specifications actually equate "pharmaceutical composition" with excipients and additives. Mylan points out that the specifications first state that "a pharmaceutical composition

[15]The Court notes, however, that Schering's proposed construction does not recite the specifications verbatim, as it omits the phrase "non-toxic compatible" before "fillers."

compris[es] [ezetimibe] and a pharmaceutically acceptable carrier," but then go on to state that "[t]he formulations and pharmaceutical compositions can be prepared using conventional pharmaceutically acceptable excipients and conventional techniques." Mylan thus argues that the specifications do not define "pharmaceutically acceptably carrier," but rather "pharmaceutical composition," as the enumerated "pharmaceutically acceptable excipients and additives."

However awkwardly worded the specifications may be, a person of ordinary skill in the art would certainly understand that their reference to "fillers, binders, disintegrants, buffers," etc., was provided as an example of inactive carriers to be used in conjunction with the claimed compounds. Schering's expert, Gerald S. Brenner, Ph.D., certified that "[d]rugs are almost always administered in a pharmaceutical composition that includes the active ingredient and one or more different carriers," which "may solubilize, suspend, thicken, add volume, preserve, emulsify, modify dissolution, improve the compressibility, and add flavor. The selection and use of suitable pharmaceutically acceptable carriers was well understood by people working in drug discovery in the mid-1990s." (Schering's Opening Br., Decl. of Gerald S. Brenner ¶ 43.) Dr. Brenner certified that "[a]lthough carriers are often necessary to formulate an active drug compound, carriers are not the 'medicine' that is administered to the patient." (Id.) The Court finds this testimony persuasive, particularly in light of dictionary definitions provided by Schering, one of which defined "carrier" as "a usually inactive substance used in association with an active substance especially for aiding in the application of the active substance." (Suh Decl., Ex. 22 (quoting Webster's Third New Int'l Dictionary, 343 (1993)).) As Mylan does not fundamentally dispute this common understanding of the term "carrier," the Court concludes that the list of excipients and additives contained in the specifications would be understood by a

person of ordinary skill in the art to be examples of "pharmaceutically acceptably carrier."

Mylan's proposed construction, "ingredients suitable for formulation as a medicine without undue toxicity" lacks the specificity of Schering's construction and appears to have no basis in the specifications. Indeed, Mylan's construction appears to imply that a carrier itself can be deemed a "medicine." This interpretation contradicts the understanding of a person of ordinary skill in the art that a carrier is an inactive substance. Mylan's addition of "without undue toxicity" likewise finds no support within the specifications and imports a limitation regarding toxicity that is unsupported by any of the intrinsic or extrinsic evidence. By contrast, Schering's proposed construction finds direct support within the specifications and comports with the understanding of a person of ordinary skill in the art. The Court thus construes "pharmaceutically acceptable carrier" to mean "a conventional pharmaceutically acceptable excipient or additive including non-toxic compatible fillers, binders, disintegrants, buffers, preservatives, antioxidants, lubricants, flavorings, thickeners, coloring agents, emulsifiers and the like," as provided in the specifications.

F. "HMG CoA reductase inhibitor," "lovastatin," "simvastatin," "pravastatin," "fluvastatin," and "atorvastatin"

The Court analyzes the statin-related terms together, as they involve the same underlying issues. The term "HMG CoA reductase inhibitor" is used in claims 1 and 3 of the '966 patent. Schering proposes the construction, "a substance that, when administered, results in the inhibition of 3-hydroxy-3-methylglutaryl coenzyme A reductase," while Mylan proposes, "a compound that inhibits 3-hydroxy-3-methylglutaryl coenzyme A reductase, which inhibition

reduces plasma cholesterol and treats/prevents atherosclerosis."[16] The terms "lovastatin," "simvastatin," "pravastatin," "fluvastatin," and "atorvastatin" are used in claim 3 of the '966 patent. Schering proposes that "lovastatin" and "simvastatin" be construed to refer to the lactone forms of those compounds and that "pravastatin," "fluvastatin," and "atorvastatin" be construed to refer to the salt forms. Mylan proposes that all five of the disputed statin terms be construed to refer to their acid forms.

