NOT FOR PUBLICATION

(Document Nos. 77, 96, 149-54, 159, 168-78, 182-83, 189-90)

IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

SCIELE PHARMA INC., (N/K/A SHIONOGI PHARMA INC.), ANDRX CORPORATION, ANDRX PHARMACEUTICALS, INC. (N/K/A WATSON LABORATORIES, INC., FLORIDA), ANDRX PHARMACEUTICALS, L.L.C., ANDRX LABORATORIES (NJ), INC. ANDRX EU LTD., and ANDRX LABS, L.L.C.,	:	
Plaintiffs,	:	Civil No. 09-0037 (RBK/JS)
v.	:	**OPINION**
LUPIN LTD., and LUPIN PHARMACEUTICALS, INC., and MYLAN INC., and MYLAN PHARMACEUTICALS, INC.	:	
Defendants.	:	

KUGLER, United States District Judge:

Presently before the Court are motions for claim construction on U.S. Patent Numbers 6,099,859 ("'859"), 6,866,866 ("'866"), 6,495,162 ("'162"), and 6,790,459 ("'459") by Plaintiffs and Counterclaim Defendants Shionogi Pharma (formerly Sciele Pharma) and the Andrx parties (collectively "Plaintiffs"), Counterclaim Plaintiffs and Defendants Lupin Ltd. and Lupin Pharmaceuticals, Inc. (together "Lupin"), and Counterclaim Plaintiffs and Defendants Mylan Inc. and Mylan Pharmaceuticals, Inc. (together "Mylan"). On September 7, 2011, the Court held a hearing pursuant to Markman v. Westview Instruments, Inc., 517 U.S. 370 (1996) ("Markman

hearing"). There, and in their briefing prior to the hearing, the parties presented proposed construction and expert testimony concerning up to twenty-four claim terms. Defendants Lupin and Mylan each submitted post-hearing briefing regarding the construction of one term ("passageway" and "after administration following dinner," respectively). Docs. 189 and 190. For the reasons set forth below, the Court adopts the Plaintiffs' construction of "passageway" and "single dose," and Mylan's construction of "after administration following dinner." The Court adopts the agreed-upon constructions of "impermeable," "mean time to maximum plasma concentration (T_{max})," "membrane," "permeable," and "semipermeable membrane." The Court declines to construe the remaining sixteen terms.

I. BACKGROUND

A. Procedural History

Plaintiffs Sciele Pharma, Inc. (n/k/a "Shionogi Pharma, Inc.") and Andrx are the exclusive licensee and patent holders of U.S. Patent Nos. 6,099,859 ("'859") and 6,866,866 ("'866"), which are embodied in Fortamet®, an extended-release metformin hydrochloride tablet developed and distributed by Shionogi. Plaintiffs allege that Defendants Lupin and Mylan "sought FDA approval to market and sell generic versions of Fortamet®." Pls.' Opening Claim Construction Br. 2.

i. Suit against Lupin

Plaintiffs' lawsuit against Defendant Lupin began when Lupin submitted Abbreviated New Drug Application ("ANDA") No. 21-574 to the FDA. That ANDA "included a certification with respect to [Plaintiffs'] '859 and '866 patents. . . ." Pls.' Compl. ¶ 20. Plaintiffs allege that Lupin's ANDA sought approval from the FDA "to manufacture, use, and sell 500 mg and 1000 mg extended-release metformin hydrochloride tablets . . . prior to the expiration of

[Plaintiffs'] patents" '859 and '866." Id. Moreover, on or about December 3, 2008, Lupin sent a notice letter to Plaintiff Andrx, in which Lupin indicated that it had filed an ANDA that included certifications for '859 and '866, "and that it sought approval of its ANDA prior to the expiration of those patents." Id. at ¶ 21.