The parties' dispute here is conceptually similar to their disputes regarding other terms of the patents-in-suit: whether the claims contemplate the administration of the claimed compound itself or the administration of a prodrug that metabolizes to form the claimed compound in vivo. However, unlike the claims directed to the administration of ezetimibe alone, in which the parties agreed as to the precise structure of the claimed compound (i.e., ezetimibe), here the parties do not agree as to precisely which chemical compounds the terms "lovastatin," "simvastatin," "pravastatin," "fluvastatin," and "atorvastatin" refer. The Court thus begins by examining the meanings of these disputed "-statin" terms, as used in conjunction with the disputed term "HMG CoA reductase inhibitor."

1. "lovastatin" and "simvastatin"

Statin drugs work by inhibiting the production of HMG CoA reductase, an enzyme that plays a role in the body's production of cholesterol. The parties agree that lovastatin and simvastatin can take either an active or inactive form. The parties refer to the active form of those compounds as the "acid" form and the inactive form as the "lactone" form. The acid form

[16]At oral argument, Mylan stated that its claim construction briefs had mistakenly omitted the phrase "treats/prevents" and assured the Court that the late addition of such language did not affect the matters in dispute. (Hr'g Tr. 56:4–13.) Schering offered no objection.

is characterized by an open ring molecular structure that allows it to bind to an HMG CoA reductase molecule and thereby inhibit its cholesterol-producing function. (Hr'g Tr. 108:5–21.) In the lactone form, this ring structure is closed, and a closed ring compound cannot bind to HMG CoA reductase. When administered to a patient, however, the lactone forms of lovastatin and simvastatin metabolize into their acid forms and thereby become active. While the parties agree that a therapeutic effect would be achieved if either the acid form or the lactone form of those statins were administered a patient, counsel for Mylan stated that significantly more of the acid form would need to be provided to the patient in order to offset unwanted metabolism of the compounds in the body. (Hr'g Tr. 66:13–67:1.) The dispute is thus whether "lovastatin" and "simvastatin" as used in claim 3 of the '966 patent refer to the active, acid forms or the inactive, lactone forms of those compounds.

Mylan points to the plain language of the claims to argue that "lovastatin" and "simvastatin" refer to their acid forms. Mylan argues that because claims 1 and 3 of the '966 patent call for an "HMG CoA reductase inhibitor," a person of ordinary skill in the art would understand this term to refer to the compound that actually does the inhibiting, i.e., the acid form. Mylan also points to the specification, which refers to HMG CoA reductase inhibitors as "active ingredients." U.S. Patent No. 5,846,966 col. 21:49–51; see Mylan's Opening Br. at 27. Mylan further cites extrinsic evidence by way of an article authored by Dr. D. Roger Illingworth[17] depicting lovastatin and simvastatin in their acid forms. (Hr'g Tr. 134:13–135:24 (citing Ravi Decl., Ex. 24 at SPV00182895).) Mylan finally points to both the deposition testimony of Dr.

[17]Dr. Illingworth is also the author of one of the articles cited in the specifications. The article to which Mylan refers here was not cited by the patents and is thus extrinsic evidence.

Antonio Gotto, who stated that an HMG CoA reductase inhibitor is "a substance that blocks the synthesis of cholesterol . . .," (Ravi Decl., Ex. 38 at 151:22–152:4), and a textbook description of how certain acids may inhibit particular enzymes, (id. at Ex. 22, citing Chemical Principles 386 (W.B. Saunders Co., 1973)). Based on this evidence, Mylan urges that "lovastatin" and "simvastatin" be construed to mean the acid forms of those compounds.

Schering does not dispute that the acid forms of lovastatin and simvastatin accomplish the actual inhibition of HMG CoA reductase. Schering instead argues that an person of ordinary skill in the art would understand "lovastatin" and "simvastatin," as used in claim 3, to refer to the drugs as they are commonly administered to patients—in their lactone forms. Schering states that lovastatin and simvastatin are not in their active form when given to patients but rather are given in an FDA-approved lactone form that metabolizes into the active form after ingestion. Schering argues that a person of ordinary skill in the art would understand the claim terms to refer to this lactone form, as it is the only form that is currently available for use as a pharmaceutical. Schering explains that the specification supports this reading, as it describes the combination of ezetimibe with "HMG CoA reductase inhibitors such as lovastatin, simvastatin, and [atorvastatin]." U.S. Patent No. 5,846,966 col. 6:38–41. This practical combination, Schering argues, implies that "a person of ordinary skill in the art reading this patent as of the filing date would have understood the authors to be referring to the statin drugs patients take," rather than the active forms created inside the body. (Hr'g Tr. 110:5–21; 123:16–22.) Schering further points to the Physicians' Desk Reference ("PDR"), which states that "[a]fter oral ingestion, simvastatin, which is an inactive lactone, is hydrolized to the corresponding [acid] form. This is an inhibitor of 3-hydroxy-3-methylglutaryl-coenzyme A (HMG-CoA) reductase."