Plaintiffs filed suit against Defendant Lupin, pursuant to the Hatch-Waxman statute, 21 U.S.C. § 355(j), claiming infringement of Claim 3 of their '859 Patent, and infringement of Claims 1, 3, 4, 5, and 25 of their '866 Patent. Pls.' Opening Claim Construction Br. 5. Defendant Lupin responded that the '859 and '866 Patents either are invalid and/or will not be infringed by Lupin's ANDA Products. Furthermore, indicating that that the '859 and '866 Patents "are listed in the Approved Drug Products with Therapeutic Equivalence Evaluations ('Orange Book') for Fortamet®, together with United States Patents No. 6,495,162 ["'162"] and 6,790,459 ["'459"]," Defendant Lupin asserted counterclaims against Plaintiffs, seeking declaratory judgment that Plaintiffs' '859, '866, '162, and '459 Patents —"are invalid and/or will not be infringed by the manufacturer [sic], sale and use of the ANDA Products." D. Lupin Am. Answer & Countercls. ¶ 54, 55. Although Plaintiffs did not originally allege infringement of their '162 and '459 Patents, they nevertheless denied the allegations of non-infringement and invalidity contained in Lupin's counterclaims. Pls.' Answer to Counterclaims of Lupin ¶ 55.

ii. Suit against Mylan

The history of the action against Defendant Mylan is similar. Mylan submitted ANDA No. 200690 to the FDA, which "included a certification with respect to the '859 and '866 Patents." Shionogi Pharma v. Mylan, DE 1:10-00135,[1] Pls.' Compl. ¶17. On or about January 4, 2010, Defendant Mylan sent a notice letter to Plaintiffs in which Mylan indicated that it had filed an ANDA that included certifications with respect to '859 and '866, "and that it sought

[1] The action against Mylan was later consolidated with the action against Lupin.

approval of its ANDA prior to the expiration of those Patents." Id. at ¶ 18. Plaintiffs filed suit against Mylan individually, pursuant to the Hatch-Waxman statute, 21 U.S.C. § 355(j), for infringement of claim 27 of its '859 Patent and claims 1, 3, 4, 5, and 25 of its '866 Patent. Pls.' Opening Claim Construction Br. 5.

Defendant Mylan responded that the '859 and '866 Patents either are invalid or will not be infringed by Mylan's ANDA Products. Shionogi Pharma v. Mylan, DE 1:10-cv-00135, D. Mylan Answer, Defenses, and Counterclaims 13. Like Lupin, Mylan alleges that "[t]he '859, '162, '459 and '866 Patents are listed in the Approved Drug Products with Therapeutic Equivalence Evaluations ('the Orange Book') for Fortamet®." Id. at ¶ 23. Accordingly, Mylan filed counterclaims against Plaintiffs, seeking declaratory judgment that Plaintiffs' '162, '459, and '859 Patents are invalid and/or are not infringed by Mylan's ANDA Products, and that the '866 Patent is invalid. Id. at ¶¶ 26-56. Although Plaintiffs did not originally allege infringement of their '162 and '459 Patents, they nevertheless denied the allegations of noninfringement and invalidity contained in Mylan's counterclaims. D. Mylan Opening Claim Construction Br. 8, 9.

The Mylan matter (Shionogi v. Mylan, DE 1:10-00135-RBK) was later consolidated in this Court with Sciele v. Lupin. D. Mylan Opening Claim Construction Br. 5, n.2.

iii. Summary of Claim Construction Dispute

Plaintiffs and Defendants conferred and narrowed their claim construction terms. They filed a Joint Claim Construction and Prehearing Statement, which "identifies the claim terms in dispute and the parties' respective proposed constructions." Pls.' Opening Claim Construction Br. 2; see J. Claim Construction and Prehearing Stmt. Ex. A. Some modifications in the parties' proposed constructions followed. See, e.g., D. Lupin Rev. Claim Construction and Prehearing Stmt. § 2. The parties all agree on the construction of five terms, and request that this Court

adopt their agreed-upon construction. See § II.A infra. However, for many of the remaining terms, the parties disagree on: (1) whether a construction should be adopted at all; (2) which construction should be adopted; or (3) both (1) and (2). The Court construes those terms for which all parties request construction, and declines to construe those for which it finds no fundamental dispute.

B. Description of the Product at Issue

At issue in this case is the construction of terms contained in the claims of four Patents embodied in a pharmaceutical drug developed and distributed by Plaintiffs. Plaintiff Andrx Labs holds New Drug Application ("NDA") No. 21-574, by which the Food and Drug Administration ("FDA") approved a drug marketed in the United States by Plaintiff Sciele Pharma. Pls.' Compl. ¶ 19. That drug, marketed under the trade name "Fortamet®," is an extended-release metformin hydrochloride tablet. Id. 500 mg and 1000 mg tablets of Fortamet® have been authorized for marketing by the FDA. Id. According to Plaintiffs' Complaint against Lupin, "[t]he metformin hydrochloride tablets described in Andrx's NDA are indicated as an adjunct to diet and exercise to lower blood glucose . . . ." Id. This "improve[s] glycemic control in adults with Type 2 diabetes mellitus." Id.

The core of the Fortamet® tablet is composed of metformin hydrochloride, an antihyperglycemic drug. Pls.' Opening Claim Construction Br. 7. The core is covered by a membrane that allows the passage of external fluids into the core, without allowing the metformin in the core to be immediately released upon ingestion of the tablet by a patient. Id. When the tablet is swallowed, "water and gastric fluid flow through the membrane and into the core. These fluids then dissolve the drug in the core, and the drug can, in a controlled way, exit the tablet" through the membrane. Id. The drug exits the tablet by means of a "passageway" in

the membrane. Id. All parties have requested that the Court adopt a construction of "passageway," and each party proposes a different construction. See III.A.i infra. The mechanism by which metformin exits the membrane is the primary subject of both the '859 and '162 Patents. See '859 and '162 Patents.

Furthermore, Fortamet® is designed not only to provide the controlled release of metformin, but also to create an extended-release dosage form of that "short-acting" drug, which will be most effective when the body produces its highest levels of glucose. Pls.' Opening Claim Construction Br. 8-9. The body's production of glucose is highest at night. '866 Patent, 9:6-7 (indicating that "[g]luconeogenesis is well known to those skilled in the art to be greatest at night"). The '866 and '459 Patents claim that Fortamet®'s mean time to maximum plasma concentration—T_{max}, the time when the level of drug in the patient is highest—coincides with the body's highest glucose production, since T_{max} occurs "between 11:30 p.m. and 1:30 a.m., based on a dose administered at 6 p.m." '866 and '459 Patents, 9:9-10.

The claim terms in dispute primarily concern the mechanism by which metformin is released from the core of the tablet, as well as the time and circumstances in which the drug is administered. The parties dispute not only the construction of each term at issue, but, for many terms, also dispute whether the Court should adopt a construction at all.

C. Claim Terms at Issue

The parties agree that the Court should construe the term "passageway," for which three different constructions have been proposed, as well as "after administration following dinner" and "single dose," each of which has received two proposed constructions. The parties also agree that the Court should adopt a construction of the terms "impermeable," "mean time to maximum plasma concentration (T_{max})," "membrane," "permeable," and "semipermeable

membrane." Moreover, for these five terms, the parties agree on the construction the Court should adopt. Defendant Mylan requests that the Court construe sixteen more terms—namely, "controlled release carrier," "dinner," "flux enhancer," "peak plasma levels," "reference standard," "$t_{1/2}$," "absorption enhancer," "dosage form," "effective amount," "effective dose," "evening meal," "mean," "plasticizer," "polymer," "water soluble seal coat," and "%." Plaintiffs, on the other hand, request that the Court decline to adopt a construction of those sixteen terms. Defendant Lupin requests that the Court construe these terms, but agrees with Plaintiffs—not Mylan—as to their meaning, and does not offer argument regarding those terms.

II. LEGAL STANDARD FOR CLAIM CONSTRUCTION

To prove patent infringement, a plaintiff must demonstrate that the accused device or method contains all the limitations of the claimed invention. Johnson Worldwide Assocs., Inc. v. Zebco Corp., 175 F.3d 985, 988 (Fed. Cir. 1995). As a prerequisite to the ultimate disposition, however, a court must determine as a matter of law the meaning and the scope of the disputed patent's claims. (Id.). Claim construction is a question of law; therefore, it is "[t]he duty of the trial judge . . . to determine the meaning of the claims at issue." Exxon Chem. Patents, Inc. v. Lubrizoil Corp., 64 F.3d 1553, 1555 (Fed. Cir. 1995).