Physicians' Desk Reference 1625 (47th ed.1993); (see Suh Decl., Ex. 23). The PDR provides a similar description for lovastatin. See id. at 1556.

Mylan responds that the specification contains no language regarding FDA approval and that the PDR itself recognizes that only the acid forms of lovastatin and simvastatin actually inhibit HMG CoA reductase. Mylan further notes that atorvastatin, one of the other statins recited in claim 3, had not been FDA-approved at the time of the invention and was noted in the specification only by a code name. (Hr'g Tr. 69:10–20; see Schering's Opening Claim Constr. Br. at 21; U.S. Patent No. 5,846,966 col. 6:38–41.) Mylan also questions how an FDA approval requirement could be reconciled with the claim language directed to administering the claimed compound to "a mammal," when FDA review is only required for human drugs. (Hr'g Tr. 69:21–24; see, e.g., U.S. Patent No. 5,846,966 claim 6.)

Mylan concedes, however, that lovastatin and simvastatin, as prescribed by practicing physicians, are inactive. (Hr'g Tr. 60:6–9.) Mylan's argument instead rests on a literal interpretation of the word "inhibitor." The relevant inquiry, however, is how that term would be understood by a person of ordinary skill in the art at the time of the invention. As the relevant claims of the '966 patent are directed to a pharmaceutical composition of ezetimibe with known statin drugs, a person of ordinary skill in the art would understand the pharmaceutical to include those statin forms that are actually available, or soon to be available, for use in a pharmaceutical. Indeed, the PDR alternatively refers to lovastatin and simvastatin by their commercial names (Mevacor and Zocor, respectively) and describes those compounds as inactive lactones. (See Suh Decl., Ex. 23 at 1556, 1625.) Claim 1 itself refers to the combination of the drugs in a "pharmaceutically acceptable carrier." While the parties agree that acid forms of lovastatin and

simvastatin could be administered to patients, Mylan has presented no evidence that such administration would be any more than a theoretical possibility. More likely is that a person of ordinary skill reading the claim language regarding HMG CoA reductase inhibitors would not interpret the word "inhibitor" in a purely literal manner, devoid of context, but would instead understand the term to refer to a drug that could be combined with ezetimibe and administered in a "conventional dosage form." U.S. Patent No. 5,846,966 col. 21:5–8 (emphasis added). While Mylan is correct that the specification in no way limits the claimed subject matter to FDA-approved compounds, the claims and specification clearly contemplate the real-world, pharmaceutical application of the claimed composition. And, contrary to Mylan's assertions, the specification's use of the term "active ingredients" actually supports this reading, as the context in which that term was used involved the combination of the active, therapeutic ingredients with inactive pharmaceutical carriers, as would be used in formulating a conventional "dosage." Id. at col. 21:2–63. The specification does not use "active ingredients" to refer to acid forms. The Court thus construes "lovastatin" and "simvastatin" to mean the lactone forms of those drugs.

2. "pravastatin," "fluvastatin," and "atorvastatin"

For similar reasons, the Court construes the disputed terms "pravastatin," "fluvastatin," and "atorvastatin" to refer to their salt forms, as the parties do not dispute that it is the salt form of those drugs that is actually administered to patients. (Hr'g Tr. 107:20-22.) Salt forms are open ring compounds that convert to acid forms when exposed to solution. (Hr'g Tr. at 109:9–11.) Mylan considers the salt forms of pravastatin, fluvastatin, and atorvastatin to be active compounds, as they exhibit an open ring structure, (Mylan's Opening Br. at 27), and Schering agrees that those salt forms do not require metabolism in vivo in order to convert to

acid form, (Hr'g Tr. at 109:9–11). The Court thus considers pravastatin, fluvastatin, and atorvastatin to be active compounds, regardless of whether they exist in their acid or salt form. This characterization is of no moment, however, because as the Court has already stated, a person of ordinary skill in the art would understand the statin drugs recited in the '966 patent to refer to the form that is actually administered to the patient, whether that form be active or inactive. Here, the salt forms of pravastatin, fluvastatin, and atorvastatin are the forms that are actually administered to patients and are thus the appropriate construction of the disputed terms.[18]