The scope of a patented invention is defined by the enumerated claims that comprise the patent. Phillips v. AWH Corp., 415 F.3d 1303, 1312 (Fed. Cir. 2005). Absent an express intent to impart a novel meaning, the words of a claim are given their "ordinary and customary meaning," which is defined as "the meaning that the term would have to a person of ordinary skill in the art in question at the time of the invention." Id. at 1312-13 (citations omitted). The court must adopt the perspective of one who "read[s] the words used in the patent documents with an understanding of their meaning in the field, and [who has] knowledge of any special

meaning and usage in the field." Id. at 1313 (citations omitted).

Intrinsic evidence, which includes the patent itself, including the claims, the specification, and the prosecution history, is the key initial component of claim construction. Id. at 1314. Claim construction begins with the language of the claims themselves, since the claim language is chosen by the inventor to distinctly claim the subject matter of the invention. ACTV, Inc. v. Walt Disney Co., 346 F.3d 1082, 1088 (Fed. Cir. 2003). Furthermore, the specification can "act[] as a dictionary when it expressly defines terms used in the claims or when it defines terms by implication." Vitronics Corp. v. Conceptronic, Inc., 90 F.3d 1576, 1582 (Fed. Cir. 1996). It is also "entirely appropriate for a court, when conducting claim construction, to rely heavily on the written description for guidance as the meaning of the claims." Phillips, 415 F.3d at 1317.

Secondarily, a court may draw on extrinsic evidence regarding "relevant scientific principles, the meaning of technical terms, and the state of the art." Id. Extrinsic evidence derives from sources outside the patent and prosecution history, such as expert testimony, dictionaries, or treatises, and although it may be useful, "it is unlikely to result in a reliable interpretation of patent claim scope unless considered in the context of the intrinsic evidence." Id. at 1319. Moreover, the Federal Circuit has cautioned, "the use of the dictionary may extend patent protection beyond what should properly be afforded by the inventor's patent." Id. at 1322.

III. DISCUSSION

A. Terms in Dispute

Plaintiffs, Defendant Mylan, and Defendant Lupin all request that this Court adopt a construction of the claim terms "passageway," "single dose," and "after administration following dinner." Moreover, the parties present conflicting constructions of those terms. "[I]t is the

court's duty to resolve" "a fundamental dispute regarding the scope of a claim term." O2 Micro Int'l Ltd. v. Beyond Innovation Tech. Co., 521 F.3d 1351, 1362 (Fed. Cir. 2008). Accordingly, the Court will construe these disputed terms, and will adopt the constructions indicated below.

i. Passageway

The term "passageway" appears in claims 1, 27, and 29 of the '859 Patent, claim 25 of the 866 Patent, and claims 1, 21, 25, 26, and 44 of the '162 Patent. Shionogi proposes the following construction: "Includes at least an aperture, orifice, bore, hole, weakened area, or erodible element such as a gelatin plug that erodes to form an osmotic passageway, for the release of the antihyperglycemic drug from the dosage form." Pls.' Opening Claim Construction Br. 16. Contending that Plaintiffs' proposed construction is "so broad that it would cover virtually any opening in a membrane," Defendant Lupin suggests that "passageway" be defined as "[a]n osmotic passageway of pre-controlled dimensions fabricated into a membrane for the release of the antihyperglycemic drug, and includes an aperture, orifice, bore, hole, weakened area or erodible element such as a gelatin plug." D. Lupin Post-Markman Hearing Br. 1, 5.[2] Defendant Mylan also disputes Plaintiffs' proposed construction, arguing that "passageway" should be construed to distinguish a passageway "from any path(s) formed by leaching or dissolving of the flux enhancer from the membrane." D. Mylan Opening Claim Construction Br. 15 (emphasis omitted). Thus Mylan suggests the following construction: "a discrete, macroscopic feature intentionally formed in the membrane during the manufacturing process that produces an opening in the semipermeable membrane for release of the antihyperglycemic drug. This opening is distinct from any path(s) formed by leaching or dissolving of the flux enhancer from the membrane." Id. at 10. The Court adopts the following construction, which is taken

[2] After the Septemer 7, 2011 Markman hearing, Lupin removed the requirement that the membrane be semipermeable from its proposed construction of "passageway." D. Lupin Post-Markman Hearing Br. 5.

directly from the Patent specifications themselves and is nearly identical to Shionogi's proposal, with the removal of the words "at least": "Includes an aperture, orifice, bore, hole, weakened area, or erodible element such as a gelatin plug that erodes to form an osmotic passageway, for the release of the antihyperglycemic drug from the dosage form." '859 5:8-11.