3. "HMG CoA reductase inhibitor"

As the Court has already stated, the lactone forms of lovastatin and simvastatin and the salt forms of pravastatin, fluvastatin, and atorvastatin are the drugs that are actually administered to patients and only result in the inhibition of HMG CoA reductase after they have been provided externally. The Court thus declines to adopt the literal interpretation of "inhibitor" advocated by Mylan. Furthermore, the Court does not adopt an ingestion limitation with respect to the combination drug claimed in the '966 patent, because, as the Court has already stated, the specification expressly contemplates the provision of that drug in both oral and non-oral dosage

[18]Mylan contends that the Court should not construe these terms to refer to salt forms, arguing that Pfizer v. Ranbaxy Laboratories, 457 F.3d 1284 (Fed. Cir. 2006), requires that salt forms be explicitly claimed, noting that Pfizer involved the patent for atorvastatin, one of the statin drugs recited in the claim 3 of the '966 patent. Unlike the '966 patent, however, the patent for atorvastatin recites "(1) atorvastatin acid; or (2) atorvastatin lactone; or (3) pharmaceutically acceptable salts thereof." Pfizer, 457 F.3d at 1291; see U.S. Patent No. 5,273,995. The Federal Circuit did not flatly hold that salt forms must be explicitly claimed under all circumstances, but rather focused its analysis on the fact that the term "pharmaceutically acceptable salts thereof" was included in one claim of the patent-in-suit but missing in another. Id. By contrast, the '966 makes no explicit claim regarding salt forms, nor does it even mention an acid or lactone form; it simply claims "atorvastatin" (along with the other statins). This Court therefore does not read Pfizer as precluding the statin drugs recited in claim 3 of the '966 patent from being construed as their salt forms.

forms. See U.S. Patent No. 5,846,966 at col. 21:49–62. The Court thus construes "HMG CoA reductase inhibitor" to mean "a substance that, when provided externally, results in the inhibition of 3-hydroxy-3-methylglutaryl coenzyme A reductase."

IV. CONCLUSION

For the foregoing reasons, the Court construes the disputed terms of United States Patent Nos. RE37,721 and 5,846,966 as follows:

1. The terms "treatment of" and "treating," as used in claims 8, 9, 12, and 13 of the '721 patent and claim 1 of the '966 patent, are construed to mean "giving for the purpose of stopping, slowing or reversing the progression of a disease";

2. The terms "reduction of plasma cholesterol levels" and "reducing plasma cholesterol levels," as used in claims 8, 9, 12, and 13 of the '721 patent and claim 1 of the '966 patent, are construed to mean "lowering the total plasma cholesterol level";

3. The term "administering," as used in claims 9 and 13 of the '721 patent, is construed to mean "to provide externally by way of ingestion";

4. The term "an effective amount," as used in claims 8, 9, 12, and 13 of the '721 patent, is construed to mean "an amount of the recited compound(s) that, when provided externally by way of ingestion, elicits a therapeutic effect of the type identified in the preamble";

5. The term "an effective amount," as used in claim 1 of the '966 patent, is construed to mean "an amount of the recited compound(s) that, when provided externally, elicits a therapeutic effect of the type identified in the preamble";

6. The term "pharmaceutically acceptable carrier," as used in claims 8 and 12 of the '721 patent and claim 1 of the '966 patent, is construed to mean "a conventional pharmaceutically acceptable excipient or additive including non-toxic compatible fillers, binders, disintegrants, buffers, preservatives, antioxidants, lubricants, flavorings, thickeners, coloring agents, emulsifiers and the like";

7. The terms "lovastatin" and "simvastatin," as used in claim 3 of the '966 patent, are construed to mean the inactive, lactone forms of those drugs; and

8. The terms "pravastatin," "fluvastatin," and "atorvastatin," as used in claim 3 of the '966 patent, are construed to mean the salt forms of those drugs; and

9. The term "HMG CoA reductase inhibitor," as used in claims 1 and 3 of the '966 patent, is construed to mean "a substance that, when provided externally, results in the inhibition of 3-hydroxy-3-methylglutaryl coenzyme A reductase."

An appropriate Order accompanies this Opinion.

DATED: June 15, 2011

/s/ Jose L. Linares
JOSE L. LINARES
UNITED STATES DISTRICT JUDGE