The analysis of a claim term begins with intrinsic evidence—"[f]irst and foremost . . . the language of the claims themselves." ACTV, Inc. v. Walt Disney Co., 346 F.3d 1082, 1088. The claims of the '859, '866, and '162 Patents indicate a minimum number of passageways contained in a tablet, and they outline a function of the passageway. See, e.g., '859 10:5-6 (noting that the patented drug contains "at least one passageway in the semipermeable membrane for the release of the antihyperglycemic drug"). The claim terms do not offer a definition of "passageway"; they simply express that the antihyperglycemic drug is released from the semipermeable membrane by means of the passageway—something all parties agree on.

Like the claim terms, a patent's specifications are also intrinsic evidence, and should be examined at the outset of claim construction. Vitronics Corp. v. Conceptronic, Inc., 90 F.3d 1576, 1582 (Fed. Cir. 1996). A specification "acts as a dictionary when it expressly defines terms used in the claims or when it defines terms by implication." Id. In this case, "passageway" is expressly defined in the "detailed description" of the '859 and '162 Patents as follows: "As used herein the term passageway includes an aperture, orifice, bore, hole, weaken [sic] area or an erodible element such as a gelatin plug that erodes to form an osmotic passageway for the release of the antihyperglycemic drug from the dosage form." '859 5:8-11, '162 5:14-18.

This construction is nearly identical to Plaintiffs' proposed construction. Defendant Lupin explains that the addition of "at least" to Plaintiffs' proposed construction renders it overly

broad. It is true that, as Plaintiffs argue, "[a]s a patent law term of art, 'includes' means 'comprising'"—both of which are considered "non-restrictive terminology." Sandisk Corp. v. Memorex Prods., 415 F.3d 1278, 1284 (Fed. Cir. 2005) (internal citations omitted). See also Hewlett-Packard Co. v. Repeat-O-Type Stencil Mfg. Corp., 123 F.3d 1445, 1451 (Fed. Cir. 1997) (explaining that "[t]he claim term 'including' is synonymous with 'comprising,' thereby permitting the inclusion of unnamed components."). A proper construction of "passageway" must therefore capture the non-restrictive nature of the examples used in the Patents to define the term. However, Plaintiffs' addition of "at least" is unnecessary when the word "includes" is itself contained in the construction.

Mylan argues that "to construe 'passageway' as expansively as Plaintiffs propose would render the 'semipermeable membrane' a fully permeable membrane, which, as explained above, is inconsistent with the plain language of the claimed limitation . . . ." (D. Mylan Responsive Claim Construction Br. at 6). Similarly, Lupin argues that it is necessary that the construction of the term state that a passageway must be "osmotic," because the '859 and '162 Patents make reference to another set of patents (the "Alza patents"),[3] which specify osmotic passageways. D. Lupin Claim Construction Br. 6-7. However, by declining to read Defendants' suggested limitations into "passageway," the Court does not erase limitations that may be imposed on the patent by its other claims. In a patent infringement action, after determining "the correct claim scope," a trial court "compares the properly-construed claim to the accused device to determine, as a matter of fact, whether all of the claim limitations are present, either literally or by a substantial equivalent, in the accused device." Johnson Worldwide Assocs. v. Zebco Corp., 175 F.3d 985, 988 (Fed. Cir. 1999) (emphasis added).

[3] The Alza patents are not explicitly incorporated into the '859 or '162 Patents.

Therefore, the Court construes "passageway" as follows: "Includes an aperture, orifice, bore, hole, weakened area or an erodible element such as a gelatin plug that erodes to form an osmotic passageway for the release of the antihyperglycemic drug from the dosage form."

ii. Single dose

The parties request that the Court adopt a construction of "single dose," which appears in claim 1 of the '866 Patent, and claim 1 of the '459 Patent. Plaintiffs and Defendant Lupin propose to construe "single dose" according to what they claim is its plain and ordinary meaning: "the amount of the drug administered to a human patient at one time." Pls.' Opening Claim Construction Br. 24. Defendant Mylan proposes "administering a dosage of the drug to a single patient at one time in a dosage interval." D. Mylan Opening Cl. Construction Br. 18-19. Because "words in a claim are generally given their ordinary and customary meaning," Vitronics Corp., 90 F.3d at 1582, and because Mylan's proposed construction would render the Patent claims redundant, the Court adopts the construction agreed upon by Plaintiffs and Lupin.

Mylan argues that Plaintiffs' definition does not restrict the administration of the drug to a once-daily occurrence. D. Mylan Responsive Claim Construction Br. 15 (explaining that "[u]nder Plaintiffs' proffered construction, any amount given to a patient would qualify as a 'single dose,' even if that amount was administered every fifteen minutes of every day"). Plaintiffs, however, indicate that their own construction "is supported by the language of the claims and specification, which refer to once-a-day administration of metformin." Pls.' Opening Claim Construction Br. 24. Indeed, claim 1 of the '866 Patent refers to a "dosage form . . . suitable for providing once-a-day oral administration of a single dose. . . ." '866 21:53-56. Claim 1 of the '459 Patent describes the claimed method as "comprising orally administering to human patients on a once-a-day basis at least one oral controlled release dosage

form . . . ." '459 22:14-16. Given that the claims themselves include the concept of "once-a-day" dosage, the Court finds it unnecessary to incorporate "once-a-day" into the construction of "single dose." Thus the Court adopts the construction proposed by Plaintiffs and Lupin.

iii. After administration following dinner

Plaintiffs' '866 Patent indicates that Fortamet® is designed to provide the controlled release of an antihyperglycemic drug, with peak levels of the drug coinciding with the body's production of peak levels of glucose. The parties all agree that Plaintiffs' drug achieves that goal when administered at dinnertime. Moreover, the parties agree that dinnertime occurs between 4:00 p.m. and 8:00 p.m. See D. Lupin Rev. Claim Construction Br. 7, D. Mylan Opening Claim Construction Br. 11. The dispute over "after administration following dinner" concerns whether or not the Patents' claims require that a meal actually be eaten before the patented drug is administered. Plaintiffs request that the Court adopt a construction that applies "regardless of whether a meal is actually eaten" at dinnertime, and Defendant Lupin agrees. Defendant Mylan, however, suggests a construction that would require that a meal be eaten. The Court adopts Mylan's proposed construction: "After administration of the drug which follows a meal generally consumed between 4:00 p.m. and 8:00 p.m."

"[W]ords in a claim are generally given their ordinary and customary meaning." Vitronics Corp., 90 F.3d at 1582. Mylan's proposed construction of "after administration following dinner," which includes a meal, reflects the ordinary and customary meaning of the term. Moreover, the specifications of the '866 Patent offer intrinsic evidence to support Mylan's contention that "after administration following dinner" should be given its plain and ordinary meaning. The specifications of Patent '866 explain that "[i]t has surprisingly been found that when biguanides such as metformin are administered orally in a controlled release dosage form

suitable for once-a-day dosing in the 'fed' state, preferably at dinner, the bioavailability is improved . . . ." ('866 8:53-56). Furthermore, they contrast the bioavailability of metformin in the fed state with "the administration of the controlled release dosage form in the 'fasted' state." (Id. at 8:57-58).

The Plaintiffs' argument for their construction of "after administration following dinner" rests on the fact that the terms "dinnertime" and "at dinner" are explicitly defined in the '866 Patent: "The term 'dinnertime' or 'at dinner' as it is used herein with respect to the dosing of the controlled release formulations of the invention means that the controlled release formulation is orally administered at a time when dinner is normally eaten (regardless of whether a meal is actually eaten at that time, unless so specified herein), generally between about 4 p.m. and 8 p.m." '866 7:10-16. This definition deviates from the plain and ordinary meaning of "dinner." However, such a deviation is acceptable where the patent manifests "an express intent to impart a novel meaning . . . ." Mars, Inc. v. JCM, 2008 U.S. Dist. LEXIS 81052 at *6 (D.N.J. July 2, 2008). Moreover, "[t]he patentee is free to act as his own lexicographer, and may set forth any special definitions of the claim terms in the patent specification or file history, either expressly or impliedly." Schoenhaus v. Genesco, Inc., 440 F.3d 1354, 1358 (Fed. Cir. 2006). Thus in this case, Plaintiffs argue, the patentees intended to give "dinnertime" and "at dinner" a novel meaning, which they explicitly express in the patent.

As Defendant Mylan points out, however, "dinnertime" and "at dinner" do not appear in the phrase "after administration following dinner." (D. Mylan Resp. Claim Construction Br. 12). Acknowledging that Plaintiffs expressly defined "at dinner and "dinnertime," Mylan explains that "even if the patentees had not acted as their own lexicographers, the plain and ordinary meaning of the terms . . . 'dinnertime' and 'at dinner' do not necessarily imply that a meal must

actually be eaten." (Id. 11). Indeed, because of their temporal markers ("-time" and "at"), "dinnertime" and "at dinner" clearly refer to a time of day. As contained in the phrase "after administration following dinner," which is the term that all parties have requested this Court to construe, "dinner" manifests no such temporal markers. Thus "after administration following dinner," does not import the temporal meaning assigned to the definitions of "dinnertime" and "at dinner." The Court adopts Mylan's proposed construction.

B. Agreed-upon Terms

Plaintiffs, Defendant Mylan, and Defendant Lupin request construction of the terms "impermeable," "membrane," "permeable," "semipermeable membrane," and "T_{max}," and all parties have agreed on the construction of the terms. The Court adopts the parties' agreed-upon constructions.

It is "the duty" of this Court to construe terms "at issue" in patent disputes. Chem. Patents, Inc. v. Lubrizoil Corp., 64 F.3d 1553, 1555 (Fed. Cir. 1995). The '859 and '162 Patents concern the mechanism by which metformin is able to exit the core of Plaintiffs' drug; therefore the Court finds that the level of permeability of the membrane surrounding that core—as expressed by the terms "impermeable," "membrane," "permeable," and "semipermeable membrane"—is unquestionably "at issue" in the dispute over those Patents. It is therefore the duty of this Court to construe them.

Furthermore, all four terms appear in claim 1 of the '859 Patent (and in claim 1 of the '162 Patent). Claim 1 of '859 has not been asserted against Defendants; however, Plaintiffs allege that Lupin has infringed claim 3 of the '859 Patent, and claim 3 is dependent on claim 1.[4]

[4] Where a claim "expressly recites the process" of a previous claim and "includes [an] additional step," the later claim "incorporates the format specified by [35 U.S.C. § 112] for dependent claims," and is therefore dependent on the previous claim. Monsanto Co. v. Syngenta Seeds, Inc., 503 F.3d 1352, 1358 (Fed. Cir. 2007). Thus here, where

‘859 Patent 9:61-10:11. “A claim in dependent form shall be construed to incorporate by reference all the limitations of the claim to which it refers.” 35 U.S.C. § 112 (2006). Likewise, claim 27 of the ‘859 Patent—which Plaintiffs allege Mylan has infringed—depends on and incorporates claim 25 of the ‘859 Patent, which contains the term “semipermeable membrane.” ‘859 Patent 11:28-12:18.

Similarly, because the ‘866 Patent describes the mechanism behind Fortamet®’s controlled-release technology, “mean time to maximum plasma concentration (T_{max})” is a term that is directly engaged by this dispute. Moreover, the term appears in claim 1 of ‘866 (and Claim 1 of ‘459), which Plaintiffs have asserted against both sets of Defendants. ‘866 Patent 21:57-58.

Because these terms appear or are incorporated in patent claims asserted by Plaintiffs against Defendants (and by Counterclaim Plaintiffs against Counterclaim Defendants), and because Plaintiffs and Defendants agree that these terms are at issue, this Court will construe them. Furthermore, the Plaintiffs and Defendants Lupin and Mylan all agree on a set of constructions. Pls.’ Opening Claim Construction Br. 28-29; D. Lupin Rev. Claim Construction Br.; D. Mylan Opening Claim Construction Br. 5. The Court sees no reason not to adopt the following agreed-upon constructions:

- Impermeable: “not allowing the passage of a substance.”
- Mean time to plasma concentration: “The term ‘T_{max}’ is the time period which elapses after administration of the dosage form at which the plasma concentration of the drug attains the highest plasma concentration of the drug attained within the dosing interval (i.e., about 24 hours).”
- Membrane: “a coating that may or may not be semipermeable”
- Permeable: “allowing the passage of a substance”

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claim 3 introduces a limitation on “[a] controlled release tablet as defined in claim 2,” and where claim 2 introduces a limitation on “ [a] controlled release pharmaceutical table as defined in claim 1,” claim 3 is dependent on claim 1.

- Semipermeable membrane: "A membrane that is permeable to the passage of an external fluid such as water and biological fluids and impermeable to the passage of the anti-hyperglycemic drug in the core."

C. Terms Which the Court Declines to Construe

It is the Court's "duty to resolve" "a fundamental dispute regarding the scope of a claim term." (O2 Micro Int'l Ltd. v. Beyond Innovation Tech. Co., 521 F.3d 1351, 1362 (Fed. Cir. 2008)). However, "district courts are not (and should not be) required to construe every limitation present in a patent's asserted claims." (Id.). Accordingly, the Court declines to construe "absorption enhancer," "dosage form," "effective amount," "effective dose," "evening meal," "mean," "plasticizer," "polymer," "%," "water soluble seal coat," "controlled release carrier," "dinner," "flux enhancer," "peak plasma levels," "reference standard," and "$t_{1/2}$."

Plaintiffs, Defendant Mylan, and Defendant Lupin agree on the construction of the first ten of these terms ("absorption enhancer," "dosage form," "effective amount," "effective dose," "evening meal," "mean," "plasticizer," "polymer," "%," and "water soluble seal coat"). However, Plaintiffs argue that construction of these terms is unnecessary. Pls.' Opening Claim Construction Br. 29. Moreover, having decided to assume that "the Court will not permit Plaintiffs to later change their positions," Mylan has declared that "these claim terms are no longer at issue." D. Mylan Opening Claim Construction Br. 5. Defendant Lupin has presented no independent argument concerning these terms. Thus the Court adopts the parties' position that these ten terms are not at issue, and declines to construe them.

The Court also finds that the six remaining terms ("controlled release carrier," "dinner," "flux enhancer," "peak plasma levels," "reference standard," and "$t_{1/2}$") present no fundamental

dispute in this case, and need not be construed.[5] As the Federal Circuit has stated, "only those terms need be construed that are in controversy, and only to the extent necessary to resolve the controversy." Vivid Techs., Inc. v. American Science & Eng'g, Inc., 200 F.3d 795, 803 (Fed. Cir. 1999). Although Defendant Mylan invites the Court to construe these terms, it gestures to no live controversy that would require their construction. Moreover, Defendant Lupin does not offer argument as to why the Court should construct these terms, and Plaintiffs point out that the terms are either "immaterial to determining infringement" or contained in "unasserted claims of the patents-in-suit." Pls.' Opening Claim Construction Br. 30, 31.

IV. CONCLUSION

Based on the foregoing reasoning, the Court will construe the claim terms contained in the '859, '866, '459, and '162 Patents as delineated above. An accompanying order shall issue today.

Dated: 9/15/2011

/s/ Robert B. Kugler
ROBERT B. KUGLER
United States District Judge

[5] Regarding the word "dinner," the Court notes that the parties have presented the Court with a fundamental dispute regarding the term "after administration following dinner," which the Court has resolved here. Moreover, the parties agree that the patentees "[a]ct[ed] as their own lexicographer" for the terms "at dinner" and "dinnertime," so that they do not require that a meal actually be eaten. D. Mylan Opening Claim Construction Br. 21. These constructions appear to cover the range of ways in which "dinner" appears in the Patents at issue, and they adequately address the parties' dispute surrounding the Patents' several uses of the word. Thus the Court will not construe "dinner" on its own.